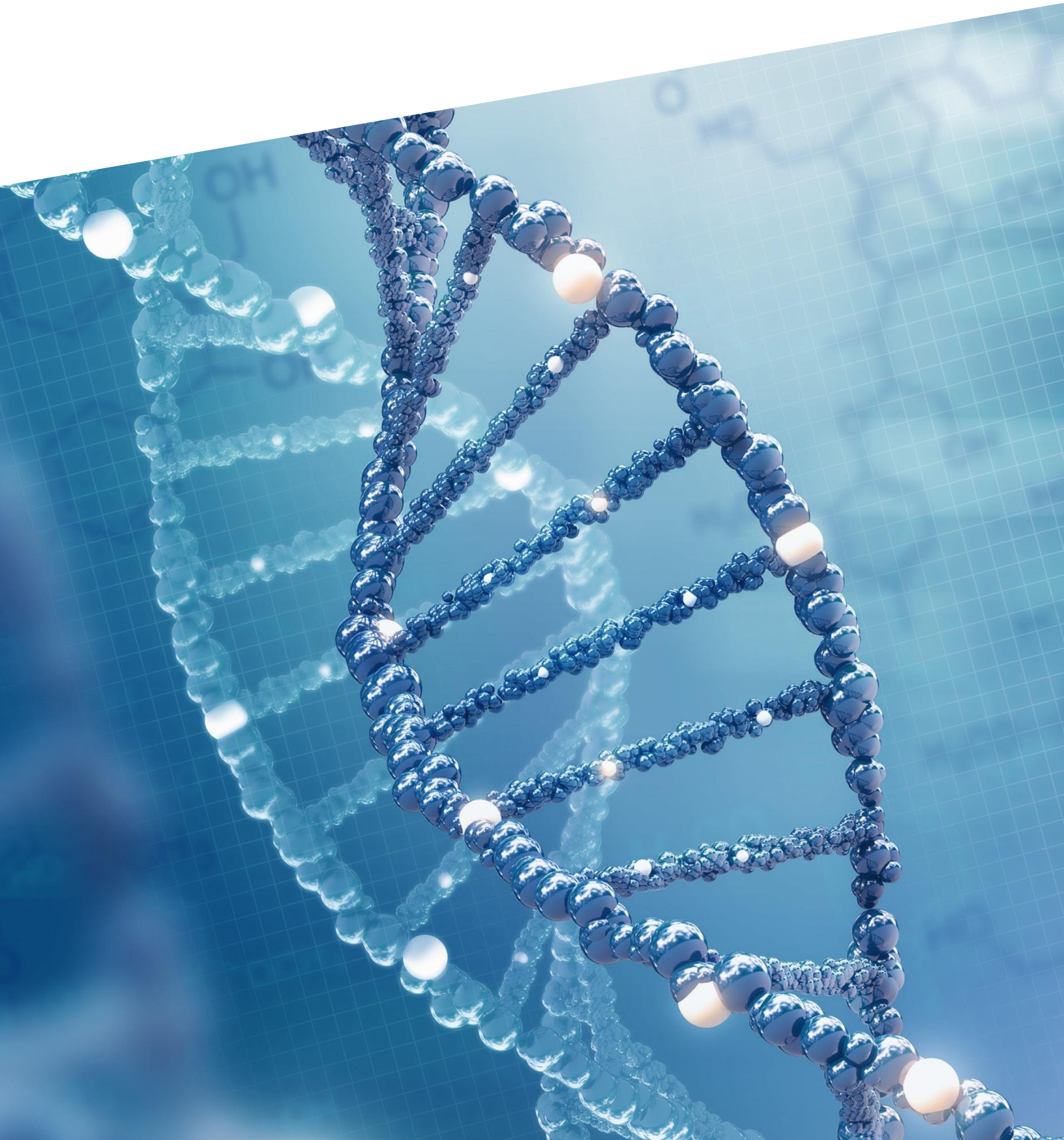
Meddevicetracker
Pharma intelligence | informa

Biomedtracker
Pharma intelligence | informa

2019 JP MORGAN HEALTHCARE CONFERENCE: DAY 3



Summary

The 37th annual JP Morgan Healthcare Conference is being held in San Francisco, CA from January 7-10, 2019. A list of events and catalysts that were announced or updated at the conference today is included in this report. Below are some key points from today's company presentations.

Key Points – Day 3

Large Cap Companies

- Mirroring the 2018 presentation, AbbVie (ABBV) focused on the company's plans to deliver sustained growth despite biosimilar competition for its top-performing product, Humira, in the immunology space. Through settlement agreements, AbbVie have delayed biosimilar competition for Humira in the US until 2023, although biosimilars are available for the product across Europe and other key international markets. Despite the decline in Humira revenues, the company expects to deliver strong double-digit growth over 2019 due to its growing immunology franchise, expanded presence within hem-oncology, as well as continued investment in other alternative therapy areas.

  The presentation reiterated the potential for the antiIL-23 antibody, risankizumab, and the oral JAK1 inhibitor, upadacitinib, across multiple immunology indications (+12), with the drugs pinned to replace Humira as the best-in-class therapeutics. Both therapies have been submitted for initial regulatory review in the US, upacitinib in rheumatoid arthritis and risankizumab in psoriasis, with further clinical trial data generated across a wide range of indications including psoriatic arthritis, atopic dermatitis, Crohn's and ulcerative colitis. The company estimates incremental risk adjusted sales of $10bn by 2025 for the two assets.

  AbbVie's management stressed that their non-Humira business platform holds substantial potential, with expected growth to more than $35bn in 2025. Key growth drivers included in this platform are the company's haematological cancer assets, Venclexta and Imbruvica, which are currently generating annual revenues over $4bn, and growing at strong double-digit rates. Through multiple large Phase III clinical trial programs, the drugs are being poised to gain for further label expansions into new indications and patient populations. The company believes that Imbruvica and Venclexta are on track to generate more than $9bn in revenues by 2025.

  Alternative assets within neuroscience, virology and women's health were also highlighted during the presentation, with Orissa (recently approved in endometriosis) predicted to generate more than $2bn in incremental risk-adjusted sales by 2025, and hepatitis C drug Mavyret expected to continue generating strong cash flow into 2020.

  The company were questioned on the recent clinical trial failure of pipeline candidate, Rova-T, the previous lead compound of Stemcentrx (acquired by AbbVie in a deal worth $5bn), in second-line small-cell lung cancer. AbbVie highlighted that whilst disappointing, the company's future success within oncology was never dependent on Stemcentrx alone and pointed to their portfolio of over 20 programs within both solid tumours and haematological cancers, covering a wide range of disease mechanisms.

- The presentation began with Perreault acknowledging that CSL Limited (CSL:AU) is not as well known since it is listed on the Australian stock exchange; nevertheless, he highlighted that it is actually the fifth largest biotech company in the world. The company's current primary focuses are upon plasma supplies, immunoglobin therapies, and influenza vaccines- with plasma therapies accounting for the majority of their ~$8 billion in revenues. CSL Limited is dedicated to spending $1 billion in capital to build its capacity and holds a solid financial position. Supplying plasma can be challenging and the company is devoted to addressing the steady, robust demand for immunoglobulins by its opening of 30-35 new collection centres. CSL Limited is the parent company of Seqirus, which is committed to the development of flu products. Perreault emphasized that it is the only scaled flu cell culture manufacturer in the world and elucidated the clinical benefits of FLUCELVAX- its cell culture quadrivalent vaccine- versus egg-based vaccines and trivalent vaccines. Over 25 million doses of FLUCELVAX were produced in 2018 and the cell culture approach is attractive compared to egg-based vaccines because it eliminates the need for adaptation from egg to cell. Adding adjuvants to cell culture is CSL's next step to enhancing its cell culture vaccines.

  In the past ten years, CSL Limited has performed consistently with a >11% compound annual growth rate. CSL has achieved five major product launches (Idelvion, Afstyla, Haegarda, Privigen, and Hizentra) in the past 24 months and Perreault singled out Idelvion for hemophilia B and Haegarda for hereditary angioedema in particular as some of the most successful launches in the industry as early market entrants. Idelvion's annualized bleed rates were recapped during the presentation and its advantageous fortnightly dosing schedule was touted compared to competitors. It was mentioned that they are looking into further extending Idelvion's convenient dosing schedule to once every three weeks with a submission planned for the third quarter of 2019. In the coming year, CSL will be preparing to launch Haegarda in additional countries amongst other product launches in new markets.

  While immunology, neurology, haematology, and thrombosis platforms are presently core to CSL's assets, the company is moving into additional transplant, respiratory, and cardiovascular and metabolic therapy areas. The serious complications associated with solid organ transplants including antibody-mediated rejection and graft-versus-host disease associated with hematopoietic stem cell transplantation, represent great opportunities. CSL's strategy here is to quickly bring products into Phase III development by curating products that have an existing real-world evidence base. On the respiratory front, a nebulized immunoglobulin therapy is being developed to address the pulmonary exacerbation issues patients with primary immunodeficiencies encounter that are potentially due to failure of the immunoglobulin to reach the surface of the lung. Prevention of infections in primary immunodeficiency patients and prevention of infection-related exacerbations in chronic obstructive pulmonary disease and bronchiectasis patients may be viable indications for the nebulized immunoglobulin. Furthermore, CSL112 is being investigated in the Phase III AEGIS II outcomes study in acute coronary syndrome that is actively recruiting with over half of the countries on board so far. Data are expected to be first reported in March 2020, with an update in October 2020, and interim efficacy data to be released in April 2021. Following a year of follow-up, a BLA is planned for submission in 2022 and the company will seek approval in the EU thereafter.

- Ipsen (IPSEY) highlighted continued growth, citing high double-digit annual sales figures fueled by the company's global specialty care offerings. Top-line, bottom-line, and pipeline growth in 2018 all helped the firm successfully achieve 2018 objectives in financial performance, business

execution (through product launches and pipeline advancement), and company transformation. CEO David Meek noted substantial growth in financials and expansions from 2014 to present, stating sales growth of +15% CAGR and core operating income at +25% CAGR (as based on 2018 guidance from October). The company's market cap now exceeds $10bn (3x 2014 figures).

In its three core therapy areas of oncology, neuroscience, and rare diseases, Meek highlighted rapid growth and continued expansion. In cancer, Ipsen is now a Top 15 oncology company by sales (over €1bn – representing two-thirds of the company's total sales), and top 5 in growth. Updates were provided on key drivers Somatuline (approaching blockbuster status in the US and a leader in the neuroendocrine tumor market; also indicated for the rare disease acromegaly), Cabometyx for renal cell carcinoma (key studies underway for first line treatment in combination with IO therapies, and as monotherapy for second line), and Onivyde. The company also reinforced its commitment to the development of systemic radiation therapies, with satoreotide in Phase I/II for multiple tumors and IPN1097 in Phase I for NTSR1-expressing tumors.

In neuroscience, Ipsen's focus is on the neurotoxin market, with Dysport (marketed for musculoskeletal and smooth muscle disorders follow neurological disease, and also for aesthetic purposes) in Phase II studies for expanded indications including bunions and vulvodynia. Earlier stage development is also underway with recombinant neurotoxins.

With an innovation model centered on ambition, strategy, and business development, Ipsen closed by revealing its objectives for 2019, which include maximizing growth and market share gains, accelerating R&D, integrating partnership transactions to further build out the pipeline, continuing consumer healthcare growth, and investing in leadership for continued transformation.

Mid Cap Companies

- Similar to last year's presentation, **Acadia Pharmaceuticals (ACAD)** gave an update on the progress of Nuplazid, the company's lead product and the first and only drug approved by the FDA for the treatment of hallucinations and delusions associated with Parkinson's Disease Psychosis. Acadia's CEO, Steve Davis, highlighted five late-stage clinical programs for label expansions to CNS indications with high unmet needs. 2018 guidance from management was around $220-225M in revenues in the second year of Nuplazid's launch and they further noted that the commercial potential for Nuplazid is significant. Management highlighted that if the Company is successful in securing the label expansions in their clinical programs, the addressable market opportunity for the selective serotonin inverse agonist is 40-fold higher than the market size of its currently approved indication.

  In an effort to change physician and patient perspectives, management highlighted initiatives to educate physicians and patients about the drug. In November of last year, Acadia initiated a DTC branded campaign to raise awareness of Parkin's Disease Psychosis. However, the company also acknowledged that it would likely take time to see the results of their campaign, which, as mentioned in the breakout session, would be measured by physician surveys, website visits, and ROI-type assessments. The Company also reiterated they were committed to patient and physician education throughout the process of their multiple clinical development programs.

In order to improve patient experience with the product, Acadia disclosed that they will be removing their 17mg Nuplazid capsule from the market and will be replacing it with a 34mg capsule. Patients receive two 17mg capsules and physicians were titrating the dose, resulting in a more diluted and delayed onset of action. By replacing the two-capsule dose with a single 34mg dose, treatment will be more convenient for patients and will not delay the drug's onset of action.

The Company is anticipating top-line results from the Phase III HARMONY Relapse prevention study in Dementia-related psychosis in the second-half of 2019, with final results in 2020. In addition, Phase 3 development of Nuplazid in Major Depressive Disorder is expected in the first half of 2019, and Phase III ENHANCE data in schizophrenia patients with inadequate response to current antipsychotic treatment are anticipated in mid-2019.

Management highlighted their newly-licensed product from Neuren, trofinetide, which is advancing to Phase 3 development in the second half of 2019 for the treatment of Rett syndrome, for which there is no FDA-approved treatment. Trofinetide is a synthetic analog of the amino-terminal tripeptide of IGF-1 and has shown statistically significant efficacy in Phase 2. In the Q&A session the CEO mentioned that trofinetide was a pillar of their strategy and a significant part of their development program and disclosed that they expect a 2021 filing for the drug.

- Amarin (AMRN) estimated that 2018 revenue would come between $224 to $228m, with Q4 at $72 to $76m and $349m in cash at year end. While the first three quarters of 2018 had seen revenue growth of 20% year over year, the fourth quarter growth estimate represents roughly a 38% increase, and officials guided for even greater growth, over 50% to ~$350m, in 2019. Officials noted the Q4 2018 growth was driven primarily by TRx growth, with limited impact from the positive REDUCE-IT CVOT, as details were presented late in the year. The 2019 estimate does not include an expanded label from the trial, with an sNDA submission expected before the end of Q1, though they will be showing published results from REDUCE-IT to physicians in their promotions.

  The company is not lead on any other drugs, so the presentation focused on the REDUCE-IT results and market opportunity for Vascepa, with plans to expand the company's sales force from ~150 to ~400 and physician targets from ~20k to over 50k. They are also expanding their supplier capacity.

  In what will likely be a marketing message, officials noted that the CV benefit of Vascepa cannot be explained solely by triglyceride lowering, but potentially a number of other mechanisms, as well, though as in the trial, patients with elevated triglycerides will be the target population.

  Vascepa is made from the omega-3 FA EPA, and officials as usual noted differences from the other omega-3 FA DHA. However, they acknowledged AZN is expected to have CVOT results for their combination EPA/DHA product Epanova in 2020 (from the clinicaltrials.gov entry, it looks like a readout could come early in the year, so details could conceivably be at next year's ACC meeting). While other such combinations have failed in CVOTs, that could be due to too low a dose, so this will be a major binary event for Amarin. Amarin will have a headstart, especially since Epanova, while already approved for very higher triglyceride levels like Vascepa, is not being marketed in the US. Officials noted that Vascepa is priced in the US similar to statins before they became generic. Of course, if the Epanova data are positive, there will be additional price

competition, and the picture is complicated by generics of another mixture, Lovaza, though these will not have a CV indication. Finally, officials also acknowledged Teva may by agreement launch a generic in August 2029.

- Galapagos (GLPG) kicked off the meeting with an overview of the company's 20-year history starting in target discovery and moving towards the goal of becoming an established global biopharmaceutical company. These plans hinge hitting commercial targets laid out sequentially with booking sales of filgotinib in the Netherlands and Belgium, expanding into additional indications in other EU markets, and launching an idiopathic pulmonary fibrosis drug in the US and other prioritized markets in the rest of the world. With 44 trials planned in 2019, the company's late-stage pipeline is led by filgotinib, which is actively being evaluated in over ten indications, GLPG1690 and GLPG1205 are being tested in idiopathic pulmonary fibrosis, GLPG1972 in Phase II osteoarthritis, MOR106 in atopic dermatitis, and they spent some time highlighting the promise of a new program under the code name 'Toledo'.

  Galapagos called attention to payments associated with four major partnerships with Gilead, Servier, and Novartis on filgotinib, GLPG1972, and MOR106, respectively, and in handing over the cystic fibrosis program to AbbVie. The presentation followed by focusing on a few programs which the company thinks have blockbuster potential starting, of course, with filgotinib. Results from the two remaining pivotal rheumatoid arthritis studies for this JAK1 inhibitor are expected in the first quarter of 2019. The company is also recruiting for filgotinib studies in inflammatory bowel disease, they have completed Phase II with ankylosing spondylitis and psoriatic arthritis and will report results from Phase II data in Sjogren's syndrome and lupus. To differentiate this drug from other JAK inhibitors, Galapagos referred to high scores on ACR50 and its safety profile. Moving on, Galapagos stated that they want to be an idiopathic pulmonary fibrosis company with the opportunity to use combinations of treatments targeting different pathways for this disease. Their Phase III ISABELA program allows patients to use GLPG1690 in addition to pirfenidone, nintedanib, or alone. This drug is also being evaluated in scleroderma. GLPG1972 for the treatment of osteoarthritis is the third product the company highlighted as having blockbuster opportunity.

  Concluding with a discussion around a new program for inflammation deemed 'Toledo' and described as having dual action in stimulating the 'good' cytokines while inhibiting 'bad' cytokines, the company is casting a wide net across multiple indications and broadly covering intellectual property. Galapagos is investing heavily in early-stage research related to this novel mechanism, where they currently see no other competitors. Because of this rapid expansion, Galapagos discussed their interest in maintaining their independence and biotech culture as they grow and bring on developers from large pharmaceutical companies.

- Halozyme (HALO) focused on two areas they believe will be significant value drivers over the next decade. The majority of the talk centered around Halozyme’s strategy of partnering with pharmaceutical companies to develop subcutaneous versions of their products through their Enhanze platform. The company announced that its subcutaneous formulation of the blockbuster Herceptin has a PDUFA date in March 2019. As Herceptin biosimilars have recently been recently approved, it will be interesting to see if prescribers will prefer the convenience of a subcutaneous Herceptin, if approved, or favor biosimilars. A subcutaneous fixed-dose combination of Herceptin and Perjeta is also in the works, with potential regulatory submission in 2020. Darzalex, which also has enjoyed a favorable rollout since its initial 2015 US approval, is also included in the

Enhanze program, with potential regulatory filings earmarked for 2H 2019. With these near-term catalysts, three successfully commercialized Enhanze products globally, and 12 additional targets for Enhanze in development in 2019, Halozyme expects revenue from milestones and royalties to be a major growth driver for the company in the future.

The last portion of the presentation centered around PEGPH20. The company reiterated that enrollment for the pivotal Phase III HALO 301 is complete, and disclosed that they expect the target number of overall survival events to be achieved between August and November 2019, with a high probability of final definitive data before the end of 2019. Finally, Halozyme discussed the early phase combination trials with PEGPH20 and Tecentriq, announcing that data releases may be on the horizon in 2019 if positive enrollment continues, particularly for the trial in gallbladder cancer and cholangiocarcinoma.

On the financial front, Halozyme issued 2019 guidance of $175-185m net revenue, operating expenses of $265-275, operating cash burn of $75-85m, debt repayment of $90m, for 2019 year-end cash of $180-190m. For 2018, they just reiterated the guidance they gave with the Q3 earnings.

- While enjoying continued growth in Ocaliva for primary biliary cholangitis (PBC) -- with 36% sales growth year-over-year for the first 3 quarters of 2018 and a reiteration of $170-180m net sales guidance for the full year – Intercept (ICPT) will have a major catalyst this quarter (a refined time estimate) with an interim analysis of Ocaliva's Phase III REGENERATE trial in at least 750 F2/F3 NASH patients. The company anticipates this will serve as a basis for accelerated approval, with the trial continuing for the final confirmatory clinical outcomes endpoint. The trial includes a lower dose, based on their hunch that it will also be effective, yet better tolerated, as well as an exploratory cohort of less severe patients.

  Much of the focus of the presentation was on NASH, where they also have the REVERSE trial in patients who already have cirrhosis, albeit compensated, with completion of enrollment targeted for this year. They intend to design a separate confirmatory outcomes trial in an overlapping but also more advanced population. They noted that most NASH patients with cirrhosis do not qualify for liver transplant due to comorbidities. Officials emphasized that they expected drugs targeting FRX, like Ocaliva, to play a pivotal role in NASH, as the pathway attenuates the major pathologies driving the condition (insulin resistance, lipid metabolism, inflammation, and fibrosis). Still, we should note, in data highlighted in the presentation, in a post-hoc analysis of Phase II patients meeting enrollment criteria for the Phase III study, the placebo subtracted proportion of patients with at least a one-stage improvement was only around 19% (40% versus 21% for placebo). Officials noted they anticipate NASH to be a specialty market, with a focus on gastroenterologists and hepatologists.

  The company also plans to start a Phase II trial of the PPAR agonist bezafibrate, already long approved outside the US, in combination with Ocaliva for PBC, with the goal of a fixed dose combination (FDC) for PBC and potentially other indications. As an NCE in the US, officials said the FDC could garner 7 years of exclusivity to prolong the productive life of the Ocaliva franchise. Later this year, they will also talk about plans for their expanding their pipeline.

- Lee's Pharmaceutical Holdings (0950.HK) presentation began with an overview of the Q3 2018 financial results, which had a finalised revenue of HK$299.2m. They noted revenue of HK$866.9m

for 9-months ended September 30, 2018, which is a 15.6% increase from 2017. Officials indicated that they were investing heavily in R&D for future returns as of 9-months in 2018 R&D expenses where at an all-time high of HK$95.8m, whilst the profit margin was held at 66.1%. The team noted that they have 7 products in Phase III in multiple disease categories with large market sizes including cardiovascular, oncology and ophthalmology. Lee officials then focused on manufacturing sites where they confirmed that the construction for the biologics drug substance and liposome production line had been completed at the Hefei manufacturing site. Additionally, they addressed the manufacturing licence for the mono-dose line at Guangzhou that they obtained in September 2018 and the cytotoxic capsules licence gained in October 2018.

Lee's Pharmaceuticals then briefly described their prospects for 2019, which included the enhancement of their sales team to maintain the strong sales growth momentum observed over the past year. They also aim to increase their R&D expenditure and progressively isolate R&D activities in oncology and ophthalmology from their core revenue stream. Pharmaceuticals concluded with an explanation of the potential challenges in 2019 and how they plan to overcome them. The China Health Commission aims to set up a national auxiliary drug list, which they will closely monitor. Officials hinted that they are in a favourable position as their products are not under the auxiliary drug category.

- At JPM, MorphoSys' (MOR) presentation focused heavily on its most advanced proprietary program MOR208, an Fc-enhanced anti-CD19 antibody. L-MIND is a pivotal Phase II trial evaluating MOR208 combined with lenalidomide in relapsed/refractory DLBCL. Dr. Moroney, MorphoSys' CEO, explained that MOR208 attracts NK cells to the tumor while lenalidomide helps activate them. Interim data from L-MIND has been impressive (33% CR rate and 16.2 months median PFS) and final results are expected in Q2 2019. A rolling BLA submission is expected to be complete by Q4 2019 and an approval is expected by mid-2020. A confirmatory Phase II/III trial, B-MIND, comparing MOR208/bendamustine to rituximab/bendamustine is ongoing with top-line results expected in late 2019 and primary completion in early 2020. With approximately 28,000 new DLBCL cases in the US every year, MorphoSys estimates that the initial addressable US market for relapsed/refractory DLBCL is 8,500 patients/year.

  Preclinical data has shown synergy between MOR208 and rituximab. A Phase Ib trial evaluating MOR208 + R-CHOP vs MOR208 + lenalidomide + R-CHOP in treatment naïve DLBCL is expected to initiate in Q3 2019. If the results are good, a pivotal Phase II/III trial could initiate in mid-2020. MOR208 is also being developed for other indications.

  An anti-CD38 antibody, MOR202, is no longer being developed for multiple myeloma in the US but MorphoSys is suing Jannsen saying that Darzalex infringes on three of its patents and the trial is expected to start in February 2019. I-Mab has received exclusive development and commercialization rights in China, Taiwan, Hong Kong and Macao. MorphoSys received an upfront payment of $20 million, up to $100 million in milestones and tiered double-digit royalties. I-Mab plans to start a pivotal Chinese study of MOR202 in multiple myeloma in Q1 2019. Finally, MorphoSys plans to develop MOR202 in the US for an autoimmune indication with a Phase II study expected to initiate in Q3 2019.

  MOR106, a first-in-class anti-IL-17C antibody was co-developed with Galapagos and was fully out-licensed to Novartis in July 2018 for EUR 95 million upfront, milestone payments of up to EUR 850 million and tiered royalties (low teens to low twenties). All payments are shared with Galapagos

50/50. MOR106 reported encouraging results in a placebo-controlled Phase I trial in atopic dermatitis. Morphosys and Galapagos will complete by Q3 2019 (i) IGUANA, an ongoing Phase II trial in ~240 patients with moderate to severe atopic dermatitis and (ii) a bridging study with a subcutaneous formulation. Development of a subcutaneous formulation is essential for a viable atopic dermatitis product. Morphosys and Galapagos have committed to initiating additional trials in atopic dermatitis while Novartis has committed to carrying out Phase II studies in two other indications as well as responsibility for all late Phase trials.

Tremfya, an anti-IL-23 antibody approved for psoriasis and licensed to Janssen, saw Q3 2018 sales increase by 36% compared to Q2 2018. Royalty income for 2018 is now expected to be at the upper end of guidance (EUR 12 to 17 million). Tremfya continues to be developed for additional indications.

Group revenues for FY2018 are expected to reach EUR 68-72 million while expenses are expected to be EUR 87-97 million for an EBIT loss of EUR 55 to 65 million. At the end of Q3 2018, the company had EUR 481.2 million in cash and total ordinary shares issued as of December 31, 2018 was 31,839,572.

As MorphoSys continues to advance MOR208 to regulatory approval it is building US commercial capabilities for an anticipated 2020 launch.

- Following a positive Q4 2018 preliminary revenue announcement days before their JPM 2019 presentation ($69.6m Q4, $248m for 2018), **Novocure (NVCR)** began with a review regarding Optune's adoption in 2018. The company emphasized a more than 40% growth in prescriptions for newly diagnosed glioblastoma, a promising collaboration with Zai Lab to accelerate clinical trial enrollment in China, and approval for national reimbursement in Sweden, which the company views as a positive signal for reimbursement in other European markets. The company also submitted a HDE application to the FDA for unresectable malignant pleural mesothelioma in 2018 and is optimistic about an approval and launch in the US in 2019. Leading up to 2022, the company expects readouts for Optune in several indications, including for the HEPANOVA trial in liver cancer, the LUNAR trial for non-small cell lung cancer (NSCLC), the METIS trial for brain metastases arising from NSCLC, the PANOVA-3 in pancreatic cancer, and the INNOVATE-3 trial in ovarian cancer.

Small Cap Companies/Private Companies

- As expected, the focus of **Acorda Therapeutics' (ACOR)** presentation was the late December 2018 approval of Inbrija and the company's commercial expectations and plans. Inbrija is an inhaled drug/device product containing levodopa, approved for the intermittent treatment of OFF episodes in Parkinson's disease patients taking carbidopa/levodopa. Acorda approximates this target population to total 350k patients in the US, projecting Inbrija peak sales to exceed $800m.

  Heading into 2019, Acorda's priorities are to execute its launch strategy for Inbrija in the US, comprising its MS-experienced field sales force, marketing activities, sampling and reimbursement assistance. Inbrija is expected to become available at pharmacies during Q1 2019, and Acorda is delaying any announcement about pricing until this time. Acorda is not intending to provide a revenue guidance for Inbrija during 2019, although will be updating on launch metrics in its quarterly statements.

Additionally, Acorda is seeking MAA approval in 2019 and advancing its ex-US partnering strategy for Inbrija. Outside of Parkinson's disease, Acorda is leveraging its ARCUS technology to reformulate acute migraine drugs for a faster onset of action. These include zolmitriptan and two other undisclosed drugs, although Acorda hinted at some technical difficulties involving bronchoconstriction in a study of asthmatics or smokers.

The company also guided for full year 2018 net revenue from Ampyra of greater than $430m, though will no longer be providing guidance going forward due to the entrance of generics. The presentation noted that they ended the year with a strong $445m cash position, and guided for 2019 R&D expenses of $70-80m and SG&A expenses of $200-210m.

- AMAG Pharmaceutical's (AMAG) presentation highlighted that compared to guidance issued a year ago, preliminary 2018 financial results exceeded their earlier expectations by $64M on the top-line and $50M on the bottom line, with total revenue expected to be $471-476m and adjusted EBITDA at $115-125m. They had announced earlier in the week, though, that there had been a negative impact from temporary supply constraints for Makena, which has also been hampered by the entry of generics in 2018, though the supply constraints have been resolved.

  The company stressed the successful performance of intravenous iron therapy, Ferraheme, which experienced 30% in growth in 2018, bringing in $135m in net revenue. Initially approved for anemia due to chronic kidney disease, Ferraheme received FDA label expansion in Feb 2018 for patients with iron-deficiency anemia who cannot tolerate oral iron formulations, further increasing its market potential.

  Whilst generic versions of the first-generation, intramuscular formulation of Makenna have been on the market for around six months, AMAG have held approximately 50% of the entire Makena product volume with the second-generation branded SC auto-injector. Furthermore, AMAG's authorised generic partner maintained a significant share of the generic Makena market, approximately 50% in Q4 2018. So while the franchise had preliminary Q4-2018 net revenues of $46-48m, down from $80.2m in Q3 2018 (partly due to a supply constraint, as noted above), the company felt the SC auto-injector has stabilized the franchise and going forward, despite the introduction of more generics, they expected continued Makena revenues for 2019 of around $40-50m/quarter. The resolution of the supply constraint would give some boost in January and there may be share gains for the SC autoinjector, but these would be offset by price pressures.

  In women's health, the company highlighted Intrarossa as a key future cash driver. Following its launch in July 2017 in moderate to severe dyspareunia due to menopause, the company announced 2018 annual revenues of $15-16m, with strong and growing physician and patient support for the therapy driven by the direct-to-consumer campaign. Looking forward, AMAG also anticipate a commercial launch for Vyleesi in 2H 2019, their investigational product for low sexual desire/libido associated with distress, following positive results from two large Phase III trials. With the condition affecting approximately 12 million women in the US, AMAG predicts an annual peak revenue opportunity of more than $700m for the therapy. In pre-eclampsia, the company also highlighted the future potential of orphan therapy, AMAG-423, which demonstrated positive results in a small Phase II trial and is currently enrolling patients in a larger Phase III study. Top-line data for the trial is expected in 1H 2020, with an FDA approval and commercial launch anticipated in 1H 2021.

The company also reported on the recent acquisition of Phase II pipeline agent, Ciraparantag, a next-generation broad spectrum reversal agent for the novel oral anticoagulants (NOACs). With 200,000 patients per year estimated to require urgent reversal of NOAC treatment, AMAG approximates an annual US peak revenue opportunity of more than $500m for the therapy. AMAG plans to initiate a Phase IIIa trial for Ciraparantag in H2 2019.

With $400m of cash and securities as of December 2018, the company continues to explore licensing/acquiring long-lived, durable products.

- Five Prime Therapeutics (FPRX) provided an overview of five assets, one in a pivotal Phase III trial (bemarituzumab), one in a Phase II trial (cabiralizumab) and three others in Phase I development.

  Bemarituzumab (bema) is a first-in-class antibody specific for FGFR2b, a splice variant of the fibroblast growth factor receptor FGFR2 expressed on tumor cells. Bema blocks growth factor binding to FGFR2b and also targets the tumor cells for killing by ADCC. FGFR2 gene amplification is seen in about 10% of gastric cancer patients and is associated with significantly reduced survival (2-year OS of 48.1% vs 19.8%). A pivotal Phase III trial (FIGHT) was initiated in September 2018 and is evaluating Bema + chemotherapy (modified FOLFOX6) compared to placebo + chemotherapy in front-line FGFR2B overexpressing gastric cancer and gastroesophageal junction (GEJ) cancer. Safety lead-in data for this trial is expected next week at the ASCO-GI meeting.

  Cabiralizumab (cabira) is an antibody that blocks the Colony Stimulating Factor 1 Receptor (CSF1-R) present on tumor activated macrophages (TAMs) and is being developed in collaboration with BMS. Binding of cabira to CSF1-R leads to depletion of TAMs. Similar to PD-L1 on tumor cells but using a different mechanism, TAMs can inhibit cytotoxic T cells and high TAM levels are associated with poor prognosis in pancreatic and other cancers. In March 2018, BMS initiated an open label Phase II study of cabira administered in combination with Opdivo with and without chemotherapy in patients with second-line pancreatic cancer. This study is expected to complete enrollment in 2019 (40 patients in each of 4 arms) and is designed to generate data supporting a front-line or second-line pivotal study. In 2018 BMS also expanded cabira development within pancreatic (including combinations with radiotherapy, anti-CD40 antibodies or gemcitabine) and into other tumor settings (including melanoma, NSCLC, RCC and in January 2019, biliary tract cancer).

  FPA150 is an antibody that inhibits activity of B7-H4, a checkpoint inhibitor that is related to PD-L1 and is present on tumor cells. This first-in-class therapy is wholly owned by Five Prime. B7-H4 is expressed in multiple solid tumors that are not well served by current checkpoint inhibitors. Moderate to high levels of B7-H4 have been reported in approximately 60% of patients with breast cancer and 50% of patients with ovarian and endometrial cancer. There is very little expression on normal tissue. FPA150 is currently being evaluated in a Phase Ia/Ib trial evaluating monotherapy activity in patients with B7-H4 overexpressing tumors. Phase Ia dose escalation was initiated in March 2018 (any solid tumor) and an exploratory cohort with a basket of B7-H4 overexpressing tumors was initiated in October 2018. Once an optimal dose has been identified (1H of 2019), the trial will expand to Phase Ib and will enroll patients with breast (HR+/HER2- and TNBC), ovarian and endometrial cancers with B7-H4 overexpression. Data from the dose escalation cohort will be presented at ASCO (Q2 2019) while data from the exploratory cohort is expected to be presented at ESMO (Q4 2019).

FPT155 is a first-in-class CD80-Fc fusion protein. CD80 is a co-stimulatory molecule expressed on antigen presenting cells and which binds CD28 on T cells to provide the co-stimulatory signal required for T cell activation (in addition to MHC-TCR binding). FPT155 is designed to bind the antigen presenting cell (through the IgG1 Fc moiety) and CD-28 present on T cells to enhance co-stimulation of T cells without superagonism. A Phase Ia/Ib trial initiated in Australia in November 2018 enrolling patients with any solid tumor to look for monotherapy activity. An exploratory cohort with a basket of solid tumors is planned and once an optimal dose is identified the trial will expand to Phase Ib with select solid tumor cohorts. Phase I data will be presented at a medical conference in 2H 2019.

The final asset presented was BMS-986258 an antibody to TIM3 licensed to BMS. TIM3 is an immune checkpoint receptor and BMS-986258 was designed to block interaction between TIM3 and phosphatidylserine, a key lipid found in the tumor microenvironment. A Phase I/II clinical trial initiated in March 2018 and starts with a dose escalation of BMS-986258 (arm A), BMS-986258 + rHuPH20 (arm A1) and BMS-986258 + Opdivo (arm B). The Phase II portion of the trial will evaluate BMS-986258 + Opdivo (arm C). BMS-986258 is the first of three candidates from the IO research collaboration with BMS. The collaboration provides for up to $300 million in milestone payments per collaboration product and tiered royalties.

As of December 31st 2018, Five Prime has $270 million in cash, cash equivalent and marketable securities. FY 2019 operating activities are estimated at $117-122 million and EOY 2019 cash is estimated at $148-153 million not including any milestone payments.

- FLX Bio presented on its pipeline which includes two early phase CCR4 antagonists being investigated in oncology and allergic disorders. The company's lead compound is FLX475, which is being investigated for oncology indications. FLX475 showed strong single agent activity in a preclinical tumor model with a high CCR4 expression at baseline. In the presentation, management said "big data analysis" was used to identify "charged" tumors as those most likely to respond to FLX475. Though no detail was given as to what this analysis entailed, "charged" tumors were defined as those expressing high levels of CCR4 and Treg. Non-small cell lung cancer, triple negative breast cancer, head and neck, nasopharyngeal, Hodgkin lymphoma and cervical cancer were identified as possible target indications. The initiation of Phase II trials investigating FLX475 as a monotherapy and in combination with Merck & Co's Keytruda are expected in 2019.

  The company's second most advanced development program is investigating its CCR4 antagonist FLX193 for the treatment of allergic disorders, atopic dermatitis and asthma. This small molecule is in early development with an Investigational New Drug (IND) filing planned for the first half of 2019 and the first in human trial planned for the second half of 2019.

- 2019 priorities for Idera Pharmaceuticals (IDRA) is straightforward according to CEO Vincent Milano; develop its TLR9 agonist key asset drug tilsotolimod for anti PD-1 refractory melanoma patients, explore the possibility for the drug's expansion into other indications, and attempt to create a diversified pipeline of products outside of this main asset.

  Milano provided updates on data from phase I (ILLUMINATE 101) and phase II (ILLUMINATE 204) trials along with clearer timeline for phase III (ILLUMINATE 301) trial

Phase I ILLUMINATE 101 (n=39) monotherapy dose escalation in patients with multiple refractory tumor types including melanoma and include ocular, esophageal, colorectal, pancreatic, sarcoma, NSCLC, breast with skin met, urothelial. The majority of subjects were dosed via administration into visceral lesions.

• Translational data confirms robust Type I IFN pathway activation in 24 hours with no reported safety concerns. Idera submitted an abstract based on these findings for a conference set later this year.
• Tilsotolimod also induces rapid gene expression demonstrated through similar log plots in both the phase I ILLUMINATE 101 (solid tumor types) and phase II ILLUMINATE 204 study in melanoma patients

Phase II ILLUMINATE 204 (n=34) single arm combination study with Yervoy (CTLA-4 MAb) in anti PD-1 refractory melanoma patients. Historical comparison against Yervoy monotherapy was provided along with reiteration of key findings from December 2018 and an updated progress on patients' status.

• Findings suggest suggesting the addition of tilsotolimod to Yervoy is more effective than Yervoy alone. DCR is substantially greater than the use of Yervoy (>30% relative improvement). However, the relative difference in improvement for the most popular measurement of response rate, ORR is not as strong (~15-20%).
• Positive impact of tilsotolimod when added to Yervoy as there were responses in tumors that were not expected to respond to Yervoy alone, based on HLA-ABC low baseline expression.
• Abscopal effect was also demonstrated as the percent change of activity and reduction of tumors from baseline in responding patients included changes in both injected and uninjected lesions similarly evolving over time.
• Patient findings:
  o Swimlane plot demonstrates the first patient to achieve CR has done so for over 2.5 years. One additional person has moved to CR as of January 9, 2018.
  o Four of the patients who began with stable disease study have evolved to PR and CR.
  o Nearly 1/3 of the patients have not been enrolled long enough to see the evolution of response rates to safely extrapolate this trend.

Patient enrollment for ILLUMINATE 204 will stop at the end of January and final data is expected in 2H 2019.

Phase III ILLUMINATE 301 in anti PD-1 refractory melanoma patients (same as ILLUMINATE 204).

• Initiated in March 2018. Enrollment will conclude at year end of 2019. Study will capture ORR and OS as primary endpoints. Idera plans to submit for accelerated approval based on ORR data at the earliest date in summer 2020.

Additionally, tilsotolimod's tumor agnosticity, which was demonstrated through similar gene expression across a number of tissue types including melanoma in (ILLUMINATE 101), has opened the possibility for commercial expansion into other indications. Initiation of ILLUMINATE 206 will investigate the drug in squamous cell carcinoma of the head and neck (SCCHN) and microsatellite stable colorectal cancer (MSS-CRC), with the possibility to expand to further indications in the

same clinical trial. Both indications align with the company's mission to focus on rare and orphan diseases and represent areas of great unmet clinical need.

Business development efforts will continue toward generating additional growth through opportunities for partnerships or possibly through acquisition of assets in the rare and orphan disease area. Idera ended Q3 2018 with $82.5mn of cash (runway to 1Q 2020) and 27mn shares outstanding.

Idera is trying to make up for lost ground as the company's rare disease pipeline no longer exists due to failed clinical trials. Additionally, a failed merger with BioCryst pharmaceuticals sent its stock price downward since June last year.

For 2019, look for final data on ILLUMINATE 204, initiation of ILLUMINATE 206, abstract submission of key translational data in ILLUMINATE 101, and completion of patient enrollment in ILLUMINATE 301.

- Immunogen (IMGN) were keen to highlight that they enter 2019 in a strong position with $262m cash having raised $163m in a second public offering in 2018, and $65m from the residual Kadcyla royalty scheme. The company's most significant catalyst in 2019 will be the Phase III data readout for mirvetuximab in ovarian cancer.

  Mirvetuximab is the only therapy in late-stage development for ovarian cancer specifically targeting patients that over express FRa and, if proven effective in these patients, could become a standard therapy for this specific ovarian cancer patient population. FRa is over expressed in approximately 70% of primary ovarian tumors and over 80% of recurrent tumors. In the Phase I IMGN-0401 trial, mirvetuximab monotherapy demonstrated signs of strong efficacy in FRa+ platinum-resistant ovarian cancer patients. In patients with low, medium, or high levels of Fra expression and who received three or fewer lines of therapy, mirvetuximab treatment resulted in a median progression-free survival (mPFS) of 6.7 months and an objective response rate (ORR) of 39%. In all FRa+ patients, regardless of the number of prior therapies, treatment with mirvetuximab resulted in a mPFS of 4.8 months and a confirmed response rate of 26%. Furthermore, the regimen was reasonably well tolerated, with mostly grade 1 or 2 adverse events. These data compare well to the current standard of care.

  The company stated that approval as a monotherapy was the first priority, with subsequent label expansions to include use as part of a combination possible. In the Phase Ib/II dose escalation and expansion FORWARD II trial, mirvetuximab is being investigated as part of separate combinations with carboplatin, PEGylated liposomal doxorubicin, Avastin, or Keytruda (pembrolizumab; Merck & Co) in FRa+ advanced ovarian cancer patients. During the breakout question session, the company were keen to downplay the mirvetuximab + Keytruda combination. As mentioned, this was because of the announcement in November 2018 that the Phase III JAVELIN Ovarian 200 trial investigating Bavencio had missed it primary endpoints. Immunogen's broad development program will insulate them if the mirvetuximab + Keytruda combination follows suit.

  Immunogen's earlier phase candidates include IMGN632 and IMGN779 which are both being investigated for AML. Early indicators for these therapies are positive and these programs will continue to progress through 2019.

- Molecular Partners (MOLN.SW) CEO Patrick Amstutz restated several milestones achieved during 2018 and updated the expected clinical progress it expects to make with its DARPin engine through 2019. To recap, DARPin-based drugs are 10% of the size of traditional monoclonal antibodies, but the peptide sequences enable high affinity and low immunogenicity against the specified targets, while also having a tunable half-life. The proof-of-concept for this technology is being provided by abicipar in wet AMD, which is a relatively simple DARPin that binds vascular endothelial growth factor (VEGF) and has a polyethylene tail that allows for extended dosing intervals compared to marketed drugs such as Lucentis.

  Molecular Partners and its partner Allergan are planning to file abicipar for approval in wet AMD from H1 2019. This will include data from the MAPLE study, which is investigating an optimized product that will theoretically reduce the 15% rate of intraocular inflammation seen in the Phase III SEQUOIA and CEDAR studies. Looking beyond wet AMD, Phase III testing in DME is expected to begin during H2 2019. Marketed anti-VEGF ophthalmological products are approved across a range of neovascular retinal disorders, so this subsequent expansion to DME is important to increase abicipar's overall competitiveness.

  The wholly-owned multi-targeting DARPin antagonist MP0250 was also presented at length, and specifically the opportunity within multiple myeloma. Binding human serum albumin (HSA), hepatocyte growth factor (HGF) and VEGF, MP0250 is hypothesized to block escape pathways and innate resistance against standard-of-care drugs, thus positioning itself as a later-line treatment. This year, Molecular Partners expects data from the ongoing Phase II multiple myeloma and EGFR-mutated NSCLC studies, as well as initiating a new multiple myeloma study in combination with immunomodulatory drugs such as Revlimid, Pomalyst and Otezla.

  Lastly, Molecular Partners highlighted its first immuno-oncology candidate MP0310, which is intended to overcome the dose-limiting systemic toxicity of current 4-1BB agonists. The drug is partnered to Amgen in a $50m upfront deal and will benefit from the company's rich portfolio of bi-specific T cell engagers. First-in-human trials are expected to start in H2 2019.

- Replimune (REPL) outlined of the existing problem with their immune checkpoint blockade therapy. They explained that the majority of patients do not respond to the therapy because they require an inflamed tumour and a pre-existing immune response to the cancer. Replimune aims to create genetically-armed oncolytic immunotherapy products to maximally activate the immune response against cancer in order to promote a response to immune checkpoint blockade therapies such as anti-PD1. Officials stated that an IPO was conducted in July 2018 and they currently have $150m, which will fund operations until H2 2021.

  Replimune summarised the trials planned for the company's most advanced oncolytic immune-gene therapy, RP1, which is based on a strain of herpes simplex virus that already has a good safety and efficacy profile demonstrated through TVEC. In collaboration with Bristol Myers Squibb, Replimune is conducting a two-part Phase I/II trial. The first part analyses the safety and tolerability of RPG-1 alone and then in combination with nivolumab in advanced solid tumours. The second part analyses the efficacy of RP1 with nivolumab in four types of solid tumours in a signal finding setting. The company has completed enrollment of the RPG-1 alone part of the Phase I study and opened recruitment for the RPG-1 plus nivolumab part. They expect results from the full Phase I portion of the Phase I/II trial to be released in H2 2019.

In addition, Replimune confirmed that the Phase II part will initiate in H1 2019 in patients with melanoma and non-melanoma skin cancers, microsatellite instability high cancers and bladder cancer. Results from this trial are expected in H2 2020 and will determine which indication they will progress into late stage development. Officials highlighted their 50/50 cost sharing partnership with Regeneron, where they plan to initiate a registration-directed Phase II trial in cutaneous squamous cell carcinoma (CSCC). They pointed out that this disease has a worsening mortality rate, which is overtaking that of melanoma. They also noted that Cemiplimab is effective with a 50% response rate, however, the complete response rate is only 5%. As a result, officials believe that CSCC is a good indication for initial approval of RP1 in an accelerated fashion. The Phase II trial is set to begin in H1 2019 and will enroll approximately 240 patients, results are anticipated for H2 2021.

Officials switched their focus from RP1 to provide an update on its pipeline product candidates RP2 and RP3. These are similar to RP1 and deliver proteins that act as the immune response is being generated. Replimune believes that systemic antibody approaches are suboptimal here. They explained that RP2 expresses GALV-GP-R and GM-CSF as well as anti-CTLA-4 antibody and aims to be used in combination with anti-PD-1/PDL-1 therapy. Officials confirmed that a Phase I trial for RP2 alone and in combination with anti-PD1 treatment will initiate in H12019.

Furthermore, Replimune revealed that the RP3 product that will be used in Phase I trials will express CD40L and 4-1BBL as well as anti-CTLA-4 and GALV-GP-R to promote both an innate and adaptive immune response. Officials reiterated that a Phase I trial is expected to begin in H1 2020. The aim for these products is to target more challenging indications compared to RP1, although these indications have not been disclosed. Finally, Replimune summarised their manufacturing status and announced that they have leased a large facility, which is sufficient to produce material for all commercial needs. Consequently, an additional facility will only be needed for redundancy purpose for later stage development and commercialisation, which will begin in H2 2020.

- Sangamo (SGMO) CEO Sandy Macrae opened its presentation stating that over the next year it will become the leading genomic medicines company active in gene editing, gene and cell therapy, and gene regulation. The firm chooses what to work on based on high unmet medical need and matches its technology to certain areas of focus. The pipeline expands across the areas of metabolic diseases, immunology, CNS, hematology, and cancer. Clinical readouts are expected in 2019 and 2020 following enrollment progress of the last twelve months. During 2018 Sangamo partnered with Pfizer and Kite and also acquired TxCell.

  Sangamo currently has five programs in the clinic – SB-318 for MPS I, SB-913 for MPS II, SB-525 for hemophilia A, SB-FIX for hemophilia B, and ST-400 for beta-thalassemia. It anticipates moving another four programs into clinical trials this year, the first being ST-400 for sickle cell disease by partner Bioverativ. The company also made known that its Fabry candidate ST-920 and Tx200 for solid organ transplant should move into human studies by year-end. Data from both MPS programs will be revealed in February at the 2019 WORLD Symposium meeting. The SB-318 presentation is expected to describe preliminary safety and biochemical measurements at up to four weeks from the first three adult patients enrolled in the EMPOWERS study, while the SB-913 presentation will include interim data on safety and biochemical measurements at up to 24 weeks from six adults enrolled in the three dose cohorts of the CHAMPIONS study.

Sangamo spoke about its gene editing platform that allows for targeted gene knock-out or therapeutic gene insertion using zinc finger DNA-binding proteins. The ZFN technology can recognize DNA with great specificity, precision, and efficiency. Through the TxCell acquisition Sangamo gained CAR-Treg technology and plans to develop products with ZFN multiplex editing. CAR-Tregs hold significant potential in the autoimmune disease space. Since Tregs are localized to tissue you don't need to know antigen causing the disease. Sangamo iterated that it's excited about the technology as no one has ever created a CAR-Treg.

- Sienna Biopharmaceuticals (SNNA) is focused on non-steroidal topical therapies suitable for chronic use in dermatological conditions, thus differentiating themselves from companies developing biologics for the more severe stages of these diseases. The company has two small molecule topical products in clinical development: SNA-120, a TrkA inhibitor, and a JAK3/TrkA inhibitor deemed SNA-125.

  The company talked at length about why the Phase II 201 study of lead asset, SNA-120, did not meet its primary endpoint of significantly reducing itch compared to placebo. In showing the graphs depicting change in itch, the company demonstrated a reduction in the 0.05% dose arm, similar to the reduction seen in the prior CT327-2003 study, however, the vehicle arm did not separate in the 201 study. Pointing to similar placebo effects seen in oral drug studies for pain, the company noted that this could be a due to a shift in the focus of the 201 being on treating the itch rather than treating psoriasis as in the prior study. Sienna also rationalized the basis for the response seen on the lower 0.05% dose and not the higher 0.5% concentration, pointing out that these results are consistent with the bell-shaped dose-response curves seen in other kinase inhibitors.

  Since reliably positive results were reported in psoriasis outcomes, the company plans to move into Phase III trials after an end-of-Phase II meeting with the FDA, which is scheduled in April. Sienna anticipates that these studies will each enroll about 300 mild-to-moderate psoriasis patients with at least moderate pruritus and will evaluate IGA 2-grade composite as the primary outcome. A key secondary outcome will look at itch, although it will be de-emphasized unlike in the 201 study, in hopes to see separation from placebo and add this important component to the label.

  Their other topical small molecule, SNA-125, is expected to start a Phase II trial for the treatment of atopic dermatitis and pruritus. Additionally, the company has SNA-001, their photoparticle therapy being used to reduce unwanted light-pigmented hair. Topline data from this program are expected in early 2019.

- Solid Biosciences' (SLDB) Co-Founder, President, and CEO Ilan Ganot gave an inspirational presentation highlighting the commitment of the company to "solving" Duchenne's Muscular Dystrophy (DMD). With a personal stake in finding a therapy that brings benefit to patients, having a son who was diagnosed with DMD, Ganot stressed the importance of the company's 360 degree approach for DMD therapies including disease-modifying therapies - to address symptoms in patients, corrective therapies - to address the genetic cause of DMD, assistive devices to support mobility, all while improving the understanding of the disease.

  The presentation was mainly focused on SGT-001, a micro-dystrophin gene therapy, Solid Biosciences' most advanced therapy for DMD, which is currently in a Phase I/II trial. Although no

new data was presented, the initial results on safety and micro-dystrophin expression are expected later in Q1 2019 and an interim analysis of data from the study should be ready for a H2 2019 readout. Based on animal models, the company is expecting micro-dystrophin expression levels of about 10% for the lower dose of SGT-001, but it also plans to initiate a dose ascending study following an analysis of data from the IGNITE DMD phase I/II trial. Data on how micro-dystrophin translates into a functional benefit is yet to be generated however, Solid Biosciences is hoping to achieve positive results from secondary endpoints in its IGNITE DMD study. Company representatives in the Q&A session noted that a key differentiator of the transgene that they developed is a unique domain that restores and localizes nNOS, which based on preclinical data, they believe leads to increased functional strength.

The issue of the Suspected Unexpected Serious Adverse Reaction in the first dosed patient in the IGNITE trial was also addressed. Company representatives in the Q&A session said that although unfortunate, the event helped the company gain important insights into platelet decreases in patients on the gene therapy and aided in the management of further patients including enabling early detection. They noted that it may be due to AAV9, rather than their particular product, though they did not elaborate. The company did not comment on the frequency of platelet decreases in patients or on whether patients beyond the first one needed eculizumab to correct the defect. They said they did not disclose the latter because they want to have a good understanding of whether it is required or not, and will disclose more information in an update in Q1.

During the Q&A session when asked about the differentiating factors between SGT-001 and other therapies the company's representatives spoke of the inclusion of adolescents in the clinical trials, a group typically omitted due to the advanced stage of disease, as well as of the superiority of the preclinical results of the individual components of the therapy, as indicated above.

The presentation ended with a brief overview of the company's pipeline and plans for further development. This included an anti-LTBP4 disease-modifying therapy to address fibrosis in DMD patients and a planned pipeline expansion with next generation screening for new vector candidates.

- Supernus' (SUPN) CEO Jack Khattar began by giving an update on the company's financials with 2018 net sales guidance around $388-395M based mainly on strong prescription growth of Trokendi XR and Oxtellar XR, and a total 2018 projected operating income of $120-125M. Annual Trokendi XR and Oxtellar XR prescriptions grew by 36% and 12%, respectively, from 2017 owing to their positive differentiating factors as compared to other products within the neurology market.

  Management further highlighted the Company's lead pipeline candidates SPN-812 for the treatment of ADHD and SPN-810 for impulsive aggression, both of which are in Phase III development. For both drugs, the company is currently developing strong IP with expected patient expirations in 2029-2033. While SPN-812 is already used in the EU as a successful antidepressant, Supernus has completed three positive Phase III trials in children/adolescents demonstrating that the norepinephrine reuptake inhibitor is a clinically efficacious in the treatment of ADHD. One Phase III trial (P304 Study) is ongoing and top-line data is expected in Q1 2019. Management emphasized that the primary endpoints were met in all three Phase III trials supported by positive and strong P-values. Significantly, the non-stimulating drug consistently

demonstrates a fast onset of action and works from Week 1, which will be a key differentiating factor. SPN-812 is also well-tolerated and is efficacious in reducing both hyperactivity and inattention, something which management believes will further differentiate it from potential competitors. Company guidance predicts a peak market share of 5-10% with 4.5-10M potential prescriptions of SPN-812.

With no approved therapies for impulsive aggression, Supernus presented a positive outlook for its dopamine-2 receptor targeted pipeline candidate, SPN-810. Impulsive aggression occurs across ADHD, autism, bipolar disorder, and PTSD, representing a $6.3B market opportunity. SPN-810 has Fast Track Designation and is currently in three ongoing Phase III trials. Supernus stated that data from the P301 and P302 trials in pediatric patients are expected in the second half of 2019, and data from the P503 trial in adolescents will be released in 2020.

- Tricida(TCDA) just went public last year with TRC101 for metabolic acidosis its only clinical stage drug. Officials reiterated an expected NDA filing in H2 2019 for accelerated approval, with results from the safety extension trial in H1, registration stability data in mid-2019, and at least near-completion of enrollment in the confirmatory VALOR-CKD trial, which will treat patients for about 3 to 4 years for 500 events.

  The presentation noted the rationale for their drug is that while inexpensive sodium bicarbonate is available to treat the condition, ~90% of the ~600k nephrologist-treated patients (out of 1.1m diagnosed and 3m total CKD patients with metabolic acidosis) have sodium sensitive comorbidities, and so would be better candidates for an alternative like TRC101 that does not deliver counterions. The Phase III trial showed a clear increase in responders, as well as a 5.2 point benefit over placebo on physical function, which officials said compares to a 3-point improvement seen with erythropoiesis-stimulating agents (ESAs) for anemia. Officials reviewed academic research they will be using to make the case for regulators that improvements in blood bicarbonate are linked to better clinical outcomes, such as normalization of blood bicarbonate in patients who can take current alkali supplementation.

  Since they will be targeting nephrologists in the US, they plan for a sales force of 80-100. Officials noted that 25-30% of patients are commercially insured, and a significant subset are dual-eligible for Medicaid/Medicare. Since there may be questions about the value of the drug in the face of inexpensive bicarbonate, officials said they do not intend to target patients who do fine on bicarbonate and they actually started health economic work even before the discover program. To make the case with payers, they noted claims database work showing that patients who have ~4mEq/L higher blood bicarbonate, the increase shown by TRC101 in its Phase III study, have $37k/year fewer costs, as well as a reduction in adverse outcomes (35% versus 51%). While there were not suggesting that the cost saving should be the pricing, it will be used to have quantitative discussions, and they believe they should share in the cost savings.

About the Author

Biomedtracker is an independent research service that offers proprietary clinical assessments of developmental drugs within a comprehensive and intuitive drug information database. Clients from the pharmaceutical, biotech, and investment industries rely on Biomedtracker for its insight on the likelihood of approval, commercial potential, and future data and regulatory catalysts for drugs within the competitive landscape of every important disease and indication. Over recent years, Biomedtracker has become the leader in providing objective information alongside evidence-based clinical assessments and investment research on pipeline drugs worldwide. For more information on getting direct access to Biomedtracker, please email BioMedSupport@sagientresearch.com.

Disclaimer

Table of Contents

Product Updates from Biomedtracker/Meddevicetracker

3SBio Inc.

TPIAO for Thrombocytopenia

Event Date:	02/28/2018
Event Type:	Trial Announcement - Regulatory Approval to Initiate (Clinical Analysis)
Trial Name:	N/A
Market Group:	Hematology
Lead Company:	3SBio Inc.
Partner Companies:	N/A
Phase:	Development Outside U.S.
Change to Likelihood of Approval:	0%
Likelihood of Approval:	0% (Same As Avg.)
Average Approval:	N/A

Analysis:

3SBio reported that it was granted a new IND approval from the SDA for clinical trials of TPIAO in pediatric ITP indication in February 2018.

Source:

J.P. Morgan Healthcare Conference 01/09/2019 (3SBio, Slide 16)

Bydureon for Diabetes Mellitus, Type II

Event Date:	05/31/2018
Event Type:	Progress Update - Product Launch (Emerging Markets) (Clinical Analysis)
Trial Name:	N/A
Market Group:	Endocrine

Lead Company:	AstraZeneca PLC (AZN)
Partner Companies:	Alkermes (ALKS) Bristol-Myers Squibb (BMY) Eli Lilly (LLY) 3SBio
Phase:	Approved
Change to Likelihood of Approval:	0%
Likelihood of Approval:	100% (Same As Avg.)
Average Approval:	100%

Analysis:

3SBio reported that it launched Bydureon for patients with type-2 diabetes in China in May 2018.

Source:

J.P. Morgan Healthcare Conference 01/09/2019 (3SBio, Slide 16)

NuPIAO for Anemia Due to Chronic Renal Failure, Dialysis-Dependent

Event Date:	05/31/2018
Event Type:	Trial Announcement - Regulatory Approval to Initiate (Clinical Analysis)
Trial Name:	N/A
Market Group:	Hematology
Lead Company:	3SBio Inc.
Partner Companies:	N/A
Phase:	Development Outside U.S.
Change to Likelihood of Approval:	0%
Likelihood of Approval:	0% (Same As Avg.)
Average Approval:	N/A

Analysis:

3SBio reported that it obtained an approval from SDA in May 2018 for Phase II and III trials of NuPIAO in anemic patients. Patient enrollment is expected to begin soon.

Source:

J.P. Morgan Healthcare Conference 01/09/2019 (3SBio, Slide 16)

NuPIAO for Anemia Due to Chronic Renal Failure, Dialysis-Independent

Event Date:	05/31/2018
Event Type:	Trial Announcement - Regulatory Approval to Initiate (Clinical Analysis)
Trial Name:	N/A
Market Group:	Hematology
Lead Company:	3SBio Inc.
Partner Companies:	N/A
Phase:	Development Outside U.S.
Change to Likelihood of Approval:	0%
Likelihood of Approval:	0% (Same As Avg.)
Average Approval:	N/A

Analysis:

3SBio reported that it obtained an approval from SDA in May 2018 for Phase II and III trials of NuPIAO in anemic patients. Patient enrollment is expected to begin soon.

Source:

J.P. Morgan Healthcare Conference 01/09/2019 (3SBio, Slide 16)

NuPIAO for Anemia Due to Oncology Treatment

Event Date:	05/31/2018
Event Type:	Trial Announcement - Regulatory Approval to Initiate (Clinical Analysis)
Trial Name:	N/A
Market Group:	Hematology
Lead Company:	3SBio Inc.
Partner Companies:	N/A
Phase:	Development Outside U.S.

Change to Likelihood of Approval:	0%
Likelihood of Approval:	0% (Same As Avg.)
Average Approval:	N/A

Analysis:

3SBio reported that it obtained an approval from SDA in May 2018 for Phase II and III trials of NuPIAO in anemic patients. Patient enrollment is expected to begin soon.

Source:

J.P. Morgan Healthcare Conference 01/09/2019 (3SBio, Slide 16)

Alphamab Oncology

KN046 for Solid Tumors

Event Date:	01/09/2019
Event Type:	Trial Announcement - Initiation (Emerging Markets) (Clinical Analysis)
Trial Name:	Phase Ia/Ib - CHN-001 (China)
Market Group:	Oncology
Lead Company:	Alphamab Oncology
Partner Companies:	N/A
Phase:	Development Outside U.S.
Change to Likelihood of Approval:	0%
Likelihood of Approval:	0% (Same As Avg.)
Average Approval:	N/A

Analysis:

Alphamab announced the development of KN046, a first in class PD-L1/CTLA4 bispecific antibody. Phase I trial is currently ongoing in Australia and China with promising initial readout.

Source:

J.P. Morgan Healthcare Conference (Alphamab, Slide 12)

Ark Biosciences

AK3280 for Idiopathic Pulmonary Fibrosis (IPF)

Event Date:	01/09/2019
Event Type:	Trial Announcement - Initiation (Clinical Analysis)
Trial Name:	Phase Ib Study
Market Group:	Respiratory
Lead Company:	Ark Biosciences
Partner Companies:	Roche (RHHBY)
Phase:	I
Change to Likelihood of Approval:	0%
Likelihood of Approval:	12% (Same As Avg.)
Average Approval:	12%

Analysis:

Ark Biosciences reported that it initiated the Phase Ib study of AK3280 in IPF.

Source:

J.P. Morgan Healthcare Conference 01/09/2019 (Ark, Slide 27)

AK0705 for Chronic Obstructive Pulmonary Disease (COPD)

Event Date:	01/09/2019
Event Type:	Progress Update (Clinical Analysis)
Trial Name:	N/A
Market Group:	Respiratory
Lead Company:	Ark Biosciences
Partner Companies:	N/A
Phase:	Preclinical
Change to Likelihood of Approval:	N/A
Likelihood of Approval:	0% (Same As Avg.)
Average Approval:	N/A

Analysis:

Ark Biosciences currently lists AK0705 for COPD in preclinical development on its pipeline. The Company expects to submit an IND in 2019. The Phase I study is anticipated to start in 2020 and the Phase II study is anticipated in 2021.

Source:

J.P. Morgan Healthcare Conference 01/09/2019 (Ark, Slide 9)

AK074 for Hepatitis B (HBV) Treatment (Antiviral)

Event Date:	01/09/2019
Event Type:	Progress Update (Clinical Analysis)
Trial Name:	N/A
Market Group:	Infectious disease
Lead Company:	Ark Biosciences
Partner Companies:	N/A
Phase:	Preclinical
Change to Likelihood of Approval:	N/A
Likelihood of Approval:	0% (Same As Avg.)
Average Approval:	N/A

Analysis:

Ark Biosciences currently lists AK0704 in preclinical development on its pipeline. The Company expects to submit an IND between end of 2019 and 2020. The Phase I study is anticipated to start in 2020.

Source:

J.P. Morgan Healthcare Conference 01/09/2019 (Ark, Slide 9)

BioCryst Pharmaceuticals, Inc. (BCRX)

BCX7353 for Hereditary Angioedema (HAE)

Event Date:	01/09/2019
Event Type:	Trial Announcement (Clinical Analysis)
Trial Name:	Phase III - Acute HAE Study

Market Group:	Autoimmune/immunology
Lead Company:	BioCryst Pharmaceuticals, Inc. (BCRX)
Partner Companies:	N/A
Phase:	III
Change to Likelihood of Approval:	0%
Likelihood of Approval:	63% (4% Above Avg.)
Average Approval:	59%

Analysis:

BioCryst announced that it expects to begin a Phase III study of BCX7353 in Acute Hereditary Angioedema (HAE) during the summer of 2019, with results expected towards the end of 2020.

Source:

J.P. Morgan Healthcare Conference 01/09/2019 (BCRX; Slide 15)

BlueRock Therapeutics

Dopaminergic Neurons Program (BlueRock) for Parkinson's Disease (PD)

Event Date:	01/09/2019
Event Type:	Trial Announcement (Clinical Analysis)
Trial Name:	N/A
Market Group:	Neurology
Lead Company:	BlueRock Therapeutics
Partner Companies:	N/A
Phase:	Preclinical
Change to Likelihood of Approval:	0%
Likelihood of Approval:	0% (Same As Avg.)
Average Approval:	N/A

Analysis:

Bluerock announced that the company has filed an IND for the Dopaminergic Neurons Program for Parkinson's Disease (PD) and plans to initiate a Phase I/IIa trial.

Phase I/IIa Design
The study is a single-center, open label, Phase I/IIa trial assessing DA01 authentic cell therapy for advanced Parkinson's Disease. The study is enrolling 10 male or female subjects with advanced PD, who are 40-72 years old, and have been diagnosed more than 5 years and less than 15 years prior to the start of the study. The primary endpoints are safety, tolerability, and PET-imaging for cell survival at one year. There will be a low-dose and high-dose cohort, and immunosuppression will be dosed up to 12 months following transplantation.

Source:

J.P. Morgan Healthcare Conference 01/09/2019 (Bluerock, Slide 20, 21)

CANbridge Life Sciences Ltd.

Caphosol for Mucositis

Event Date:	04/02/2018
Event Type:	Regulatory - Approval (Emerging Markets) (Clinical Analysis)
Trial Name:	N/A
Market Group:	Autoimmune/immunology
Lead Company:	CANbridge Life Sciences Ltd.
Partner Companies:	N/A
Phase:	Approved
Change to Likelihood of Approval:	0%
Likelihood of Approval:	100% (Same As Avg.)
Average Approval:	100%

Analysis:

CANbridge announced that it received an Import Medical Device Market Approval from the China Food and Drug Administration (CFDA) for CAN002 as a cancer adjuvant therapy, on April 2, 2018. CAN002, marketed as Caphosol in 47 countries, is an oral rinse for the treatment of oral mucositis, the inflammation and ulceration of the mucous membranes lining the mouth that occurs frequently in cancer patients undergoing high-dose chemotherapy, radiation and hematopoietic stem cell transplants. CAN002 is CANbridge's first commercialized product.

In 2014, CANbridge entered into an exclusive partnership with EUSA for the right to commercialize Caphosol in China.

Source:

Press Release 04/26/2018 (CANbridge)
J.P. Morgan Healthcare Conference 01/09/2019 (CANbridge)

Hunterase for Mucopolysaccharidosis II (MPS II; Hunter Syndrome)

Event Date:	01/07/2019
Event Type:	Partnership - Licensing Deal (Emerging Markets) (Clinical Analysis)
Trial Name:	N/A
Market Group:	Metabolic
Lead Company:	Green Cross Corporation (006280.KS)
Partner Companies:	CANbridge Life Sciences
Phase:	Development Outside U.S.
Change to Likelihood of Approval:	0%
Likelihood of Approval:	0% (Same As Avg.)
Average Approval:	N/A

Analysis:

CANbridge Pharmaceuticals and GC Pharma announced an exclusive licensing agreement in the greater China area to commercialize Hunterase, a human recombinant iduronate-2-sulfatase (IDS) enzyme replacement therapy for the treatment of Hunter syndrome. Developed by GC Pharma, Hunterase is marketed in more than ten countries worldwide.

Source:

Press Release 01/07/2019 (CANbridge)
Press Release 01/08/2019 (GC Pharma, Korean)
J.P. Morgan Healthcare Conference 01/09/2019 (CANbridge)

Cell Medica Ltd.

CMD-502 for Hematologic Cancer

Event Date:	01/09/2019
Event Type:	Trial Announcement (Clinical Analysis)
Trial Name:	N/A
Market Group:	Oncology
Lead Company:	Cell Medica Ltd.
Partner Companies:	Baylor College of Medicine

Phase:	Preclinical
Change to Likelihood of Approval:	0%
Likelihood of Approval:	0% (Same As Avg.)
Average Approval:	N/A

Analysis:

Cell Medica announced that the first patient is expected to be treated in a Phase I trial of CMD-502 in the second half of 2019 at Baylor.

Source:

J.P. Morgan Healthcare Conference 01/09/2019 (Cell Medica, Slide 14)

CMD-503 for Hepatocellular (Liver) Cancer (HCC) (Including Secondary Metastases)

Event Date:	01/09/2019
Event Type:	Progress Update (Clinical Analysis)
Trial Name:	N/A
Market Group:	Oncology
Lead Company:	Cell Medica Ltd.
Partner Companies:	Baylor College of Medicine
Phase:	Preclinical
Change to Likelihood of Approval:	0%
Likelihood of Approval:	0% (Same As Avg.)
Average Approval:	N/A

Analysis:

Cell Medica announced that preclincal POC is expected in the second half of 2019 for CMD-503 and CMD-504.

Source:

J.P. Morgan Healthcare Conference 01/09/2019 (Cell Medica, Slide 15)

CMD-504 for Solid Tumors

Event Date:	01/09/2019
Event Type:	Progress Update (Clinical Analysis)
Trial Name:	N/A
Market Group:	Oncology
Lead Company:	Cell Medica Ltd.
Partner Companies:	Baylor College of Medicine
Phase:	Preclinical
Change to Likelihood of Approval:	0%
Likelihood of Approval:	0% (Same As Avg.)
Average Approval:	N/A

Analysis:

Cell Medica announced that preclinical POC is expected in the second half of 2019 for CMD-503 and CMD-504.

Source:

J.P. Morgan Healthcare Conference 01/09/2019 (Cell Medica, Slide 15)

ChemoCentryx, Inc. (CCXI)

Avacopan for Renal Disease / Renal Failure

Event Date:	01/09/2019
Event Type:	Trial Announcement - Trial Progressing (Clinical Analysis)
Trial Name:	Phase II - C3G
Market Group:	Renal
Lead Company:	ChemoCentryx, Inc. (CCXI)
Partner Companies:	Kissei (4547:JP) Vifor Pharma (GNHAY)
Phase:	II
Change to Likelihood of Approval:	0%

Likelihood of Approval:	24% (Same As Avg.)
Average Approval:	24%

Analysis:

ChemoCentryx announced the Phase II C3G trial of Avacopan is about 40% enrolled. The company reported that the trial may be fully enrolled by the middle of 2019, with a read out in the early part of 2020.

Source:

J.P. Morgan Healthcare Conference 01/09/2019 (CCXI)

Avacopan for Hidradenitis Suppurativa

Event Date:	01/09/2019
Event Type:	Trial Announcement - Initiation (Clinical Analysis)
Trial Name:	Phase II - 001
Market Group:	Dermatology
Lead Company:	ChemoCentryx, Inc. (CCXI)
Partner Companies:	Kissei (4547:JP) Vifor Pharma (GNHAY)
Phase:	II
Change to Likelihood of Approval:	24%
Likelihood of Approval:	24% (Same As Avg.)
Average Approval:	24%

Analysis:

ChemoCentryx announced the company is starting a registration-grade study of Avacopan for the treatment of hidradenitis suppurativa. The study will enroll 390 patients across 3 arms and is placebo controlled. The primary endpoint is a 12-week endpoint. The company expects to complete enrollment in 2019 and report a 12-week readout in early or mid-2020.

Source:

J.P. Morgan Healthcare Conference 01/09/2019 (CCXI)

Crinetics Pharmaceuticals, Inc. (CRNX)

CRN00808 for Acromegaly

Event Date:	01/09/2019
Event Type:	Trial Announcement - Initiation (Clinical Analysis)
Trial Name:	Phase II - ACROBAT EDGE , Phase II - ACROBAT EVOLVE
Market Group:	Endocrine
Lead Company:	Crinetics Pharmaceuticals, Inc. (CRNX)
Partner Companies:	N/A
Phase:	II
Change to Likelihood of Approval:	10%
Likelihood of Approval:	24% (Same As Avg.)
Average Approval:	24%

Analysis:

Crinetics announced the initiation of the CRN00808 Phase II ACROBAT program for the treatment of acromegaly. The Phase II program will consist of the EDGE and EVOLVE studies. ACROBAT EDGE is a Phase II, open label exploratory study which evaluates the safety, pharmacokinetics and efficacy of CRN00808 in patients with acromegaly treated with somatostatin analogue based treatment regimens. ACROBAT EVOLVE is a Phase II double-blind, placebo-controlled, randomized withdrawal study which evaluates the safety, pharmacokinetics and efficacy of CRN00808 in patients with acromegaly that are responders to octreotide LAR or lanreotide Depot.

Source:

www.clinicaltrials.gov
www.clinicaltrials.gov
J.P. Morgan Healthcare Conference 01/09/2019 (CRNX, Slide 14-16)

ACTH Antagonist (Crinetics) for Cushing's Syndrome

Event Date:	01/09/2019
Event Type:	Progress Update (Clinical Analysis)
Trial Name:	N/A
Market Group:	Endocrine
Lead Company:	Crinetics Pharmaceuticals, Inc. (CRNX)
Partner Companies:	N/A
Phase:	Preclinical

Change to Likelihood of Approval:	N/A
Likelihood of Approval:	0% (Same As Avg.)
Average Approval:	N/A

Analysis:

Crinetics lists its oral ACTH antagonist in preclinical development for the treatment of Cushing's disease in its pipeline.

Source:

J.P. Morgan Healthcare Conference 01/09/2019 (CRNX)

Eagle Pharmaceuticals, Inc. (EGRX)

EA-111 for Undisclosed

Event Date:	01/09/2019
Event Type:	Progress Update (Clinical Analysis)
Trial Name:	N/A
Market Group:	Not Specified
Lead Company:	Eagle Pharmaceuticals, Inc. (EGRX)
Partner Companies:	N/A
Phase:	Preclinical
Change to Likelihood of Approval:	N/A
Likelihood of Approval:	0% (Same As Avg.)
Average Approval:	N/A

Analysis:

Eagle reported that it is developing EA-111, an intramuscular (IM) formulation with new chemical entities (NCE) related to dantrolene. The product provides in vivo dantrolene levels similar to Ryanodex. The Company anticipates 5 year NCE regulatory exclusivity after FDA approval.

Source:

J.P. Morgan Healthcare Conference 01/09/2019 (EGRX, Slide 12)

Eidos Therapeutics, Inc. (EIDX)

AG10 for Transthyretin Amyloid Cardiomyopathy (ATTR-CM, Wild Type Or Hereditary)

Event Date:	12/31/2018
Event Type:	Regulatory - Meeting with FDA (Clinical Analysis)
Trial Name:	N/A
Market Group:	Metabolic
Lead Company:	Eidos Therapeutics, Inc. (EIDX)
Partner Companies:	BridgeBio
Phase:	II
Change to Likelihood of Approval:	0%
Likelihood of Approval:	26% (2% Above Avg.)
Average Approval:	24%

Analysis:

Eidos reported that it had an End of Phase II meeting with the FDA for ATTR patients in 2018.

Source:

J.P. Morgan Healthcare Conference 01/09/2019 (EIDX, Slide 30)

FLX Bio, Inc.

FLX193 for Atopic Dermatitis (Eczema)

Event Date:	01/09/2019
Event Type:	Progress Update (Clinical Analysis)
Trial Name:	N/A
Market Group:	Allergy
Lead Company:	FLX Bio, Inc.
Partner Companies:	N/A

Phase:	Preclinical
Change to Likelihood of Approval:	N/A
Likelihood of Approval:	0% (Same As Avg.)
Average Approval:	N/A

Analysis:

FLX announced that FLX193 is in preclinical development for allergic disorders. FLX193 is the second CCR4 molecule advancing into development.

Source:

J.P. Morgan Healthcare Conference 01/09/2019 (FLX, Slide 3, 17)

Galapagos NV (GLPG)

GLPG3312 for Inflammatory Disorders

Event Date:	01/07/2019
Event Type:	Trial Announcement - Initiation (Clinical Analysis)
Trial Name:	Phase I - GLPD3312/Toledo Compound Study
Market Group:	Autoimmune/immunology
Lead Company:	Galapagos NV (GLPG)
Partner Companies:	N/A
Phase:	I
Change to Likelihood of Approval:	14%
Likelihood of Approval:	14% (Same As Avg.)
Average Approval:	14%

Analysis:

Galapagos announced it has initiated a Phase I trial of GLPG3312 (Toledo), a first generation compound against a novel and undisclosed inflammation target class discovered by Galapagos.

"Toledo" is a code name for a novel class discovered by Galapagos. The target family has a dual mode of action on inflammation by stimulating anti-inflammatory cytokines and inhibiting pro-inflammatory cytokines.

Study Design

The Phase I trial is a double-blind, placebo-controlled, single-center study evaluating the efficacy,

safety, tolerability, and PK/PD of GLPG3312 in 76 adult healthy male volunteers.

Source:

Press Release 01/07/2019
J.P. Morgan Healthcare Conference 01/09/2019 (GLPG)

Genmab A/S (GEN:DC)

Tisotumab Vedotin for Solid Tumors

Event Date:	01/09/2019
Event Type:	Trial Announcement - Trial Completed (Clinical Analysis)
Trial Name:	Phase I/IIa - innovaTV 201 (GEN701)
Market Group:	Oncology
Lead Company:	Genmab A/S (GEN:DC)
Partner Companies:	Seattle Genetics (SGEN)
Phase:	II
Change to Likelihood of Approval:	0%
Likelihood of Approval:	10% (Same As Avg.)
Average Approval:	10%

Analysis:

Genmab reported that the Phase I/IIa InnovaTV 201 trial has been completed.

Source:

J.P. Morgan Healthcare Conference 01/09/2019 (Genmab, Slide 13)

Genscript Biotech (GNNSF)

LCAR-B38M for Multiple Myeloma (MM)

Event Date:	03/31/2018
Event Type:	Trial Announcement - Regulatory Approval to Initiate (Clinical Analysis)
Trial Name:	Phase II - China
Market Group:	Oncology

Lead Company:	Johnson & Johnson (JNJ)
Partner Companies:	Genscript Biotech (GNNSF)
Phase:	II
Change to Likelihood of Approval:	0%
Likelihood of Approval:	15% (5% Above Avg.)
Average Approval:	10%

Analysis:

Legend Biotech reported that the IND for the registration trial of LCAR-B38M in patients with relapsed or refractory Multiple Myeloma (MM) was cleared by the CFDA in March 2018.

Source:

J.P. Morgan Healthcare Conference 01/09/2019 (Legend Biotech, Slide 10)

Halozyme Therapeutics, Inc. (HALO)

PEGPH20 for Biliary Tract Cancer

Event Date:	09/30/2018
Event Type:	Trial Announcement - Trial Progressing (Clinical Analysis)
Trial Name:	Phase Ib - w/Tecentriq
Market Group:	Oncology
Lead Company:	Halozyme Therapeutics, Inc. (HALO)
Partner Companies:	Nektar (NKTR)
Phase:	I
Change to Likelihood of Approval:	0%
Likelihood of Approval:	6% (Same As Avg.)
Average Approval:	6%

Analysis:

Halozyme Therapeutics lists that they initiated dose expansion in the Phase Ib study of Tecentriq in combination with PEGPH20 for the treatment of gall bladder cancer and cholangiocarcinoma in the third quarter of 2018.

Source:

J.P. Morgan Healthcare Conference 01/09/2019 (HALO, Slide 24)

PEGPH20 for Pancreatic Cancer

Event Date:	12/31/2018
Event Type:	Trial Announcement - Patient Enrollment Completed (Clinical Analysis)
Trial Name:	Phase III - HALO-301
Market Group:	Oncology
Lead Company:	Halozyme Therapeutics, Inc. (HALO)
Partner Companies:	Nektar (NKTR)
Phase:	III
Change to Likelihood of Approval:	0%
Likelihood of Approval:	38% (3% Above Avg.)
Average Approval:	35%

Analysis:

Halozyme Therapeutics lists that the Phase III HALO-301 study of PEGPH20 for the treatment of pancreatic cancer completed enrollment in 2018.

Source:

J.P. Morgan Healthcare Conference 01/09/2019 (HALO, Slide 3)

Hutchison MediPharma Limited (HCM)

Theliatinib for Esophageal Cancer

Event Date:	01/09/2019
Event Type:	Progress Update (Clinical Analysis)
Trial Name:	N/A
Market Group:	Oncology
Lead Company:	Hutchison MediPharma Limited (HCM)
Partner Companies:	N/A

Phase:	Development Outside U.S.
Change to Likelihood of Approval:	N/A
Likelihood of Approval:	0% (Same As Avg.)
Average Approval:	N/A

Analysis:

Hutchison currently lists theliatinib in development in China for the treatment of EGFR wild-type esophageal cancer in the dose expansion/proof-of-concept phase.

Source:

J.P. Morgan Healthcare Conference 01/09/2019 (HCM, Slide 7)

Savolitinib for Prostate Cancer

Event Date:	01/09/2019
Event Type:	Progress Update (Clinical Analysis)
Trial Name:	N/A
Market Group:	Oncology
Lead Company:	AstraZeneca PLC (AZN)
Partner Companies:	Hutchison (HCM)
Phase:	II
Change to Likelihood of Approval:	0%
Likelihood of Approval:	10% (Same As Avg.)
Average Approval:	10%

Analysis:

Hutchison currently lists Savolitinib for the 1st/2nd line treatment of MET+ prostate cancer in the dose expansion/proof-of-concept phase in its pipeline.

Source:

J.P. Morgan Healthcare Conference 01/09/2019 (HCM, Slide 7)

ImmunoGen, Inc. (IMGN)

Mirvetuximab Soravtansine for Ovarian Cancer

Event Date:	12/31/2018
Event Type:	Trial Announcement - Trial Progressing (Clinical Analysis)
Trial Name:	Phase Ib/II - FORWARD II
Market Group:	Oncology
Lead Company:	ImmunoGen, Inc. (IMGN)
Partner Companies:	N/A
Phase:	III
Change to Likelihood of Approval:	0%
Likelihood of Approval:	39% (4% Above Avg.)
Average Approval:	35%

Analysis:

Immunogen announced that it began enrolling the Avastin cohort of the FORWARD II trial in late December 2018. Enrollment of this cohort is expected to be completed in 2019.

Source:

J.P. Morgan Healthcare Conference 01/09/2019 (IMGN)

Intercept Pharmaceuticals, Inc. (ICPT)

Bezalip SR for Primary Biliary Cholangitis (PBC) and Hepatic Fibrosis

Event Date:	01/07/2019
Event Type:	Progress Update - Development Review (Clinical Analysis)
Trial Name:	N/A
Market Group:	Autoimmune/immunology
Lead Company:	Intercept Pharmaceuticals, Inc. (ICPT)
Partner Companies:	N/A
Phase:	Preclinical
Change to Likelihood of Approval:	0%

Likelihood of Approval:	0% (Same As Avg.)
Average Approval:	N/A

Analysis:

Intercept announced that it has acquired from Aralez its license to develop and commercialize bezafibrate in the U.S., its IND on file with the FDA and other associated regulatory documentation, and a non-exclusive license to certain of Aralez's intellectual property.

Intercept intends to initiate a Phase II study to evaluate the efficacy, safety and tolerability of bezafibrate in combination with Ocaliva in patients with PBC, with the longer term goal to develop and seek regulatory approval for a fixed dose combination regimen in this indication and potentially other liver diseases.

Source:

Press Release 01/07/2019
J.P. Morgan Healthcare Conference 01/09/2019 (ICPT, Slide 23)

Ocaliva for Primary Sclerosing Cholangitis (PSC)

Event Date:	01/07/2019
Event Type:	Progress Update - Development Review (Clinical Analysis)
Trial Name:	N/A
Market Group:	Autoimmune/immunology
Lead Company:	Intercept Pharmaceuticals, Inc. (ICPT)
Partner Companies:	Sumitomo Dainippon Pharma (4506:JP)
Phase:	II
Change to Likelihood of Approval:	0%
Likelihood of Approval:	21% (1% Above Avg.)
Average Approval:	20%

Analysis:

Intercept announced that it has acquired from Aralez its license to develop and commercialize bezafibrate in the U.S., its IND on file with the FDA and other associated regulatory documentation, and a non-exclusive license to certain of Aralez's intellectual property.

Intercept intends to initiate a Phase II study to evaluate the efficacy, safety and tolerability of bezafibrate in combination with Ocaliva in patients with PBC, with the longer term goal to develop and seek regulatory approval for a fixed dose combination regimen in this indication and potentially other liver diseases.

Source:

Press Release 01/07/2019
J.P. Morgan Healthcare Conference 01/09/2019 (ICPT, Slide 23)

Intrexon Corporation (XON)

INXN-3004 for Acute Myelogenous Leukemia (AML)

Event Date:	01/09/2019
Event Type:	Progress Update (Clinical Analysis)
Trial Name:	N/A
Market Group:	Oncology
Lead Company:	Intrexon Corporation (XON)
Partner Companies:	N/A
Phase:	I
Change to Likelihood of Approval:	N/A
Likelihood of Approval:	6% (Same As Avg.)
Average Approval:	6%

Analysis:

Precigen lists INXN-3004 in Phase I development for the treatment of AML in its pipeline.

Source:

J.P. Morgan Healthcare Conference 01/09/2019 (XON, Slide 15)

PRGN-3005 for Solid Tumors

Event Date:	01/09/2019
Event Type:	Progress Update (Clinical Analysis)
Trial Name:	N/A
Market Group:	Oncology
Lead Company:	Intrexon Corporation (XON)
Partner Companies:	N/A
Phase:	Preclinical

Change to Likelihood of Approval:	N/A
Likelihood of Approval:	0% (Same As Avg.)
Average Approval:	N/A

Analysis:

Precigen lists PRGN-3005 in preclinical development for the treatment of solid tumors in its pipeline.

Source:

J.P. Morgan Healthcare Conference 01/09/2019 (XON, Slide 15)

PRGN-2009 for Solid Tumors

Event Date:	01/09/2019
Event Type:	Progress Update (Clinical Analysis)
Trial Name:	N/A
Market Group:	Oncology
Lead Company:	Intrexon Corporation (XON)
Partner Companies:	N/A
Phase:	Preclinical
Change to Likelihood of Approval:	N/A
Likelihood of Approval:	0% (Same As Avg.)
Average Approval:	N/A

Analysis:

Precigen lists PRGN-2009 in preclinical development for the treatment of solid tumors in its pipeline.

Source:

J.P. Morgan Healthcare Conference 01/09/2019 (XON, Slide 15)

PRGN-2010 for Solid Tumors

Event Date:	01/09/2019
Event Type:	Progress Update (Clinical Analysis)
Trial Name:	N/A
Market Group:	Oncology

Lead Company:	Intrexon Corporation (XON)
Partner Companies:	N/A
Phase:	Preclinical
Change to Likelihood of Approval:	N/A
Likelihood of Approval:	0% (Same As Avg.)
Average Approval:	N/A

Analysis:

Precigen lists PRGN-2010 in preclinical development for the treatment of solid tumors in its pipeline.

Source:

J.P. Morgan Healthcare Conference 01/09/2019 (XON, Slide 15)

Inventiva (IVA)

ABBV-157 for Psoriasis

Event Date:	12/31/2018
Event Type:	Trial Announcement - Initiation (Clinical Analysis)
Trial Name:	N/A
Market Group:	Autoimmune/immunology
Lead Company:	AbbVie Inc. (ABBV)
Partner Companies:	Inventiva (IVA)
Phase:	I
Change to Likelihood of Approval:	14%
Likelihood of Approval:	14% (Same As Avg.)
Average Approval:	14%

Analysis:

Inventiva announced that AbbVie has started a Phase I study with ABBV-157 in 2018, and data will be available in 2019.

With the initiation of Phase I with ABBV-157 and the discovery of a back-up to this lead candidate, the work of Inventiva's team to discover new orally available ROR inverse agonists is completed. Inventiva remains eligible to future milestone payments and sales royalties on all ROR molecules identified during the collaboration.

Source:

J.P. Morgan Healthcare Conference 01/09/2019 (Inventiva, Slide 29)

Lanifibranor for Scleroderma

Event Date:	01/09/2019
Event Type:	Progress Update - Development Review (Clinical Analysis)
Trial Name:	N/A
Market Group:	Autoimmune/immunology
Lead Company:	Inventiva S.A. (IVA)
Partner Companies:	N/A
Phase:	II
Change to Likelihood of Approval:	0%
Likelihood of Approval:	20% (Same As Avg.)
Average Approval:	20%

Analysis:

Inventiva announced that they will explore the possibility of conditional marketing approval with the EMA in the second half of 2019 in regards to the Lanifibranor FASST Phase IIb trial in SSc, as well as the FDA potential breakthrough therapy status. Pending the results of the Phase IIb study, they will also explore the the start of a pivotal Phase III study in the EU and U.S.

Source:

J.P. Morgan Healthcare Conference 01/09/2019 (Inventiva, Slide 20)

La Jolla Pharmaceutical Company (LJPC)

Giapreza for Hypotension/Shock

Event Date:	10/01/2018
Event Type:	Reimbursement - Progress Update (Clinical Analysis)
Trial Name:	N/A
Market Group:	Cardiovascular
Lead Company:	La Jolla Pharmaceutical Company (LJPC)

Partner Companies:	HealthCare Royalty Partners
Phase:	Approved
Change to Likelihood of Approval:	0%
Likelihood of Approval:	100% (Same As Avg.)
Average Approval:	100%

Analysis:

La Jolla Pharmaceutical announced the Centers for Medicare & Medicaid Services (CMS) has granted a New Technology Add-on Payment (NTAP) for Giapreza. The NTAP is effective for the CMS 2019 fiscal year, which began on October 1, 2018.

Source:

J.P. Morgan Healthcare Conference 01/09/2019 (LJPC, Slide 5)

LJPC-0118 for Malaria

Event Date:	01/07/2019
Event Type:	Progress Update (Clinical Analysis)
Trial Name:	N/A
Market Group:	Infectious disease
Lead Company:	La Jolla Pharmaceutical Company (LJPC)
Partner Companies:	N/A
Phase:	I
Change to Likelihood of Approval:	N/A
Likelihood of Approval:	19% (Same As Avg.)
Average Approval:	19%

Analysis:

La Jolla plans to file a New Drug Application (NDA) with the U.S. Food and Drug Administration (FDA) in the fourth quarter of 2019 for LJPC-0118. LJPC-0118 is La Jolla's new investigational product for the treatment of severe malaria. The active pharmaceutical ingredient in LJPC-0118 was demonstrated to be superior to quinine in reducing mortality in patients with severe falciparum malaria infection in two randomized, controlled, clinical studies. La Jolla is currently conducting a clinical trial needed for NDA submission. The trial is underway, fully recruited, and expected to complete in Q1 2019.

Source:

Press Release 01/07/2019
J.P. Morgan Healthcare Conference 01/09/2019 (LJPC, Slide 19)

MediciNova, Inc. (MNOV)

MN-166 for Brain Cancer (Malignant Glioma; AA and glioblastoma (GBM))

Event Date:	01/08/2019
Event Type:	Trial Announcement - Initiation (Clinical Analysis)
Trial Name:	Phase I/II - w/Temozolomide
Market Group:	Oncology
Lead Company:	MediciNova, Inc. (MNOV)
Partner Companies:	Kyorin (4569:JP)
Phase:	II
Change to Likelihood of Approval:	10%
Likelihood of Approval:	10% (Same As Avg.)
Average Approval:	10%

Analysis:

MediciNova announced that the first glioblastoma patient has enrolled in the clinical trial of MN-166 (ibudilast) in combination with temozolomide (TMZ, Temodar) for the treatment of recurrent glioblastoma (GBM).

Combination treatment of MN-166 (ibudilast) with TMZ resulted in significantly extended survival times compared to TMZ monotherapy in a GBM animal model study with complete tumor regression observed in two out of 16 mice. This is the first clinical trial to evaluate the safety, tolerability and preliminary efficacy of MN-166 (ibudilast) in combination with temozolomide for the treatment of recurrent GBM.

Source:

Press Release 01/08/2019 (MNOV)
J.P. Morgan Healthcare Conference 01/09/2019 (MNOV)

Microbio Group

FB825 for Atopic Dermatitis (Eczema)

Event Date:	01/09/2019
Event Type:	Trial Data - Top-Line Results (Clinical Analysis)

Trial Name:	Phase IIa - Atopic Dermatitis Study (Taiwan)
Market Group:	Allergy
Lead Company:	Microbio Group
Partner Companies:	N/A
Phase:	Development Outside U.S.
Change to Likelihood of Approval:	0%
Likelihood of Approval:	0% (Same As Avg.)
Average Approval:	N/A

Analysis:

Fountain Biopharma announced clinical outcomes of FB825 in an exploratory Phase IIa proof-of-concept study.

Design

This is an exploratory, investigator initiated Phase IIa study of FB825 in patients with atopic dermatitis.

Results

In 24 weeks (2 doses), 12 subjects with moderate to severe atopic dermatitis (AD) showed:

- EASI score reduction by 72%
- IgE level reduction by 46%
- Pruritus reduction by 46%
- AD-related inflammatory cytokines reduce significantly

In addition, Fountain reported that

- FB825 showed comparable EASI-75 improvement in week 16 to dupilumab with only 2 doses
- FB825 continuously reduced EASI score and IgE in 6 months
- Most of AD-related Th2 cytokines were significantly declined during FB825 treatment
- For the same patient, EASI score showed a significant reduction after FB825 as compared to baseline (1 month period before FB825)
- Only 10% of subjects received rescue by super high TCS during 24 week FB825 treatment

Source:

J.P. Morgan Healthcare Conference 01/09/2019 (Fountain, Slides 14-18)

Mirati Therapeutics (MRTX)

KRAS G12D Inhibitor Program (Mirati) for Solid Tumors

Event Date:	01/09/2019

Event Type:	Progress Update (Clinical Analysis)
Trial Name:	N/A
Market Group:	Oncology
Lead Company:	Mirati Therapeutics (MRTX)
Partner Companies:	N/A
Phase:	Preclinical
Change to Likelihood of Approval:	N/A
Likelihood of Approval:	0% (Same As Avg.)
Average Approval:	N/A

Analysis:

Mirati currently lists its KRAS G12D Program for the treatment of solid tumors in preclinical development in its pipeline. Mirati expects to identify a lead candidate in the fourth quarter of 2019.

Source:

J.P. Morgan Healthcare Conference 01/09/2019 (MRTX, Slide 4, 24)

MorphoSys AG (MOR)

MOR208 for Diffuse Large B-Cell Lymphoma (DLBCL) - NHL

Event Date:	01/09/2019
Event Type:	Trial Announcement (Clinical Analysis)
Trial Name:	Phase Ib - FRONTLINE DLBLC
Market Group:	Oncology
Lead Company:	MorphoSys AG (MOR)
Partner Companies:	Xencor (XNCR)
Phase:	III
Change to Likelihood of Approval:	0%
Likelihood of Approval:	39% (4% Above Avg.)
Average Approval:	35%

Analysis:

MorphoSys announced the Phase Ib trial investigating effects of MOR-208 and R-CHOP (rituximab + chemotherapy) versus MOR-208, R-CHOP, and lenalidomide (LEN) in patients with frontline diffuse large B-cell lymphoma (DLBCL). The company plans for the study to start in third quarter of 2019.

Source:

J.P. Morgan Healthcare Conference 01/09/2019 (MOR, Slide 22)

MOR202 for Autoimmune Disorders

Event Date:	01/09/2019
Event Type:	Trial Announcement (Clinical Analysis)
Trial Name:	Phase II - Autoimmune Disorders
Market Group:	Autoimmune/immunology
Lead Company:	MorphoSys AG (MOR)
Partner Companies:	I-Mab Biopharma
Phase:	Preclinical
Change to Likelihood of Approval:	N/A
Likelihood of Approval:	0% (Same As Avg.)
Average Approval:	N/A

Analysis:

MorphoSys announced that it plans to initiate a Phase II study investigating MOR202 for the treatment of autoimmune disorders in the third quarter of 2019.

Source:

J.P. Morgan Healthcare Conference 01/09/2019 (MOR, Slide 15)

Nevro Corp. (NVRO)

Senza for Migraine and Other Headaches

Event Date:	01/09/2019
Event Type:	Trial Announcement (Clinical Analysis)
Trial Name:	Preclinical Studies
Market Group:	Neurology

Lead Company:	Nevro Corp. (NVRO)
Partner Companies:	N/A
Phase:	Development Outside U.S.
Change to Likelihood of Approval:	0%
Likelihood of Approval:	0% (Same As Avg.)
Average Approval:	N/A

Analysis:

Nevro announced a prospective, 6-month proof-of-concept open-label study of Senza for chronic migraines is planned to commence in 2019.

Source:

J.P. Morgan Healthcare Conference 01/09/2019 (NVRO, Slide 15)

Novavax, Inc. (NVAX)

ResVax for Respiratory Syncytial Virus (RSV)

Event Date:	06/11/2018
Event Type:	Trial Announcement - Patient Enrollment Completed (Clinical Analysis)
Trial Name:	Phase III - Prepare (Pregnant Women)
Market Group:	Infectious disease
Lead Company:	Novavax, Inc. (NVAX)
Partner Companies:	N/A
Phase:	III
Change to Likelihood of Approval:	0%
Likelihood of Approval:	55% (6% Below Avg.)
Average Approval:	61%

Analysis:

Novavax announced the company completed enrollment of 4636 mothers in the Phase III Prepare study of ResVax in the second quarter of 2019.

Source:

www.clinicaltrials.gov
J.P. Morgan Healthcare Conference 01/09/2019 (NVAX, Slide 12)

NovoCure Limited (NVCR)

Optune for Brain Cancer (Malignant Glioma; AA and glioblastoma (GBM))

Event Date:	01/09/2019
Event Type:	Reimbursement - Individual Country (Europe) - Positive Recommendation (Clinical Analysis)
Trial Name:	N/A
Market Group:	Oncology
Lead Company:	NovoCure Limited (NVCR)
Partner Companies:	N/A
Phase:	Approved
Change to Likelihood of Approval:	0%
Likelihood of Approval:	100% (Same As Avg.)
Average Approval:	100%

Analysis:

Novocure announced that it received national reimbursement in Sweden for Optune.

Source:

J.P. Morgan Healthcare Conference 01/09/2019 (NVCR)

Orchard Therapeutics Limited (ORTX)

OTL-101 for Primary Immunodeficiencies

Event Date:	12/31/2018
Event Type:	Regulatory - Meeting with FDA (Clinical Analysis)
Trial Name:	N/A
Market Group:	Autoimmune/immunology

Lead Company:	Orchard Therapeutics Limited (ORTX)
Partner Companies:	Oxford BioMedica (OXB:LN)
Phase:	II
Change to Likelihood of Approval:	0%
Likelihood of Approval:	20% (Same As Avg.)
Average Approval:	20%

Analysis:

In 2018, Orchard Therapeutics completed pre-biologics license application (BLA) and CMC specific meetings with the U.S. Food and Drug Administration (FDA) for OTL-101 for ADA-SCID, following which the program remains on track for a BLA filing in the U.S. in 2020.

Source:

J.P. Morgan Healthcare Conference 01/07/2019 (ORTX)
J.P. Morgan Healthcare Conference 01/09/2019 (ORTX, Slide 18)

OTL-201 for Mucopolysaccharidosis IIIA (MPS IIIA; Sanfilippo A Syndrome)

Event Date:	12/31/2018
Event Type:	Regulatory - Progress Update (Clinical Analysis)
Trial Name:	N/A
Market Group:	Metabolic
Lead Company:	Orchard Therapeutics Limited (ORTX)
Partner Companies:	Oxford BioMedica (OXB:LN)
Phase:	Preclinical
Change to Likelihood of Approval:	0%
Likelihood of Approval:	0% (Same As Avg.)
Average Approval:	N/A

Analysis:

Orchard Therapeutics obtained Rare Pediatric Disease Designation from the FDA for OTL-201 for the treatment of MPS-IIIA in 2018.

Source:

J.P. Morgan Healthcare Conference 01/07/2019 (ORTX)
J.P. Morgan Healthcare Conference 01/09/2019 (ORTX, Slide 7)

OTL-103 for Thrombocytopenia

Event Date:	12/31/2018
Event Type:	Regulatory - Progress Update (Clinical Analysis)
Trial Name:	N/A
Market Group:	Hematology
Lead Company:	Orchard Therapeutics Limited (ORTX)
Partner Companies:	MolMed (MLM.MI)
Phase:	III
Change to Likelihood of Approval:	0%
Likelihood of Approval:	60% (Same As Avg.)
Average Approval:	60%

Analysis:

Orchard Therapeutics obtained Rare Pediatric Disease Designation from the FDA for OTL-103 for the treatment of WAS.

Source:

J.P. Morgan Healthcare Conference 01/09/2019 (ORTX, Slide 7)

Pliant Therapeutics

PLN-1474 for Non-Alcoholic Steatohepatitis (NASH)

Event Date:	01/09/2019
Event Type:	Progress Update - Development Review (Clinical Analysis)
Trial Name:	N/A
Market Group:	Endocrine
Lead Company:	Pliant Therapeutics
Partner Companies:	N/A
Phase:	Preclinical
Change to Likelihood of Approval:	N/A
Likelihood of Approval:	0% (Same As Avg.)

Average Approval:	N/A

Analysis:

Pliant Therapeutics lists that IND-enabling studies of PLN-1474 have been initiated. The Company plans to file an IND for PLN-1474 in the third quarter of 2019.

Efficacy in animal models of NASH-fibrosis has been confirmed, and potent antifibrotic effects were established in human NASH-F4 liver fibrosis tissue. The Company has also demonstrated PLN-1474 to be highly potent (aVß1 IC50 < 5 nM), highly selective (>100-fold aVß1 selectivity versus other integrins), and preclinical data supports b.i.d. or q.d. oral dosing.

Source:

J.P. Morgan Healthcare Conference 01/09/2019 (Pliant, Slide 20)

Puma Biotechnology, Inc. (PBYI)

Nerlynx for Breast Cancer

Event Date:	12/31/2018
Event Type:	Regulatory - Filing for Approval (Emerging Markets) (Clinical Analysis)
Trial Name:	N/A
Market Group:	Oncology
Lead Company:	Puma Biotechnology, Inc. (PBYI)
Partner Companies:	Pfizer (PFE) Medison CANbridge Life Sciences Specialised Therapeutics Asia Pint Pharma International S.A.,
Phase:	Approved
Change to Likelihood of Approval:	0%
Likelihood of Approval:	100% (Same As Avg.)
Average Approval:	100%

Analysis:

Puma expects to receive regulatory approval of Nerlynx for breast cancer in Israel in mid-2019. As such, we assume the company filed for approval in 2018.

Source:

Sagient Analysis
J.P. Morgan Healthcare Conference 01/09/2019 (PBYI, Slide 10)

Replimune Inc. (REPL)

RP2 for Solid Tumors

Event Date:	01/09/2019
Event Type:	Progress Update (Clinical Analysis)
Trial Name:	N/A
Market Group:	Oncology
Lead Company:	Replimune Inc. (REPL)
Partner Companies:	N/A
Phase:	Preclinical
Change to Likelihood of Approval:	N/A
Likelihood of Approval:	0% (Same As Avg.)
Average Approval:	N/A

Analysis:

Replimune currently lists RP2 in preclinical development in its pipeline. The company remains on track to initiate the clinical development of RP2 in a Phase I clinical trial of RP2 alone and in combination with anti-PD1 therapy in the first half of 2019.

Source:

Press Release 01/03/2019
Company Website (Pipeline)
J.P. Morgan Healthcare Conference 01/09/2019 (REPL)

Stemline Therapeutics, Inc. (STML)

Elzonris for Blastic Plasmacytoid Dendritic Cell Neoplasm (BPDCN)

Event Date:	01/07/2019
Event Type:	Regulatory - MAA Submission (Europe) (Clinical Analysis)

Trial Name:	N/A
Market Group:	Oncology
Lead Company:	Stemline Therapeutics, Inc. (STML)
Partner Companies:	N/A
Phase:	Approved
Change to Likelihood of Approval:	0%
Likelihood of Approval:	100% (Same As Avg.)
Average Approval:	100%

Analysis:

Stemline announced that it has submitted the marketing authorization application (MAA) for ELZONRIS (tagraxofusp) to the European Medicines Agency (EMA). The MAA seeks approval for treating patients with blastic plasmacytoid dendritic cell neoplasm (BPDCN). In November 2018, the EMA granted the ELZONRIS MAA accelerated assessment.

On December 21, 2018, ELZONRIS was approved by the U.S. Food and Drug Administration (FDA) for the treatment of BPDCN in adult and pediatric patients, two years and older, in both treatment-naïve and previously-treated populations. ELZONRIS is the first treatment approved for BPDCN and the first approved CD123-targeted therapy.

Source:

Press Release 01/07/2019
J.P. Morgan Healthcare Conference 01/09/2019 (STML, Slide 3)

Elzonris for Blastic Plasmacytoid Dendritic Cell Neoplasm (BPDCN)

Event Date:	01/09/2019
Event Type:	Progress Update - Product Launch (U.S.) (Clinical Analysis)
Trial Name:	N/A
Market Group:	Oncology
Lead Company:	Stemline Therapeutics, Inc. (STML)
Partner Companies:	N/A
Phase:	Approved
Change to Likelihood of Approval:	0%
Likelihood of Approval:	100% (Same As Avg.)
Average Approval:	100%

Analysis:

Stemline announced that the US launch for Elzonris is currently underway. Stemline plans to establish Elzonris as the standard of care in Blastic Plasmacytoid Dendritic Cell Neoplasm (BPDCN) via a disease awareness campaign to raise profile of BPDCN, the usage of CD123 testing, and continue reimbursement effort to ensure patient access.

Source:

J.P. Morgan Healthcare Conference 01/09/2019 (STML, Slides 15-19)

SL-901 for Solid Tumors

Event Date:	01/09/2019
Event Type:	Trial Data - Top-Line Results (Clinical Analysis)
Trial Name:	Phase I - Europe
Market Group:	Oncology
Lead Company:	Stemline Therapeutics, Inc. (STML)
Partner Companies:	N/A
Phase:	I
Change to Likelihood of Approval:	0%
Likelihood of Approval:	6% (Same As Avg.)
Average Approval:	6%

Analysis:

Stemline announced early findings from a Phase I study of SL-901 in patients with solid tumors.

Context
IND-enabling studies are underway.

Design
This is an European Phase I trial of SL-901 in patients with solid tumors.

Results
1 durable partial response in a patient with heavily pre-treated lung cancer was observed.

Most Common Adverse Events
The trial demonstrated safety up to 40mg/day dose level. DLT/MTD was not reached, suggesting the potential for further dose escalation.

Source:

J.P. Morgan Healthcare Conference 01/09/2019 (STML, Slide 34)

Biomedtracker JPM New Catalysts - Day 3

Expected Date Range	Company	Symbol	Drug	Indication	Phase	Expected Catalyst	Catalyst Title	Analysis	Link
01/09/2019-03/31/2019	3SBio Inc.		NuPIAO	Anemia Due to Chronic Renal Failure, Dialysis-Dependent	Development Outside U.S.	Trial Announcement - Initiation (Emerging Markets)	Phase II - Trial to Start	3SBio reported that it obtained an approval from SDA in May 2018 for Phase II and III trials of NuPIAO in anemic patients. Patient enrollment is expected to begin soon. As such we await an update in the time frame above.	148481
01/09/2019-03/31/2019	3SBio Inc.		NuPIAO	Anemia Due to Oncology Treatment	Development Outside U.S.	Trial Announcement - Initiation (Emerging Markets)	Phase II - Trial to Start	3SBio reported that it obtained an approval from SDA in May 2018 for Phase II and III trials of NuPIAO in anemic patients. Patient enrollment is expected to begin soon. As such we await an update in the time frame above.	148483
01/09/2019-03/31/2019	3SBio Inc.		NuPIAO	Anemia Due to Chronic Renal Failure, Dialysis-Independent	Development Outside U.S.	Trial Announcement - Initiation (Emerging Markets)	Phase II - Trial to Start	3SBio reported that it obtained an approval from SDA in May 2018 for Phase II and III trials of NuPIAO in anemic patients. Patient enrollment is expected to begin soon. As such we await an update in the time frame above.	148482
01/09/2019-03/31/2019	Alphamab Oncology		KN035	Solid Tumors	I	Trial Announcement - Initiation	US Pivotal Trial to Start	Alphamab expects a US pivotal trial of KN035 is planned for the first quarter of 2019.	148438
01/09/2019-03/31/2019	Eagle Pharmaceuticals, Inc.	EGRX	Ryanodex	Neurology - Other	III	Regulatory - Meeting with FDA	Meeting with FDA	Eagle reported that it plans on meeting with the FDA to discuss the next steps for Ryanodex for exertional heat stroke. As such we await an update in the time frame above.	148418
01/09/2019-03/31/2019	Puma Biotechnology, Inc.	PBYI	Nerlynx	Breast Cancer	Approved	Regulatory - Meeting with FDA	Meeting with FDA (SUMMIT Results)	Puma plans to meet with the FDA to discuss clinical development and regulatory strategy for the SUMMIT trial of PB272 in the first quarter of 2019.	148381
Now-04/30/2019	Acadia Pharmaceuticals, Inc.	ACAD	Nuplazid	Major Depressive Disorder (MDD)	II	Regulatory - Meeting with FDA	Meeting with FDA	Acadia announces that an end-of-Phase II meeting with the FDA is planned for early 2019.	148453
Now-04/30/2019	AngioDynamics, Inc.	ANGO	NanoKnife System	Pancreatic Cancer	PMA	Regulatory - IDE Approval Decision	IDE Approval	AngioDynamics announced the company has filed through the PMA process for its NanoKnife technology for the treatment of pancreatic cancer. The company expects its IDE to be approved soon. Therefore we look for an update in the time frame above.	148320
Now-04/30/2019	AstraZeneca PLC	AZN	Savolitinib	Renal Cell Cancer (RCC)	III	Trial Data - Top-Line Results	Phase II CALYPSO - Top-Line Results	Hutchison expects to have preliminary proof of concept data from the Phase II CALYPSO study of Savolitinib at a medical conference in early 2019.	148476
04/01/2019-04/30/2019	Sienna Biopharmaceuticals, Inc.	SNNA	SNA-120	Pruritus	IIb	Regulatory - Meeting with FDA	Meeting with FDA	Sienna anticipates an end of Phase II meeting with the FDA in April 2019.	148445
05/31/2019-06/04/2019	Five Prime Therapeutics, Inc.	FPRX	FPA150	Solid Tumors	I	Trial Data - Top-Line Results	Phase Ia/Ib - Top-Line Results at ASCO	Five Prime expects preliminary data from the Phase Ia/Ib trial of FPA150 during the American Society of Clinical Society (ASCO) conference during May 31 - June 4 2019.	148412
01/09/2019-06/30/2019	Crinetics Pharmaceuticals, Inc.	CRNX	CRN01941	Neuroendocrine Tumors (NET)	Preclinical	Trial Announcement - Initiation	Phase I - Trial to Start	Crinetics expects to initiate a Phase I study with CRN01941 in the first half of 2019.	148428
01/09/2019-06/30/2019	Crinetics Pharmaceuticals, Inc.	CRNX	ACTH Antagonist (Crinetics)	Cushing's Syndrome	Preclinical	Progress Update - Development Review	Candidate Selection	Crinetics expects to announce a candidate selection from its ACTH antagonist program in H1 2019.	148432
04/01/2019-06/30/2019	FLX Bio, Inc.		GCN2 Program (FLX)	Cancer	Preclinical	Progress Update - Development Review	Preclinical Candidate Selection	FLX expects to select a preclinical candidate for its GCN2 program in the second quarter of 2019.	148326
01/09/2019-06/30/2019	FLX Bio, Inc.		FLX193	Atopic Dermatitis (Eczema)	Preclinical	Regulatory - IND Filing	IND Filing	FLX plans to file an IND for its FLX193 program in the first half of 2019.	148328
01/09/2019-06/30/2019	Integra LifeSciences Holdings Corporation	IART	AMNIOEXCEL	Diabetic Foot and Other Ulcers	361 HCT/P	Trial Announcement - Trial Completion	AMNIOEXCEL Plus - Trial Completion	Integra expects to complete its AMNIOEXCEL Plus study in the first half of 2019.	148421
01/09/2019-06/30/2019	Inventiva S.A.	IVA	Odiparcil	Mucopolysaccharidosis VI (MPS VI)	II	Trial Announcement - Initiation	Phase Ib Children Study to Start	Inventiva expects to start a Phase Ib study of Odiparcil in children with MPS VI in the first half of 2019.	148407
Now-06/30/2019	Jounce Therapeutics, Inc.	JNCE	JTX-2011	Solid Tumors	I/II	Trial Data - Updated Results	Phase I/II ICONIC - Updated Results	Jounce expects updated data from the Phase I/II ICONIC study of JTX-2011 including PFS and OS readout in the first half of 2019.	148457
Now-06/30/2019	Mersana Therapeutics, Inc.	MRSN	XMT-1536	Ovarian Cancer	I	Trial Data - Updated Results	Phase Ib First-in-Human (NaPi2b) - Updated Results	Mersana plans to report Phase I dose escalation data in the first half of 2019.	148436
Now-06/30/2019	Mersana Therapeutics, Inc.	MRSN	XMT-1536	Ovarian Cancer	I	Trial Announcement - Other	Phase Ib - Dose Expansion Cohorts to Start	Mersana expects to select a dose for use in its Phase I expansion studies and to initiate enrollment of patients in the expansion cohorts in the first half of 2019. The expansion cohorts will focus on platinum-resistant ovarian cancer and NSCLC adenocarcinoma.	148433
01/09/2019-06/30/2019	Mirati Therapeutics	MRTX	Sitravatinib	Renal Cell Cancer (RCC)	II	Trial Data - Top-Line Results	Phase II - Top-Line Results	Mirati expects to have early mechanism of action data from its RCC and HNSCC pre-surgical studies of Sitravatinib in the second half of 2019.	148337
01/09/2019-06/30/2019	Puma Biotechnology, Inc.	PBYI	Nerlynx	Breast Cancer	Approved	Progress Update - Product Launch (Europe)	Product Launch (EU)	Puma expects to launch Nerlynx in Germany in the first half of 2019 with France and United Kingdom in the second half of 2019.	148370
01/09/2019-06/30/2019	Puma Biotechnology, Inc.	PBYI	Nerlynx	Breast Cancer	Approved	Regulatory - Approval (Australia/New Zealand)	Australian Approval Decision	Puma expects to receive regulatory approval for Nerlynx in Australia via Specialized Therapeutics in the first half of 2019.	148371
01/09/2019-06/30/2019	Puma Biotechnology, Inc.	PBYI	Nerlynx	Breast Cancer	Approved	Regulatory - Meeting with FDA	Meeting with FDA (NALA Results)	Puma plans to meet with the FDA/EMA to discuss data from the Phase III NALA trial in third-line MBC patients in the first half of 2019.	148377
Now-06/30/2019	Puma Biotechnology, Inc.	PBYI	Nerlynx	Breast Cancer	Approved	Regulatory - Meeting with European Medicines Agency	Meeting with EMA (NALA Results)	Puma plans to meet with the FDA/EMA to discuss data from the Phase III NALA trial in third-line MBC patients in the first half of 2019.	148378
01/09/2019-06/30/2019	Puma Biotechnology, Inc.	PBYI	Nerlynx	Breast Cancer	Approved	Trial Data - Updated Results	Phase II CONTROL - Updated Results	Puma plans to report additional data from the Phase II CONTROL trial of PB272 in the first half of 2019.	148383
01/09/2019-06/30/2019	Puma Biotechnology, Inc.	PBYI	Nerlynx	Breast Cancer	Approved	Trial Data - Updated Results	Phase II SUMMIT - Updated Results	Puma plans to report Phase II data from SUMMIT basket trial of neratinib in patients with HER2 mutations in the first half of 2019.	148385
01/09/2019-06/30/2019	Replimune Inc.	REPL	RP2	Solid Tumors	Preclinical	Trial Announcement - Initiation	Phase I Study to Start	Replimune remains on track to initiate the clinical development of RP2 in a Phase 1 clinical trial of RP2 alone and in combination with anti-PD1 therapy in the first half of 2019.	148347
Now-06/30/2019	Tricida, Inc.	TCDA	TRC101	Renal Disease / Renal Failure	III	Trial Data - Top-Line Results	Phase IIII TRCA-301E - Top-Line Results	Tricida anticipates data from the Phase III TRCA-301E in the first half of 2019.	148364
04/01/2019-09/30/2019	AstraZeneca PLC	AZN	Savolitinib	Gastric Cancer	Development Outside U.S.	Trial Data - Top-Line Results	Phase II VIKTORY - Top-Line Results	Hutchison expects to have preliminary proof of concept data from the Phase II VIKTORY study of savollitinib at a medical conference in mid-2019.	148478
06/01/2019-09/30/2019	BioCryst Pharmaceuticals, Inc.	BCRX	BCX7353	Hereditary Angioedema (HAE)	III	Trial Announcement - Initiation	Phase III Acute HAE Study to Start	BioCryst announced that it expects to begin a Phase III study of BCX7353 in Acute Hereditary Angioedema (HAE) during the summer of 2019 with results expected towards the end of 2020.	148360
04/01/2019-09/30/2019	ChemoCentryx, Inc.	CCXI	Avacopan	Renal Disease / Renal Failure	II	Trial Announcement - Patient Enrollment Completed	Phase II - Enrollment Completion	ChemoCentryx announced that the company expects to complete enrollment in the Phase II C3G trial of Avacopan in mid-2019.	148450
07/01/2019-09/30/2019	CSL Limited	CSL:AU	Idelvion	Hemophilia B	Approved	Regulatory - sNDA/sBLA Filing	sBLA Filing	CSL plans to file for approval for a 21-day dosing schedule for Idelvion in the third quarter of 2019.	148346
07/01/2019-09/30/2019	Esperion Therapeutics, Inc.	ESPR	ETC-1002	Dyslipidemia / Hypercholesterolemia	III	Trial Announcement - Patient Enrollment Completed	Phase III CLEAR Outcomes Patient Enrollment Completion	Esperion announced they anticipate enrollment of the CLEAR outcomes study of ETC-1002 to be completed in the third quarter of 2019.	148485

Biomedtracker JPM New Catalysts - Day 3

Expected Date Range	Company	Symbol	Drug	Indication	Phase	Expected Catalyst	Catalyst Title	Analysis	Link
07/01/2019-09/30/2019	MorphoSys AG	MOR	MOR202	Autoimmune Disorders	Preclinical	Trial Announcement - Initiation	Phase II Trial to Start	MorphoSys announced that it plans to initiate a Phase II study investigating MOR202 for the treatment of autoimmune disorders in the third quarter of 2019.	148406
07/01/2019-09/30/2019	MorphoSys AG	MOR	MOR208	Diffuse Large B-Cell Lymphoma (DLBCL) - NHL	II/III	Trial Announcement - Initiation	Phase Ib - FRONTLINE DLBCL Trial to Start	MorphoSys announced the Phase Ib trial investigating effects of MOR-208 and R-CHOP (rituximab + chemotherapy) versus MOR-208 R-CHOP and lenalidomide (LEN) in patients with frontline diffuse large B-cell lymphoma (DLBCL). The company plans for the study to start in third quarter of 2019.	148399
07/01/2019-09/30/2019	Novartis AG	NVS	MOR106	Atopic Dermatitis (Eczema)	II	Trial Announcement - Trial Completion	Phase II IGUANA - Trial Completion	MorphoSys announced that the company plans to complete the Phase II IGUANA trial investigating MOR106 for the treatment of atopic dermatitis in the third quarter of 2019.	148408
07/01/2019-09/30/2019	Novartis AG	NVS	MOR106	Atopic Dermatitis (Eczema)	II	Trial Announcement - Trial Completion	Phase I Bridging Study - Trial Completion	MorphoSys announced that the company plans to complete the Phase I bridging study investigating MOR106 for the treatment of atopic dermatitis in the third quarter of 2019.	148409
07/01/2019-09/30/2019	Pliant Therapeutics		PLN-1474	Non-Alcoholic Steatohepatitis (NASH)	Preclinical	Regulatory - IND Filing	IND Filing	Pliant Therapeutics plans to file an IND for PLN-1474 in the third quarter of 2019.	148372
04/01/2019-09/30/2019	Pliant Therapeutics		PLN-74809	Idiopathic Pulmonary Fibrosis (IPF)	I	Trial Data - Top-Line Results	Phase I - Top-Line Results	Pliant Therapeutics plans to release Phase Ia and Phase Ib data of PLN-74809 in mid-2019.	148393
04/01/2019-09/30/2019	Puma Biotechnology, Inc.	PBYI	Nerlynx	Breast Cancer	Approved	Regulatory - Approval Decision (Emerging Markets)	Israeli Approval Decision	Puma expects to receive regulatory approval of Nerlynx for breast cancer in Israel in mid-2019.	148374
07/01/2019-09/30/2019	Stemline Therapeutics, Inc.	STML	Elzonris	Blastic Plasmacytoid Dendritic Cell Neoplasm (BPDCN)	Approved	Regulatory - CHMP (European Panel) Results	CHMP Opinion	Stemline announced that it has submitted the marketing authorization application (MAA) for ELZONRIS (tagraxofusp) to the European Medicines Agency (EMA). The MAA seeks approval for treating patients with blastic plasmacytoid dendritic cell neoplasm (BPDCN). Based on an internal analysis of the centralized European accelerated approval procedure we estimate the European marketing authorization for this drug for this indication will be granted in approximately 8-10 months. As the approval decision is normally issued 67 days from adoption of a positive Committee for Medicinal Products for Human Use (CHMP) opinion we then estimate the CHMP opinion to occur between July and September 2019.	148488
09/27/2019-10/01/2019	Five Prime Therapeutics, Inc.	FPRX	FPA150	Solid Tumors	I	Trial Data - Updated Results	Phase Ia/Ib - Updated Results at ESMO	Five Prime expects preliminary data from the Phase Ia/Ib trial of FPA150 during the European Society for Medical Oncology (ESMO) conference.	148413
12/07/2019-12/10/2019	Magenta Therapeutics	MGTA	MGTA-145	Bone Marrow Transplant and Stem Cell Transplant	Preclinical	Trial Data - Top-Line Results	Phase I - Top-Line Results at ASH	Magenta expects to have the first clinical data of its MGTA-145 program at the ASH annual meeting in December 7-10 2019.	148392
12/07/2019-12/10/2019	Magenta Therapeutics	MGTA	MGTA-456	Hematologic Cancer	Investigator Initiated	Trial Data - Top-Line Results	Phase II - Top-Line Results at ASH	Magenta expects to have Phase II data of MGTA-456 at ASH 2019 on December 7-10 2019.	148397
01/09/2019-12/31/2019	AbbVie Inc.	ABBV	ABBV-157	Psoriasis	I	Trial Data - Top-Line Results	Phase I - Top-Line Results	Inventiva announced that data will be available in 2019 from the Phase I study of ABBV-157.	148400
07/01/2019-12/31/2019	Acadia Pharmaceuticals, Inc.	ACAD	Nuplazid	Dementia	III	Trial Data - Top-Line Results	Phase III-HARMONY Top-Line Results	Acadia announced that the Phase III-HARMONY trial investigating Nuplazid for dementia is progressing and expects an interim data read-out in the second half of 2019 followed by final results in 2020.	148460
07/01/2019-12/31/2019	Acadia Pharmaceuticals, Inc.	ACAD	Nuplazid	Schizophrenia	III	Trial Announcement - Patient Enrollment Completed	Phase II - ADVANCE Patient Enrollment Completion	Acadia announced that the company plans to complete enrollment for the Phase II - ADVANCE study of Nuplazid in patients with Schizophrenia by the second half of 2019.	148466
01/09/2019-12/31/2019	Akebia Therapeutics, Inc.	AKBA	Vadadustat	Anemia Due to Chronic Renal Failure, Dialysis-Dependent	III	Trial Announcement - Initiation	Phase III EXPLO2RE Study to Start	Akebia plans to initiate the Phase III EXPLO2RE study for Vadadustat in 2019.	148365
01/09/2019-12/31/2019	Akebia Therapeutics, Inc.	AKBA	Vadadustat	Anemia Due to Chronic Renal Failure, Dialysis-Dependent	III	Trial Data - Top-Line Results	Phase III HD-CKD Correction (Japan) - Top-Line Resutls	Akebia anticipates data readout for the Phase III HD-CKD correction trial in Japan in 2019.	148403
01/09/2019-12/31/2019	Akebia Therapeutics, Inc.	AKBA	Vadadustat	Anemia Due to Chronic Renal Failure, Dialysis-Dependent	III	Trial Announcement - Initiation	Phase III TRILO2GY Study to Start	Akebia anticipates to initiate the Phase III TRILO2GY study in 2019.	148380
01/09/2019-12/31/2019	Akebia Therapeutics, Inc.	AKBA	Vadadustat	Anemia Due to Chronic Renal Failure, Dialysis-Dependent	III	Trial Data - Top-Line Results	Phase III PD-CKD (Japan) - Top-Line Results	Akebia anticipates data readout for the Phase III PD-CKD trial in Japan in 2019.	148391
01/09/2019-12/31/2019	Akebia Therapeutics, Inc.	AKBA	Vadadustat	Anemia Due to Chronic Renal Failure, Dialysis-Dependent	III	Trial Data - Top-Line Results	Phase III HD-CKD Conversion (Japan) - Top-Line Results	Akebia anticipates data readout for the Phase III HD-CKD conversion trial in Japan in 2019.	148398
09/01/2019-12/31/2019	AMAG Pharmaceuticals, Inc.	AMAG	AMAG-423	Eclampsia/Pre-Eclampsia	II/III	Trial Announcement - Patient Enrollment Completed	Phase IIb/IIIa - Patient Enrollment Complete	AMAG Pharmaceuticals announced that the Phase IIb/IIIa study of AMAG-423 is anticipated to be enrolled by year-end 2019.	148325
Now-12/31/2019	AVEO Pharmaceuticals, Inc.	AVEO	Tivopath (Oncology)	Renal Cell Cancer (RCC)	III	Progress Update - Product Launch (Europe)	Tivopath Launch- Italy, France, and Spain	AVEO announced they anticipate product launch of Tivopath in RCC in Italy France and Spain pending reimbursement decisions. We await an update in the time frame above.	148456
Now-12/31/2019	Bristol-Myers Squibb Company	BMY	Cabiralizumab	Pancreatic Cancer	II	Trial Announcement - Patient Enrollment Completed	Phase II - Patient Enrollment Completed	Five Prime anticipates Bristol-Myers Squibb to complete enrollment of Phase II trial of cabiralizumab in pancreatic cancer in 2019.	148415
Now-12/31/2019	Bristol-Myers Squibb Company	BMY	BMS-986258	Solid Tumors	I/II	Trial Announcement - Other	Phase I/II - Phase II to Start	Five Prime anticipates Bristol Myers Squibb to transition its TIM-3 antibody (BMS-986258) to Phase II and receive milestone payment in 2019.	148441
07/01/2019-12/31/2019	Celgene Corporation	CELG	Tislelizumab	Solid Tumors	I	Trial Data - Top-Line Results	Phase Ib w/Sitravatinib - Top-Line Results	Mirati expects to have proof of concept data from its Sitravatinib in combination with Tislelizumab for the treatment of NSCLC RCC and ovarian cancer in the second half of 2019.	148363
Now-12/31/2019	Celgene Corporation	CELG	CC-92480	Multiple Myeloma (MM)	I	Trial Data - Top-Line Results	Phase I - Top-Line Results	Clinical data are expected in 2019 for the Phase I trial of CC-92480 (CELMoD) in RRMM.	148410
Now-12/31/2019	Celgene Corporation	CELG	CC-93269	Multiple Myeloma (MM)	I	Trial Data - Top-Line Results	Phase I - Top-Line Results	Clinical data are expected in 2019 for the Phase I trial of CC-93269 (BCMA TCE) in RRMM.	148411
07/01/2019-12/31/2019	Cell Medica Ltd.		CMD-501	Neuroendocrine Tumors (NET)	Investigator Initiated	Trial Data - Top-Line Results	Phase I - Top-Line Results	Cell Medica expects interim neuroblastoma Phase I CMD-501 clinical data in the second half of 2019.	148423
01/09/2019-12/31/2019	ChemoCentryx, Inc.	CCXI	Avacopan	Hidradenitis Suppurativa	II	Trial Announcement - Patient Enrollment Completed	Phase II - Enrollment Completion	ChemoCentryx announced that the company expects to complete enrollment in the Phase II HS trial of Avacopan in 2019.	148465
01/09/2019-12/31/2019	Constellation Pharmaceuticals, Inc.	CNST	CPI-0610	Myelofibrosis (MF)	I/II	Regulatory - Meeting with FDA	Meeting with FDA	Constellation reported that it is on track for discussions with regulatory authorities in 2019 for CPI-0610 in MF.	148451
09/01/2019-12/31/2019	Crinetics Pharmaceuticals, Inc.	CRNX	CRN00808	Acromegaly	II	Trial Announcement - Initiation	Long Term Safety - Trial to Start	Crinetics expects to initiate a long term safety trial for CRN00808 later this year. We await the start of this trial in the time frame above.	148487
01/09/2019-12/31/2019	CSL Limited	CSL:AU	CSL730	Autoimmune Disorders	I	Trial Announcement - Trial Completion	Phase I SAD (Healthy) Trial Completion	Momenta announced that CSL expects the Phase I trial in healthy volunteers to be completed in 2019.	148351

Biomedtracker JPM New Catalysts - Day 3

Expected Date Range	Company	Symbol	Drug	Indication	Phase	Expected Catalyst	Catalyst Title	Analysis	Link
01/09/2019-12/31/2019	Eidos Therapeutics, Inc.	EIDX	AG10	Transthyretin Amyloid Cardiomyopathy (ATTR-CM, Wild Type Or Hereditary)	II	Trial Data - Top-Line Results	Phase II Open-Label Extension - Top-Line Results	Eidos reported that data for the Phase II open label extension study in ATTR-CM is expected in 2019.	148477
07/01/2019-12/31/2019	Five Prime Therapeutics, Inc.	FPRX	FPT155	Solid Tumors	I	Trial Data - Top-Line Results	Phase I - Top-Line Results at Medical Conference	Five Prime expects to present Phase I clinical data for FPT155 at a medical conference in the second half of 2019.	148416
07/01/2019-12/31/2019	FLX Bio, Inc.		FLX475	Cancer	I/II	Trial Data - Top-Line Results	Phase I/II - Top-Line Results	FLX announced that the Phase I/II study of FLX475 expects proof-of-concept/efficacy results in 2019.	148324
07/01/2019-12/31/2019	FLX Bio, Inc.		FLX193	Atopic Dermatitis (Eczema)	Preclinical	Trial Announcement - Initiation	Phase I to Start	FLX announced that it plans to initiate the first in humans study of FLX193 in the second half of 2019.	148329
01/09/2019-12/31/2019	Genmab A/S	GEN:DC	HexaBody-DR5/DR5	Solid Tumors	I/II	Trial Data - Top-Line Results	Phase I/II Dose-escalation - Top-Line Results	Genmab reported that the initial dose escalation clinical data of GEN1029 is expected in 2019.	148447
01/09/2019-12/31/2019	Genmab A/S	GEN:DC	GEN3013	Hematologic Cancer	I/II	Trial Data - Top-Line Results	Phase I/II GCT3013-01 - Top-Line Results	Genmab reported that the dose escalation clinical data of GEN3013 is expected in 2019.	148448
10/01/2019-12/31/2019	Hutchison MediPharma Limited	HCM	Sulfatinib	Neuroendocrine Tumors (NET)	I/II	Regulatory - Filing for Approval (Emerging Markets)	Chinese NDA Filing	Hutchison is targeting to potentially file an NDA for surufatinib in neuroendocrine tumors in China in late 2019.	148480
07/01/2019-12/31/2019	Idera Pharmaceuticals, Inc.	IDRA	Tilsotolimod	Melanoma	III	Trial Data - Final Results	Phase I/II ILLUMINATE 204 - Final Results	Idera Pharmaceuticals lists that final data from the Phase I/II ILLUMINATE 204 study of tilsotolimod are anticipated in the second half of 2019.	148349
01/09/2019-12/31/2019	Idera Pharmaceuticals, Inc.	IDRA	Tilsotolimod	Melanoma	III	Trial Announcement - Patient Enrollment Completed	Phase III ILLUMINATE 301 - Patient Enrollment Completed	Idera Pharmaceuticals lists that the Phase III ILLUMINATE 301 study of tilsotolimod is planned to be closed to enrollment by year-end 2019.	148350
01/09/2019-12/31/2019	Idera Pharmaceuticals, Inc.	IDRA	Tilsotolimod	Solid Tumors	I	Trial Data - Top-Line Results	Phase Ib ILLUMINATE 101 - Top-Line Results	Idera Pharmaceuticals lists that translational data from the Phase Ib ILLUMINATE 101 study of tilsotolimod are anticipated in 2019.	148352
07/01/2019-12/31/2019	ImmunoGen, Inc.	IMGN	Mirvetuximab Soravtansine	Ovarian Cancer	III	Regulatory - MAA Submission (Europe)	MAA Submission	ImmunoGen expects to submit a MAA for Mirvetuximab in the second half of 2019.	148390
07/01/2019-12/31/2019	ImmunoGen, Inc.	IMGN	Mirvetuximab Soravtansine	Ovarian Cancer	III	Regulatory - NDA/BLA Filing	BLA Submission	ImmunoGen expects to submit a BLA for Mirvetuximab in the second half of 2019.	148388
01/09/2019-12/31/2019	ImmunoGen, Inc.	IMGN	IMGN632	Blastic Plasmacytoid Dendritic Cell Neoplasm (BPDCN)	I	Trial Data - Updated Results	Phase I - Updated Results	ImmunoGen announced that it plans to present updated data with additional AML and BPDCN patients in 2019.	148402
01/09/2019-12/31/2019	ImmunoGen, Inc.	IMGN	Mirvetuximab Soravtansine	Ovarian Cancer	III	Trial Data - Updated Results	Phase Ib/II FORWARD II - Triplet and Mature Expansion Cohort Data	Immunogen announced that it expects to present initial FORWARD II triplet and mature expansion cohort data in 2019.	148379
01/09/2019-12/31/2019	ImmunoGen, Inc.	IMGN	Mirvetuximab Soravtansine	Ovarian Cancer	III	Trial Announcement - Patient Enrollment Completed	Phase Ib/II FORWARD II - Avastin Cohort Enrolled	Immuogen expects to complete enrollment for the FORWARD II Avastin cohort in 2019.	148382
01/09/2019-12/31/2019	ImmunoGen, Inc.	IMGN	IMGN632	Acute Myelogenous Leukemia (AML)	I	Trial Data - Updated Results	Phase I - Updated Results	ImmunoGen announced that it plans to present updated data with additional AML and BPDCN patients in 2019.	148401
Now-12/31/2019	Intercept Pharmaceuticals, Inc.	ICPT	Ocaliva	Non-Alcoholic Steatohepatitis (NASH)	III	Trial Announcement - Patient Enrollment Completed	Phase III REVERSE - Patient Enrollment Completed	Intercept also expects to complete enrollment of its Phase III REVERSE trial evaluating Ocaliva in NASH patients with compensated cirrhosis in 2019.	148420
Now-12/31/2019	Intercept Pharmaceuticals, Inc.	ICPT	Bezalip SR	Primary Biliary Cholangitis (PBC) and Hepatic Fibrosis	Preclinical	Trial Announcement - Initiation	Phase II w/Ocaliva - Study to Start	Intercept intends to initiate a Phase II study to evaluate the efficacy safety and tolerability of bezafibrate in combination with ocaliva in patients with PBC.	148425
Now-12/31/2019	Jounce Therapeutics, Inc.	JNCE	JTX-4014	Solid Tumors	I	Trial Data - Top-Line Results	Phase I - Top-Line Results	Jounce expects to establish safety andRP2D for JTX-4014 in 2019. We await an update on the readout of the study in the same time frame.	148464
Now-12/31/2019	Jounce Therapeutics, Inc.	JNCE	JTX-8064	Solid Tumors	Preclinical	Regulatory - IND Filing	IND Filing	Jounce expects an IND filing and initiation of Phase I for JTX-8064 in 2019.	148469
Now-12/31/2019	Jounce Therapeutics, Inc.	JNCE	JTX-8064	Solid Tumors	Preclinical	Trial Announcement - Initiation	Phase I Study to Start	Jounce expects an IND filing and initiation of Phase I for JTX-8064 in 2019.	148471
07/01/2019-12/31/2019	La Jolla Pharmaceutical Company	LJPC	LJPC-401	Thalassemia	III	Trial Data - Top-Line Results	Phase II Hereditary Hemochromatosis - Top-Line Results	La Jolla Pharmaceutical announced the company expects topline results for the Phase II study of LJPC-401 in patients with hereditary hemochromatosis in the second half of 2019.	148386
10/01/2019-12/31/2019	La Jolla Pharmaceutical Company	LJPC	LJPC-0118	Malaria	I	Regulatory - NDA/BLA Filing	505(b)(2) NDA Filing	La Jolla plans to file a New Drug Application (NDA) with the U.S. Food and Drug Administration (FDA) in the fourth quarter of 2019 for LJPC-0118.	148484
07/01/2019-12/31/2019	Mirati Therapeutics	MRTX	Sitravatinib	Bladder Cancer	II	Trial Data - Top-Line Results	Phase II - Top-Line Results	Mirati expects to have initial proof of concept clinical data from its Phase II Bladder trial of Sitravatinib in the second half of 2019.	148336
07/01/2019-12/31/2019	Mirati Therapeutics	MRTX	Sitravatinib	Solid Tumors	I	Trial Data - Top-Line Results	Phase II - Top-Line Results	Mirati expects Beigene to announce initial proof of concept data in NSCLC and RCC of Sitravatinib in the second half of 2019.	148338
07/01/2019-12/31/2019	Mirati Therapeutics	MRTX	MRTX849	Solid Tumors	IND	Trial Data - Top-Line Results	Phase I/II - Top-Line Results	Mirati announced the potential for early proof of concept data from its Phase I/II study of MRTX849 in the second half of 2019.	148341
10/01/2019-12/31/2019	Mirati Therapeutics	MRTX	KRAS G12D Inhibitor Program (Mirati)	Solid Tumors	Preclinical	Progress Update - Development Review	Lead Candidate Identification	Mirati currently lists its KRAS G12D Program for the treatment of solid tumors in preclinical development in its pipeline. Mirati expects to identify a lead candidate in the fourth quarter of 2019.	148357
07/01/2019-12/31/2019	Mirati Therapeutics	MRTX	Sitravatinib	Head and Neck Cancer	I	Trial Data - Top-Line Results	Phase I SNOW - Top-Line Results	Mirati expects to have early mechanism of action data from its RCC and HNSCC pre-surgical studies of Sitravatinib in the second half of 2019.	148359
07/01/2019-12/31/2019	Mirati Therapeutics	MRTX	Sitravatinib	Solid Tumors	I	Trial Data - Top-Line Results	Phase Ib w/Tislelizumab - Top-Line Results	Mirati expects to have proof of concept data from its Sitravatinib in combination with Tislelizumab for the treatment of NSCLC RCC and ovarian cancer in the second half of 2019.	148362
Now-12/31/2019	Nevro Corp.	NVRO	Senza	Chronic Pain	Approved	Trial Data - Top-Line Results	SENZA-UEP (EU) Top-Line Results	Nevro announced that it plans to release 12 month results of the European SENZA-UEP study of Senza for upper extremity pain in 2019.	148426
Now-12/31/2019	Nevro Corp.	NVRO	Senza	Chronic Pain	Approved	Trial Data - Updated Results	SENZA-ULN Updated Results	Nevro announced that the company plans to release 12 month results of the SENZA-ULN study investigating Senza for upper limb and neck pain in 2019.	148431
Now-12/31/2019	Nevro Corp.	NVRO	Senza	Migraine and Other Headaches	Development Outside U.S.	Trial Announcement - Initiation	Preclinical Study to Start	Nevro announced a prospective 6-month proof-of-concept open-label study of Senza for chronic migraines planned to commence in 2019.	148443
Now-12/31/2019	Nevro Corp.	NVRO	Senza Deep Brain Stimulation	Neurology - Other	Development	Trial Data - Top-Line Results	SENZA-PPN Top-Line Results	Nevro announced that it plans to release the 24 month results from the SENZA-PPN study investigating Senza Deep Brain Stimulation for peripheral Polyneuropathy.	148444
01/09/2019-12/31/2019	Nevro Corp.	NVRO	Senza	Chronic Pain	Approved	Trial Data - Top-Line Results	U.S. Study (Post Surgical)- Top-Line Results	Nevro announced that it expects to release top-line results from the U.S. study of Senza for post-surgical pain in 2019.	148427
Now-12/31/2019	Nevro Corp.	NVRO	Senza	Chronic Pain	Approved	Trial Data - Top-Line Results	European Study (Post-Surgical) Top-Line Results	Nevro announced that it expects to release top-line results from the European study of Senza for post-surgical pain in 2019.	148446
Now-12/31/2019	Nevro Corp.	NVRO	Senza	Chronic Pain	Approved	Trial Data - Top-Line Results	ULN-AUS Top-Line Results	Nevero announced that it plans to complete 12 month results of the ULN-AUS study of Senza for upper limb and neck pain in 2019.	148437

Biomedtracker JPM New Catalysts - Day 3

Expected Date Range	Company	Symbol	Drug	Indication	Phase	Expected Catalyst	Catalyst Title	Analysis	Link
Now-12/31/2019	Nevro Corp.	NVRO	Senza	Chronic Pain	Approved	Trial Data - Top-Line Results	SENZA-CPP Top-Line Results	Nevro announced that it plans to release interim 12 month results of the SENZA-CPP study of Senza for pelvic pain in 2019.	148422
Now-12/31/2019	Nevro Corp.	NVRO	Senza	Chronic Pain	Approved	Trial Data - Updated Results	SENZA-CAP Updated Results	Nevro announced that the company plans to release 12 month results from the SENZA-CAP study of Senza for abdominal pain in 2019.	148430
Now-12/31/2019	Orchard Therapeutics Limited	ORTX	OTL-201	Mucopolysaccharidosis IIIA (MPS IIIA; Sanfilippo A Syndrome)	Preclinical	Regulatory - IND Filing	CTA Filing	Orchard Therapeutics plan to submit a clinical trial application (CTA) for OTL-201 for mucopolysaccharidosis type IIIA (MPS-IIIA) and support initiation of a clinical trial in 2019.	148455
Now-12/31/2019	Orchard Therapeutics Limited	ORTX	OTL-101	Primary Immunodeficiencies	I/II	Trial Data - Top-Line Results	Clinical Studies Readout	Orchard Therapeutics plans to release two-year follow-up data in 20 patients from the fresh formulation registrational trial of OTL-101 in adenosine deaminase severe combined immune deficiency (ADA-SCID) as well as engraftment data in 10 patients from a cryopreserved formulation clinical trial of OTL-101 in ADA-SCID in 2019.	148458
Now-12/31/2019	Orchard Therapeutics Limited	ORTX	OTL-103	Thrombocytopenia	III	Trial Data - Top-Line Results	Phase I/II - Top-Line Results	Orchard Therapeutics plans to release three-year follow-up data in eight patients from the fresh formulation registrational trial of OTL-103 in Wiskott-Aldrich syndrome (WAS) in 2019.	148461
Now-12/31/2019	Orchard Therapeutics Limited	ORTX	OTL-103	Thrombocytopenia	III	Trial Announcement - Initiation	Cryopreservation Formulation Trial to Start	Orchard Therapeutics plans to initiate a cryopreservation formulation clinical trial for OTL-103 in WAS in 2019.	148463
Now-12/31/2019	Orchard Therapeutics Limited	ORTX	OTL-300	Thalassemia	I	Trial Data - Top-Line Results	POC - Top-Line Results	Orchard Therapeutics plans to report clinical proof-of-concept data for OLT-300 in transfusion-dependent beta-thalassemia (TDBT) in 2019.	148473
07/01/2019-12/31/2019	Sanofi	SNY	BIVV009	Complement Deficiencies / Abnormalities	III	Trial Data - Top-Line Results	Phase III - Pivotal Top-Line Results	Sanofi expects pivotal trial read-outs for sutimlimab in cold aglutinnin disease (CAD) during Q3-Q4 2019.	148339
Now-12/31/2019	Sanofi	SNY	ST-400	Sickle Cell Anemia	Preclinical	Trial Announcement - Initiation	Clinical Trial to Start	At the JP Morgan Conference Sangamo announced that in 2019 ST-400 will move into the clinic for sickle cell disease becoming Sangamo's sixth clinical program.	148404
07/01/2019-12/31/2019	Supernus Pharmaceuticals, Inc.	SUPN	SPN-810	Attention Deficit Hyperactivity Disorder (ADHD)	III	Trial Data - Top-Line Results	Phase III CHIME 2 - Top-Line Results	Supernus expects to have Phase III P302 data for SPN-810 in the second half of 2019.	148354
07/01/2019-12/31/2019	Tricida, Inc.	TCDA	TRC101	Renal Disease / Renal Failure	III	Trial Announcement - Patient Enrollment Completed	Phase III VALOR-CKD - Patient Enrollment Completed	Tricida expects to complete enrollment or near completion of enrollment in the VALOR-CKD postmarketing trial of TRC101 in the second half of 2019.	148369
01/09/2019-01/31/2020	Sumitomo Dainippon Pharma Co., Ltd.	4506:JP	SB623	Traumatic Brain Injury (TBI)	II	Regulatory - J-NDA Filing (Japan)	Filing for Approval (Japan)	SanBio announced that it expects to file for approval of SB623 for TBI in Japan by January 2020.	148414
01/01/2020-03/31/2020	Momenta Pharmaceuticals, Inc.	MNTA	M254	Autoimmune Disorders	Preclinical	Trial Data - Top-Line Results	Phase I/II Proof of Concept - Top-Line Results	Momenta anticipates to see results from the Phase I/II proof of concept study of M254 in the first quarter of 2020.	148424
01/01/2020-04/30/2020	ChemoCentryx, Inc.	CCXI	Avacopan	Renal Disease / Renal Failure	II	Trial Data - Top-Line Results	Phase II - Top-Line Results	ChemoCentryx expects a data readout for the Phase II C3G trial of Avacopan in early 2020.	148452
09/01/2019-04/30/2020	Crinetics Pharmaceuticals, Inc.	CRNX	CRN01941	Neuroendocrine Tumors (NET)	Preclinical	Trial Data - Top-Line Results	Phase I - Top-Line Results	Crinetics expects top-line results from its Phase I study of CRN01941 in late 2019 or early 2020.	148429
01/01/2020-04/30/2020	Pliant Therapeutics		PLN-74809	Idiopathic Pulmonary Fibrosis (IPF)	I	Trial Data - Top-Line Results	Phase IIa - Top-Line Results	Pliant Therapeutics plans to release Phase IIa data of PLN-74809 for the treatment of IPF in early 2020.	148395
01/01/2020-06/30/2020	BioCryst Pharmaceuticals, Inc.	BCRX	BCX7353	Hereditary Angioedema (HAE)	III	Regulatory - MAA Submission (Europe)	BCX7353 - MAA Filing	BioCryst announced that it expects to submit a MAA Filing for BCX7353 for Prophylactic HAE in the first half of 2020.	148366
01/01/2020-06/30/2020	FLX Bio, Inc.		FLX193	Atopic Dermatitis (Eczema)	Preclinical	Trial Data - Top-Line Results	Phase I - Top-Line Results	FLX expects to have clinical proof-of-concept from its Phase Ib study in the first half of 2020.	148330
01/01/2020-06/30/2020	FLX Bio, Inc.		GCN2 Program (FLX)	Cancer	Preclinical	Regulatory - IND Filing	IND Filing	FLX announced that it plans to file an IND for its GCN2 program in the first half of 2020.	148332
01/01/2020-06/30/2020	Inventiva S.A.	IVA	Lanifibranor	Non-Alcoholic Steatohepatitis (NASH)	IIb	Trial Data - Top-Line Results	Phase II - Top-Line Results	Inventiva announced that the U.S. Food and Drug Administration (FDA) has accepted the investigator initiated Investigational New Drug (IND) application providing clearance to proceed with the Phase II study of lanifibranor in type 2 diabetic patients with nonalcoholic fatty liver disease (NAFLD). The first patient is expected to be enrolled in the third quarter of 2018 and topline results are expected beginning of 2020.	148405
01/01/2020-06/30/2020	Mirati Therapeutics	MRTX	Sitravatinib	Solid Tumors	I	Trial Data - Updated Results	Phase II - Updated Results	Mirati expects Beigene to announce initial proof of concept data in Ovarian HCC and gastric cancer of Sitravatinib in the second half of 2019.	148340
01/01/2020-06/30/2020	Pliant Therapeutics		PLN-1474	Non-Alcoholic Steatohepatitis (NASH)	Preclinical	Trial Data - Top-Line Results	Phase I - Top-Line Results	Pliant Therapeutics expects top-line Phase I data of PLN-1474 for the treatment of NASH/liver-fibrosis in the first half of 2020.	148389
01/01/2020-06/30/2020	Rigel Pharmaceuticals, Inc.	RIGL	Tavalisse	Anemia	II	Trial Announcement - Patient Enrollment Completed	Pivotal Phase III - Patient Enrollment Completed	Rigel anticipates to complete trial enrollment for the Phase III pivotal study of Fostamatinib for AIHA in the first half of 2020.	148474
04/01/2020-09/30/2020	Akebia Therapeutics, Inc.	AKBA	Vadadustat	Anemia Due to Chronic Renal Failure, Dialysis-Independent	III	Trial Data - Top-Line Results	Phase III PRO2TECT Conversion - Top-Line Results	Akebia expects top-line results for the Phase III PRO2TECT Conversion study in mid-2020.	148373
01/01/2020-09/30/2020	ChemoCentryx, Inc.	CCXI	Avacopan	Hidradenitis Suppurativa	II	Trial Data - Top-Line Results	Phase II - Top-Line Results	ChemoCentryx expects a data readout for the Phase II HS trial of Avacopan in early or mid-2020.	148467
04/01/2020-09/30/2020	La Jolla Pharmaceutical Company	LJPC	LJPC-401	Thalassemia	III	Trial Data - Updated Results	Phase III - Top-Line Results	La Jolla Pharmaceutical expects top-line results from the pivotal study of LJPC-401 in patients with beta thalassemia in mid-2020.	148387
01/01/2020-12/31/2020	Acadia Pharmaceuticals, Inc.	ACAD	Nuplazid	Dementia	III	Trial Data - Final Results	Phase III - HARMONY Final Results	Acadia announced that the Phase III-HARMONY trial investigating Nuplazid for dementia is progressing and expects an interim data read-out in the second half of 2019 followed by final results in 2020.	148462
07/01/2020-12/31/2020	Akebia Therapeutics, Inc.	AKBA	Vadadustat	Anemia Due to Chronic Renal Failure, Dialysis-Dependent	III	Trial Data - Top-Line Results	Phase III EXPLO2RE - Top-Line Results	Akebia plans to release Phase III EXPLO2RE top-line results in the second half of 2020.	148367
10/01/2020-12/31/2020	BioCryst Pharmaceuticals, Inc.	BCRX	BCX7353	Hereditary Angioedema (HAE)	III	Trial Data - Top-Line Results	Phase III Acute HAE Study - Top Line Results	BioCryst announced that it expects to begin a Phase III study of BCX7353 in Acute Hereditary Angioedema (HAE) during the summer of 2019 with results expected towards the end of 2020.	148361
07/01/2020-12/31/2020	BioCryst Pharmaceuticals, Inc.	BCRX	BCX7353	Hereditary Angioedema (HAE)	III	Progress Update - Product Launch (U.S.)	Product Launch (US)	BioCryst anticipates launching BCX7353 for Prophylactic HAE in the second half of 2020 pending an expected Q4 2019 NDA filing and estimated 2020 NDA approval in the second half of 2020.	148368
01/01/2020-12/31/2020	ChemoCentryx, Inc.	CCXI	CCX140	Focal Segmental Glomerulosclerosis (FSGS)	II	Trial Data - Top-Line Results	Phase II - Non-Nephrotic - Top-Line Results	ChemoCentryx announced that data from its CCX140 Phase II FSGS program is expected in 2020.	148468
01/01/2020-12/31/2020	ChemoCentryx, Inc.	CCXI	CCX140	Focal Segmental Glomerulosclerosis (FSGS)	II	Trial Data - Top-Line Results	Phase II - Nephrotic - Top-Line Results	ChemoCentryx announced that data from its CCX140 Phase II FSGS program is expected in 2020.	148472
07/01/2020-12/31/2020	FLX Bio, Inc.		FLX475	Cancer	I/II	Trial Announcement - Initiation	Registrational Trials to Start	FLX plans to initiate registrational studies for FLX475 in the second half of 2020.	148327

Biomedtracker JPM New Catalysts - Day 3

Expected Date Range	Company	Symbol	Drug	Indication	Phase	Expected Catalyst	Catalyst Title	Analysis	Link
07/01/2020-12/31/2020	FLX Bio, Inc.		FLX193	Atopic Dermatitis (Eczema)	Preclinical	Trial Announcement - Initiation	Phase II to Start	FLX plans to initiate Phase II studies in atopic dermatitis and additional indications of FLX193 in the second half of 2020.	148331
07/01/2020-12/31/2020	FLX Bio, Inc.		GCN2 Program (FLX)	Cancer	Preclinical	Trial Announcement - Initiation	Phase I to Start	GLX announced that it plans to start its first in humans study of its GCN2 program in the second half of 2020.	148333
01/01/2020-12/31/2020	Jounce Therapeutics, Inc.	JNCE	JTX-2011	Solid Tumors	I/II	Trial Data - Top-Line Results	Phase II Combination Study - Top-Line Results	Jounce expects preliminary efficacy from the Phase II combination studies of JTX-2011 in 2020	148459
12/01/2020-12/31/2020	Magenta Therapeutics	MGTA	MGTA-145	Bone Marrow Transplant and Stem Cell Transplant	Preclinical	Trial Data - Top-Line Results	Phase II MM/NHL - Top-Line Results at ASH	Magenta expects to have the first MM/NHL data of MGTA-145 by ASH 2020.	148394
10/01/2020-12/31/2020	Mirati Therapeutics	MRTX	Sitravatinib	Non-Small Cell Lung Cancer (NSCLC)	II	Trial Data - Top-Line Results	Phase III - Interim ORR Analysis	Mirati expects to have the interim ORR analysis from its Phase III study of Sitravatinib + Nivolumab by year-end 2020.	148334
01/01/2020-12/31/2020	Momenta Pharmaceuticals, Inc.	MNTA	M281	Myasthenia Gravis (MG)	II	Trial Data - Top-Line Results	Phase II - Top-Line Results	Momenta anticipates data read-out for the Phase II Myasthenia Gravis Study (U.S.) in 2020.	148419
01/01/2020-12/31/2020	NovoCure Limited	NVCR	Optune	Hepatocellular (Liver) Cancer (HCC) (Including Secondary Metastases)	Development Outside U.S.	Trial Data - Top-Line Results	Phase II HEPANOVA Top Line Results	Novocure announced that data from the Phase II HEPANOVA trial in advanced liver cancer will be announced in 2020.	148440
09/01/2020-12/31/2020	Pliant Therapeutics		PLN-74809	Primary Sclerosing Cholangitis (PSC)	Preclinical	Trial Data - Top-Line Results	Phase II - Top-Line Results	Pliant Therapeutics plans to release Phase II data of PLN-74809 for the treatment of PSC in late 2020.	148396
01/09/2019-12/31/2020	Puma Biotechnology, Inc.	PBYI	Nerlynx	Breast Cancer	Approved	Trial Announcement - Initiation	Phase I w/DS-8201 Trial to Start	Based on positive nonclinical results Puma expects a combination study of PB272 and DS8201 will start either this year or next year.	148376
07/01/2020-12/31/2020	Replimune Inc.	REPL	RP1	Solid Tumors	I/II	Trial Data - Updated Results	Phase I/II - Phase II Data	Replimune expects to present Phase II data from the Phase I/II study (RP1 alone and RP1 combined with nivolumab) in the second half of 2020.	148356
01/01/2020-12/31/2020	Roche Holding AG	RHHBY	RG6264	Breast Cancer	III	Regulatory - NDA/BLA Filing	BLA Filing	Halozyme Therapeutics lists that regulatory submissions for the Perjeta and Herception fixed dose combination product with Enhanze are anticipated in 2020.	148358
01/01/2020-12/31/2020	Roivant Sciences, Inc.		Vibegron	Irritable Bowel Syndrome (IBS)	II	Trial Data - Top-Line Results	Phase IIa Top-Line Results	Urovant announced that top-line results from the Phase IIa study of IBS associated pain are expected to be announced in 2020.	148345
07/01/2020-12/31/2020	Supernus Pharmaceuticals, Inc.	SUPN	SPN-810	Attention Deficit Hyperactivity Disorder (ADHD)	III	Regulatory - NDA/BLA Filing	NDA Filing	Supernus plans to file an NDA for SPN-810 for the treatment of impulsive aggression in the second half of 2020.	148353
01/01/2020-12/31/2020	Supernus Pharmaceuticals, Inc.	SUPN	SPN-810	Attention Deficit Hyperactivity Disorder (ADHD)	III	Trial Data - Top-Line Results	Phase III P503 - Top-Line Results	Supernus expects to have data from tis Phase III P503 study of SPN-810 in 2020.	148355
04/01/2021-04/30/2021	CSL Limited	CSL:AU	CSL112	Atherosclerosis	III	Trial Data - Top-Line Results	Phase III - Top-Line Results	CSL expects to have interim efficacy data from its Phase III AEGIS-II study of CSL112 by April 2021.	148342
07/01/2020-06/30/2021	Orchard Therapeutics Limited	ORTX	OTL-101	Primary Immunodeficiencies	I/II	Regulatory - MAA Submission (Europe)	MAA Submisionn	In 2018 Orchard Therapeutics completed pre-biologics license application (BLA) and CMC specific meetings with the U.S. Food and Drug Administration (FDA) for OTL-101 for ADA-SCID following which the program remains on track for a BLA filing in the U.S. in 2020. This will be followed by a MAA submission.	148475
10/01/2021-12/31/2021	Mirati Therapeutics	MRTX	Sitravatinib	Non-Small Cell Lung Cancer (NSCLC)	II	Trial Data - Updated Results	Phase III - Primary OS Analysis	Mirati expects to have the primary OS analysis from its Phase III study of Sitravatinib + Nivolumab by year-end 2021.	148335
01/01/2021-12/31/2021	NovoCure Limited	NVCR	Optune	Non-Small Cell Lung Cancer (NSCLC)	IDE	Trial Data - Final Results	Phase III LUNAR Final Results	Novocure announced that final data from the Phase III Pivotal LUNAR trial is expected in 2021.	148439
01/01/2021-12/31/2021	Orchard Therapeutics Limited	ORTX	OTL-103	Thrombocytopenia	III	Regulatory - NDA/BLA Filing	BLA Filing	Orchard Therapeutics expects to submit a BLA and MAA for OTL-103 for WAS in 2021.	148479
01/01/2022-12/31/2022	CSL Limited	CSL:AU	CSL112	Atherosclerosis	III	Regulatory - NDA/BLA Filing	BLA Filing	CSL plans to file for approval of CSL112 in the US and Europe in 2022.	148343
01/01/2022-12/31/2022	CSL Limited	CSL:AU	CSL112	Atherosclerosis	III	Regulatory - MAA Submission (Europe)	MAA Submission	CSL plans to file for approval of CSL112 in the US and Europe in 2022.	148344
01/01/2022-12/31/2022	NovoCure Limited	NVCR	Optune	Ovarian Cancer	Development Outside U.S.	Trial Data - Top-Line Results	Phase III INNOVATE-3 Interim Analysis	Novocure announced that an interim analysis of the Phase III pivotal INNOVATE-3 trial in recurrent ovarian cancer is expected to be reported in 2022.	148434
08/01/2029-08/31/2029	Amarin Corporation plc	AMRN	Vascepa	Dyslipidemia / Hypercholesterolemia	Approved	Progress Update - Product Launch	Generic Launch	Amarin announced that the patents listed in the FDA's Orange Book for its product Vascepa will expire in 2030. Per an agreement between Amarin and Teva Teva may launch a generic of Vascepa in August 2029.	148442
Now-12/31/2030	Amarin Corporation plc	AMRN	Vascepa	Dyslipidemia / Hypercholesterolemia	Approved	Patent - Expiration	Patent Expiration	Amarin announced that the patents listed in the FDA's Orange Book for its product Vascepa will expire in 2030.	148417

Biomedtracker JPM Updated Catalysts - Day 3

Expected Date Range	Company	Symbol	Drug	Indication	Phase	Expected Catalyst	Catalyst Title	Analysis	Updated Analysis	Link
01/09/2019-12/31/2019	Intercept Pharmaceuticals, Inc.	ICPT	Ocaliva	Primary Sclerosing Cholangitis (PSC)	II	Progress Update - Development Review	Development Update	Intercept plans to define a path forward for Ocaliva in the treatment of PSC in 2018.	Date Range Delayed (01/09/2019) - Intercept announced that it has acquired from Aralez its license to develop and commercialize bezafibrate in the U.S. its IND on file with the FDA and other associated regulatory documentation and a non-exclusive license to certain of Aralez's intellectual property. Intercept intends to initiate a Phase II study to evaluate the efficacy safety and tolerability of bezafibrate in combination with Ocaliva in patients with PBC with the longer term goal to develop and seek regulatory approval for a fixed dose combination regimen in this indication and potentially other liver diseases. We await an update on PSC development.	137892
01/17/2019-01/19/2019	Five Prime Therapeutics, Inc.	FPRX	Bemarituzumab	Gastric Cancer	III	Trial Data - Other	Phase I/III - Phase I Data	Five Prime Therapeutics announced that the company completed the Phase I safety lead-in portion and has initiated the Phase III portion of the FIGHT Phase I/III clinical trial of bemarituzumab (FPA144) an isoform-selective anti-FGF receptor 2b antibody in combination with chemotherapy in patients with previously untreated advanced gastric cancer (GC) or gastroesophageal junction (GEJ) cancer.Five Prime plans to submit the Phase I lead-in data for presentation at a medical conference in the first half of 2019.	Date Range Refined (01/09/2019) - Five Prime expects safety lead-in data fromthe pivotal FIGHT trial for bemarituzumab during the ASCO GI conference on January 17-19 2019.	145340
01/09/2019-01/31/2019	Idera Pharmaceuticals, Inc.	IDRA	Tilsotolimod	Melanoma	III	Trial Announcement - Patient Enrollment Completed	Phase I/II ILLUMINATE 204 - Patient Enrollment Completed	Idera is currently conducting the Phase II portion of the ipilimumab combination arm of a Phase I/II clinical trial of intratumoral IMO-2125 in patients with anti-PD-1 refractory metastatic melanoma. Idera announced that it expects to complete enrollment of the Phase II multicenter trial in the second half of 2017 with overall response rate (ORR) data available in the first quarter of 2018.	Date Range Expedited (01/09/2019) - Idera Pharmaceuticals lists that the Phase I/II ILLUMINATE 204 study of tilsotolimod is planned to be closed to enrollment by the end of January 2019.	134321
01/09/2019-01/31/2019	NovoCure Limited	NVCR	Optune	Brain Cancer (Malignant Glioma; AA and glioblastoma (GBM))	Approved	Reimbursement - Medicare/Payer (US) Decision	Optune LCD Decision	Novocure announced that it submitted a local coverage determination or LCD request to the Medicare Durable Medical Equipment (DME) Medicare Administrative Contractor's (MAC) on June 20 2018. The Company said that the decision to file for coverage followed an announcement by the Centers for Medicare and Medicaid	Date Range Refined (01/09/2019) - Optune announced that the company is making progress with Medicare and is poised for ultimate approval in 2019.	144569
01/09/2019-01/31/2019	NovoCure Limited	NVCR	Optune	Ovarian Cancer	Development Outside U.S.	Trial Announcement - Initiation	Phase III Pivotal Trial to Start (Recurrent)	Novocure announced that a Phase III pivotal trial for recurrent ovarian cancer is in development. We await an update on the initiation of this trial in the time frame above.	New Information (01/09/2019) - Novocure announced that it anticipates starting the Phase III pivotal trial in recurrent ovarian cancer in 2019.	128382
2/7/2019	Sangamo Therapeutics, Inc.	SGMO	SB-913	Mucopolysaccharidosis II (MPS II; Hunter Syndrome)	I/II	Trial Data - Updated Results	Phase I/II CHAMPIONS - Updated Results at WORLDSymposium	Sangamo reported 16 week reductions in urinary glycosaminoglycans (GAGs) a key biomarker of Mucopolysaccharidosis Type II (MPS II) disease pathophysiology in Cohort 2 of the Phase I/II CHAMPIONS Study evaluating SB-913 at the 2018 Annual Symposium of the Society for the Study of Inborn Errors of Metabolism (SSIEM). Two subjects in Cohort 3 (high dose 5x the mid dose) have recently been infused and the study's safety monitoring committee will review cumulative data from all three dose cohorts later this year. Sangamo will work with site investigators to determine when withdrawal of ERT is appropriate for individual patients. Sangamo plans to present longer-term safety and efficacy results from the CHAMPIONS Study in February at the 2019 WORLDSymposium meeting.	Exact Date (01/04/2019) - Sangamo Therapeutics announced that interim clinical data from the Company's inherited metabolic diseases development programs will be presented at WORLDSymposium. An abstract entitled CHAMPIONS: A Phase 1/2 clinical trial with dose escalation of SB-913 ZFN-mediated in vivo human genome editing for treatment of MPS II (Hunter syndrome) will be presented on February 7th 2019. The SB-913 (MPS II) presentation is expected to include interim data on safety and biochemical measurements at up to 24 weeks from six subjects enrolled in the three dose cohorts of the CHAMPIONS Study. New Information (01/09/2019) - Sangamo reiterated that it plans to provide interim data on SB-913 at the WORLDSymposium on February 7th.	145206
2/7/2019	Sangamo Therapeutics, Inc.	SGMO	SB-318	Mucopolysaccharidosis I (MPS I; Hurler Syndrome)	I/II	Trial Data - Top-Line Results	Phase I/II - Top-Line Results at WORLDSymposium	Sangamo announced it expects data from the Phase I/II of SB-318 in MPS I in late 2017 or early 2018.	Exact Date (01/04/2019) - Sangamo Therapeutics announced that interim clinical data from the Company's inherited metabolic diseases development programs will be presented at WORLDSymposium. An abstract entitled EMPOWERS: A Phase 1/2 clinical trial of SB-318 ZFN-mediated in vivo human genome editing for treatment of MPS I (Hurler Syndrome) will be presented on February 7th 2019. The SB-318 (MPS I) presentation is expected to describe the scientific rationale for SB-318 the clinical trial design and preliminary safety and biochemical measurements at up to four weeks from the first three patients enrolled in the EMPOWERS Study.New Information (01/09/2019) - Sangamo reiterated that it plans to provide interim data on SB-318 at the WORLDSymposium on February 7th.	129005
03/01/2019-03/31/2019	Akebia Therapeutics, Inc.	AKBA	Vadadustat	Anemia Due to Chronic Renal Failure, Dialysis-Dependent	III	Trial Announcement - Patient Enrollment Completed	Phase III INNO2VATE - Enrollment Complete	Akebia expects to initiate a Phase III vadadustat program in dialysis-dependent CKD patients INNO2VATE in 2016 anticipating full enrollment by early 2018.	Date Range Delayed (01/09/2019) - Akebia anticipates to have patient enrollment completed for INNO2VATE in March 2019.	123843
01/09/2019-03/31/2019	BlueRock Therapeutics		Dopaminergic Neurons Program (BlueRock)	Parkinson's Disease (PD)	Preclinical	Trial Announcement - Initiation	Clinical Trial to Start	According to BlueRock's pipeline the Company is developing dopaminergic neurons that can replace the dopamine-secreting cells that have been lost in Parkinson's patients. BlueRock plans to submit an Investigational New Drug (IND) application to the FDA in 2018 with the goal of treating the first patient that year.	Date Range Delayed (12/31/2018) - We await an update.Date Range Delayed (01/09/2019) - Bluerock announced that the company has filed an IND for Dopaminergic Neurons Program for Parkinson's Disease (PD) and plans to initiate a Phase I/IIa trial. We await an update on the trial initiation through the time frame above.	142043
01/09/2019-03/31/2019	Gilead Sciences, Inc.	GILD	Filgotinib	Rheumatoid Arthritis (RA)	III	Trial Data - Top-Line Results	Phase III FINCH 1 - Top-Line Results	Gilead expects to have data from its Phase III FINCH 1 study of Filgotinib in patients with rheumatoid arthritis in the first half of 2019.	Date Range Expedited (01/09/2019) - Galapagos announced that data from the FINCH I study is expected in the first quarter of 2019.	142424
01/09/2019-03/31/2019	Gilead Sciences, Inc.	GILD	Filgotinib	Rheumatoid Arthritis (RA)	III	Trial Data - Top-Line Results	Phase III FINCH 3 - Top-Line Results	Gilead expects to have data from its Phase III FINCH 3 study of Filgotinib in patients with rheumatoid arthritis in the first half of 2019.	Date Range Expedited (01/09/2019) - Galapagos announced that data from the FINCH III study is expected in the first quarter of 2019.	142423
Now-03/31/2019	Intercept Pharmaceuticals, Inc.	ICPT	Ocaliva	Non-Alcoholic Steatohepatitis (NASH)	III	Trial Data - Top-Line Results	Phase III REGENERATE - Top Line Results	Intercept expects interim results from its Phase III REGENERATE trial of Ocaliva for NASH in 2019.	Date Range Refined (01/09/2019) - Intercept anticipates that it will read-out top-line data from the interim analysis of its Phase III REGENERATE trial evaluating obeticholic acid (Ocaliva) in non-cirrhotic NASH patients with advanced liver fibrosis in the first quarter of 2019.	125821
01/09/2019-03/31/2019	Inventiva S.A.	IVA	Lanifibranor	Scleroderma	IIb	Trial Data - Top-Line Results	Phase IIb Diffuse Cutaneous - Top-Line Results	Inventiva announced that results from the IVA-337 SSc clinical trial are expected in the second half of 2018 while those of the NASH trial are due for early 2019.	Date Range Delayed (12/19/2018) - According to the company website recruitment has been completed for the Phase II study to evaluate lanifibranor in the treatment of SSc and compare for 48 weeks two doses of lanifibranor with a placebo control level top-line results are expected in early 2019. Date Range Refined (01/09/2019) - Inventiva announced that pivotal Phase IIb results of lanifibranor for systemic sclerosis (SSc) are expected in the first quarter of 2019.	136385

Biomedtracker JPM Updated Catalysts - Day 3

Expected Date Range	Company	Symbol	Drug	Indication	Phase	Expected Catalyst	Catalyst Title	Analysis	Updated Analysis	Link
01/09/2019-03/31/2019	MorphoSys AG	MOR	MOR202	Multiple Myeloma (MM)	Development Outside U.S.	Trial Announcement - Initiation (Emerging Markets)	Clinical Trials to Start - China	MorphoSys and I-Mab announced that they have entered into an exclusive regional licensing agreement to develop and commercialize MOR202 in China Taiwan Hong Kong and Macao. I-Mab Biopharma intends to start clinical development of MOR202 to treat patients with multiple myeloma in China in 2018.	New Information (08/08/2018) - MorphoSys and I-Mab Biopharma announced that I-Mab has submitted an investigational new drug (IND) application to China National Drug Administration (CNDA) for TJ202/MOR202 a human monoclonal antibody directed against CD38 for the treatment of multiple myeloma. We continue to await an update through 2018.Date Range Delayed (08/29/2018) - I-Mab will commence a pivotal study of MOR202in multiple myeloma (MM) in the first quarter of 2019.New Information (01/09/2019) - MorphoSys announced that the company has chosen to suspend development of MOR202 outside of China and will fully out-license the development of the drug to I-Mab Biopharma. The study of MOR202 in multiple myeloma is expected to commence in the first quarter of 2019.	138509
Now-03/31/2019	Novavax, Inc.	NVAX	ResVax	Respiratory Syncytial Virus (RSV)	III	Trial Data - Top-Line Results	Phase III Prepare - Top-line Results	Novavax expects to report data from their Phase III PREPARE trial of RSV F Vaccine in pregnant women in 2018.	Date Range Delayed (01/09/2019) - Novavax plans to report the interim data from the Prepare Phase III study in the first quarter of 2019 after January.	125585
03/01/2019-03/31/2019	Roche Holding AG	RHHBY	Herceptin-rHuPH20 (Subcutaneous)	Breast Cancer	BLA	Regulatory - PDUFA/Approval Decision (US)	PDUFA for BLA - First Review	Halozyme Therapeutics announced that the U.S. Food and Drug Administration (FDA) has accepted a Biologics License Application from Genentech a member of the Roche Group for a subcutaneous (SC) formulation of trastuzumab (Herceptin) in its FDA-approved breast cancer indications. In accordance with federal regulation the FDA has 60 days from the date of receipt of the application to determine acceptability of the filing. Based on a standard 12-month BLA filing under PDUFA V guidelines the PDUFA decision should occur in the time frame above.	Date Range Expedited (01/09/2019) - Halozyme Therapeutics lists that FDA action for the SC formulation of Herceptin will occur in March 2019.	144050
01/09/2019-04/30/2019	Hutchison MediPharma Limited	HCM	Fruquintinib	Gastric Cancer	I	Trial Data - Top-Line Results	Phase III FRUTIGA - Top-Line Results	An interim analysis on FRUTIGA to establish proof-of-concept (POC) is anticipated during the first half of 2019 and if successful could trigger a POC milestone from Lilly.	Date Range Refined (01/09/2019) - Hutchison expects to have interim data from the Phase III FRUTIGA study of Fruquintinib in early 2019.	145217
01/09/2019-04/30/2019	Hutchison MediPharma Limited	HCM	Sulfatinib	Neuroendocrine Tumors (NET)	I/II	Trial Data - Top-Line Results	Phase III - SANET-ep - Top-Line Results	Hutchison China MediTech announced that approximately 270 patients will be enrolled in the SANET-ep study from more than 20 centres across China with top-line results expected in 2018.	Date Range Refined (01/09/2019) - Hutchison expects to have interim data from its Phase III study of surufatinib for non-pancreatic NET in early 2019.	117518
Now-06/30/2019	Acadia Pharmaceuticals, Inc.	ACAD	Nuplazid	Major Depressive Disorder (MDD)	II	Trial Announcement - Initiation	Phase III Study to Start	ACADIA plans to initiate a Phase III program of Nuplazid in adjunctive MDD in the first half of 2019.	New Information (01/09/2019) - Acadia announces that it plans to initiate two Phase III parallel design placebo-controlled trials in adjunctive Major depressive Disorder (MDD) on top of baseline SSRI/SNRI therapy in the first half of 2019.	146599
Now-06/30/2019	AVEO Pharmaceuticals, Inc.	AVEO	Tivopath (Oncology)	Renal Cell Cancer (RCC)	III	Regulatory - NDA/BLA Filing	NDA Filing	Aveo plans to file for approval of Tivozanib based on the Phase III TIVO-1 and TIVO-3 studies for RCC in the second half of 2018.	Date Range Delayed (11/05/2018) - AVEO announced topline results from the primary analysis of the TIVO-3 trial the Company's Phase III randomized controlled multi-center open-label study to compare tivozanib (FOTIVDA) to sorafenib in 351 subjects with highly refractory advanced or metastatic renal cell carcinoma (RCC). Based on results from the TIVO-3 trial together with the previously completed Phase III TIVO-1 trial of tivozanib in the first line treatment of RCC the Company's goal is to submit a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) in approximately six months.Date Range Delayed (01/09/2019) - Aveo announced they anticipate filing an NDA for tivozanib in RCC in the first half of 2019.	139824
01/09/2019-06/30/2019	BioCryst Pharmaceuticals, Inc.	BCRX	BCX7353	Hereditary Angioedema (HAE)	III	Trial Announcement - Initiation	Phase III APeX-J (Japan) Trial to Start	BioCryst Pharmaceuticals announced that the Company has reached agreement on the design of a Phase III trial and regulatory requirements for marketing authorization of BCX7353 for Hereditary Angioedema ("HAE") with the Pharmaceuticals and Medical Devices Agency ("PMDA") in Japan. With the agreement on the regulatory requirements for marketing authorization of BCX7353 in Japan BioCryst can move forward with executing APeX-J and selecting a commercialization partner for this region. We await an update on the trial initiation over the coming months.	Date Range Delayed (10/26/2018) - We await an update through February 2019.Date Range Delayed (01/09/2019) - BioCryst announced that the small 24 patient Phase III - APeX-J study of BCX7353 for Prophylactic HAE will begin soon sometimes in the first half of 2019. We continue to await an update.	143764
04/01/2019-06/30/2019	InflaRx N.V.	IFRX	IFX-1	Hidradenitis Suppurativa	IIb	Trial Data - Top-Line Results	Phase IIb SHINE - Top-Line Results	InflaRx announced that patient enrollment has been completed in the Phase IIb study to determine the safety and efficacy of IFX-1 a first-in-class anti-human complement factor C5a antibody in patients suffering from moderate or severe Hidradenitis Suppurativa (HS). Topline results from the trial are expected in the first half of 2019.	Date Range Refined (01/09/2019) - InflaRx anticipates key results of the international Phase IIb study in the second quarter of 2019.	146902
01/09/2019-06/30/2019	Intrexon Corporation	XON	PRGN-3006	Hematologic Cancer	IND	Trial Announcement - Initiation	Phase I/Ib - Trial to Start	Precigen announced that the US Food and Drug Administration has cleared the Investigational New Drug (IND) application for PRGN-3006 a first-in-class investigational therapy using Precigen's UltraCAR-T platform. This first-in-human Phase I dose escalation study to evaluate the safety and maximal tolerated dose of PRGN-3006 UltraCAR-T will be conducted in collaboration with Moffitt Cancer Center. We await an update on the start of the trial in the time frame above.	Date Range Delayed (01/09/2019) - Intrexon announced the Phase I/Ib study to evaluate the safety and MTD of PRGN-3006 is expected to initiate in the first half of 2019.	147752
06/01/2019-06/30/2019	La Jolla Pharmaceutical Company	LJPC	Giapreza	Hypotension/Shock	Approved	Regulatory - CHMP (European Panel) Results	CHMP Opinion	La Jolla Pharmaceutical announced that the Marketing Authorisation Application (MAA) for GIAPREZA (angiotensin II) Injection for Intravenous Infusion was validated by the European Medicines Agency (EMA). Based on an internal analysis of the centralized European approval procedure we estimate the European marketing authorization for this drug for this indication will be granted in approximately 11-17 months. As the approval decision is normally issued 67 days from adoption of a positive Committee for Medicinal Products for Human Use (CHMP) opinion we then estimate the CHMP opinion to occur between March and September 2019.	Date Range Refined (01/09/2019) - La Jolla Pharmaceutical expects a decision on the GIAPREZA Marketing Authorisation Application (MAA) by the European Medicines Agency (EMA) in June of 2019.	143800
Now-06/30/2019	Magenta Therapeutics	MGTA	MGTA-145	Bone Marrow Transplant and Stem Cell Transplant	Preclinical	Trial Announcement - Initiation	Clinical Trials to Start	Magenta will be moving the MGTA-145 program into the clinic in the first half of 2019 as a investigational first-line therapy for stem cell mobilization.	New Information (01/09/2019) - Magenta plans to move forward into clinical development of MGTA-145 + plerixafor in the first half of 2019.	147330
04/01/2019-06/30/2019	MorphoSys AG	MOR	MOR208	Diffuse Large B-Cell Lymphoma (DLBCL) - NHL	II/III	Trial Data - Published Results	Phase II L-MIND - Published Data	MorphoSys announced that the primary analysis for the L-MIND study of MOR208 is anticipated to be published in the fourth quarter of 2019.	Date Range Refined (01/09/2019) - Morphosys announced that it plans to release final data from the Phase II L-MIND study investigating MOR208 in combination with lenalidomide for the treatment of diffuse large B-cell lymphoma in the second quarter of 2019.	141480
Now-06/30/2019	Novavax, Inc.	NVAX	NanoFlu	Seasonal Influenza Vaccines	II	Regulatory - Meeting with FDA	End of Phase II Meeting w/FDA	Novavax announced the initiation of a Phase II dose and formulation confirmation clinical trial in older adults of NanoFlu its nanoparticle seasonal influenza vaccine candidate. Top-line immunogenicity and safety data are expected in the first quarter of 2019. The Phase II results will support meeting with the U.S. Food and Drug Administration (FDA) in an End of Phase II meeting and Phase III clinical trial design. A pivotal Phase III clinical trial is expected to initiate in the second half of 2019. As such we await a meeting update in the time frame listed above.	New Information (01/04/2019) - Novavax announced top-line results of its Phase II clinical trial of NanoFlu. Novavax will again meet with the FDA in the first half of 2019 to discuss the Phase II clinical trial data the proposed Phase III trial design and the use of accelerated approval for licensure. Date Range Refined (01/09/2019) - Novavax expects to hold an End of Phase II Meeting with the FDA for NanoFlu in Q2 2019.	145720

Biomedtracker JPM Updated Catalysts - Day 3

Expected Date Range	Company	Symbol	Drug	Indication	Phase	Expected Catalyst	Catalyst Title	Analysis	Updated Analysis	Link
01/09/2019-06/30/2019	Puma Biotechnology, Inc.	PBYI	Nerlynx	Breast Cancer	Approved	Trial Data - Updated Results	Phase III - NALA Updated Results	Puma announced top-line results from the Phase III – NALA trial of the company's lead drug candidate PB272 (neratinib) in patients with HER2-positive metastatic breast cancer who have failed two or more prior lines of HER2-directed treatments (third-line disease) in the setting of metastatic disease. Full results of the trial will be submitted to health authorities around the world including the U.S. Food and Drug Administration and European Medicines Agency. Results of the trial will be submitted for presentation at a major medical conference in 2019. We await an update through the time frame above.	Date Range Delayed (01/09/2019) - Puma expects to present data from the Phase III NALA trial in Nerlynx in third-line MBC patients in the first half of 2019.	147641
Now-07/31/2019	Sumitomo Dainippon Pharma Co., Ltd.	4506:JP	SB623	Ischemic Stroke	IIb	Trial Data - Top-Line Results	Phase IIb ACTIsSIMA - Top-Line Results	SanBio announced that enrollment for the ACTIsSIMA study isexpected to be complete in March 2018. Patients will be monitored for 12 months with results reported in 2019.	New Information (01/10/2018) - SanBio announced enrollment of the last patient of all 163 subjects (initially planned with 156 subjects) in the Phase IIb clinical trial of SB623 for the treatment of chronic stroke being jointly conducted in the U.S. with Sunovion an indirect wholly-owned subsidiary of Sumitomo Dainippon. Patients will be monitored for 12 months and the top line results will be reported in 2019. Date Range Expedited (01/09/2019) - SanBio announced that it anticipates reporting results from the Phase II stroke trial by July 2019.	136637
08/07/2019-09/05/2019	La Jolla Pharmaceutical Company	LJPC	Giapreza	Hypotension/Shock	Approved	Regulatory - Approval Decision (Europe)	European Approval Decision	La Jolla Pharmaceutical announced that the Marketing Authorisation Application (MAA) for GIAPREZA (angiotensin II) Injection for Intravenous Infusion was validated by the European Medicines Agency (EMA). Based on an internal analysis of the centralized European approval procedure we estimate the European marketing authorization for this drug for this indication will be granted in approximately 11-17 months.	Date Range Refined (01/09/2019) - La Jolla Pharmaceutical expects a decision on the GIAPREZA Marketing Authorisation Application (MAA) by the European Medicines Agency (EMA) in June of 2019. As the approval decision is normally issued 67 days from adoption of a positive Committee for Medicinal Products for Human Use (CHMP) opinion we await the approval decision in the time frame above.	143801
04/01/2019-09/30/2019	Acadia Pharmaceuticals, Inc.	ACAD	Nuplazid	Schizophrenia	III	Trial Data - Top-Line Results	Phase III ENHANCE - Top-Line Results	Acadia announced that data from the Phase III ENHANCE study of pimavanserin in schizophrenia patients with inadequate response to current antipsychotic treatment are expected in 2019.	Date Range Refined (01/09/2019) - Acadia announced that the company plans for a top-line data readout of the Phase III-ENHANCE study investigating Nuplazid in patients with Schizophrenia in mid-2019.	139546
04/01/2019-09/30/2019	Allergan plc	AGN	EDIT-101	Leber's Congenital Amaurosis (Ophthalmology)	IND	Trial Announcement - Initiation	Phase I/II - Trial to Start	Editas announced that the Company is aiming to initiate a clinical trial in 2017 for the treatment of Leber Congenital Amaurosis 10 (LCA10).	Delayed (01/09/2019) - Editas plans to start EDIT-101 patient screening in its trial in mid-2019.	129790
04/01/2019-09/30/2019	Eidos Therapeutics, Inc.	EIDX	AG10	Hereditary Transthyretin (hATTR) Amyloidosis With Polyneuropathy (Familial Amyloid Polyneuropathy)	I	Trial Announcement - Initiation	Phase III - Trial to Start	Eidos plans to initiate Phase III studies with AG10 for the treatment of ATTR cardiomyopathy (ATTR-CM) and ATTR polyneuropathy (ATTR-PN) in the first half of 2019.	Date Range Delayed (01/09/2019) - Eidos plans to initiate pivotal Phase III studies of AG10 in mid-2019.	146491
04/01/2019-09/30/2019	Eidos Therapeutics, Inc.	EIDX	AG10	Transthyretin Amyloid Cardiomyopathy (ATTR-CM, Wild Type Or Hereditary)	II	Trial Announcement - Initiation	Phase III - Trial to Start	Eidos plans to initiate Phase III studies with AG10 for the treatment of ATTR cardiomyopathy (ATTR-CM) and ATTR polyneuropathy (ATTR-PN) in the first half of 2019.	Date Range Delayed (01/09/2019) - Eidos plans to initiate pivotal Phase III studies of AG10 in mid-2019.	146494
01/09/2019-12/31/2019	Akebia Therapeutics, Inc.	AKBA	Vadadustat	Anemia Due to Chronic Renal Failure, Dialysis-Dependent	III	Trial Data - Top-Line Results	Phase II FO2RWARD - Top-Line Results	Akebia expects to generate clinical data in hyporesponsive dialysis-dependent patients in the Phase II trial of Vadadustat by 2017.	Date Range Delayed (01/09/2019) - Akebia anticipates top-line results for the Phase II FO2RWARD study in 2019.	121027
07/01/2019-12/31/2019	Allergan plc	AGN	Abicipar Pegol	Diabetic Macular Edema (Ophthalmology)	II	Trial Announcement - Initiation	Phase III - Trial to Start	Allegan reported that the Phase III trial of Abicipar for DME is expected to start in 2017.	Date Range Delayed (01/09/2019) - Allergan announced that the company plans to start the Phase III trial investigating Abicipar for diabetic macular edema (DME) in the second half of 2019.	129304
07/01/2019-12/31/2019	AMAG Pharmaceuticals, Inc.	AMAG	Bremelanotide	Female Sexual Arousal Disorder	NDA	Progress Update - Product Launch (U.S.)	Product Launch (U.S.)	AMAG anticipates FDA action and commercial launch of bremelanotide for the treatment of hypoactive sexual desire disorder (HSDD) in early 2019.	Date Range Delayed (01/07/2019) - AMAG and Palatin the North American licensee of Vyleesi (bremelanotide) announced an update on the regulatory development of Vyleesi noting that the U.S. Food and Drug Administration has extended the Prescription Drug User Fee Act (PDUFA) date by three months to June 23 2019. We await an update on the commercialization of Vyleesi in the time frame above.New Information (01/09/2019) - AMAG Pharmaceuticals lists that they plan to launch Vyleesi in the second half of 2019.	132972
07/01/2019-12/31/2019	Amgen, Inc.	AMGN	MP0310 DARPin Program	Cancer	Preclinical	Trial Announcement - Initiation	Phase I Trial to Start	Molecular Partners announced that it expects to begin first-in-human (FIH) studies of MP0310 in 2019.	Date Range Refined (01/09/2019) - Molecular Partners announced that the drug MP0310 is currently in preclinical development and partnered with Amgen. The company plans for the Phase I trial to start in the second half of 2019.	139646
01/09/2019-12/31/2019	AVEO Pharmaceuticals, Inc.	AVEO	CAN017	Esophageal Cancer	I	Trial Announcement - Initiation	Clinical Development to Start	Aveo announced that CANbridge submitted an IND for AV-203 for esophageal cancer in December 2017 for which the company expects to go into the clinic in 2018.	Date Range Delayed (01/09/2019) - AVEO did not provide an update in timing for the planned Phase I trial of CAN017 in esophageal cancer at the JP Morgan healthcare conference. As such we await an update in the time frame above.	139833
07/01/2019-12/31/2019	BioCryst Pharmaceuticals, Inc.	BCRX	BCX9499	Fibrodysplasia Ossificans Progressiva (FOP)	Preclinical	Trial Announcement - Initiation	Phase I - Trial to Start	BioCryst plans to complete IND-enabling manufacturing and nonclinical safety studies of BCX9499 and BCX9250 with the goal of progressing to Phase I clinical trials in the first half of 2019.	Date Range Delayed (01/09/2019) - BioCryst announced that the Phase I trials of BCX9499 or BCX9250 are expected to begin in the second half of 2019.	139300
07/01/2019-12/31/2019	BioCryst Pharmaceuticals, Inc.	BCRX	BCX9250	Fibrodysplasia Ossificans Progressiva (FOP)	Preclinical	Trial Announcement - Initiation	Phase I to Start	BioCryst announced that the company has advanced a discovery program exploring activin receptor-like kinase-2 (ALK2) inhibitors for treatment of Fibrodysplasia Ossificans Progressiva (FOP) into Investigational New Drug Application (IND) enabling nonclinical development. The Company's optimized lead candidates BCX9250 and BCX9499 are projected to enter Phase I clinical trials during the first half of 2019.	Date Range Delayed (01/09/2019) - BioCryst announced that the Phase I trials of BCX9499 or BCX9250 are expected to begin in the second half of 2019.	140979
Now-12/31/2019	Celgene Corporation	CELG	Iberdomide	Multiple Myeloma (MM)	I/II	Trial Data - Top-Line Results	Phase I/II MM-001 - Top-Line Results	Celgene plans to have data from Phase I/II trials with CC-122 and CC-220 in patients with relapsed and/or refractory multiple myeloma in 2017.	Date Range Delayed (01/09/2019) - Celgene expects to announce data from the Phase I/II trial with CC-220 in relapsed and/or refractory multiple myeloma in 2019.	129117
10/01/2019-12/31/2019	ChemoCentryx, Inc.	CCXI	Avacopan	Antineutrophil Cytoplasmic Antibodies (ANCA) Associated Vasculitis	III	Trial Data - Top-Line Results	Phase III ADVOCATE - Top-Line Results	ChemoCentryx announced the company is targeting a top-line data release from ADVOCATE in the second half of 2019.	Date Range Delayed (01/09/2019) - ChemoCentryx announced the company is targeting a top-line data release from ADVOCATE in the fourth quarter of 2019.	143949
07/01/2019-12/31/2019	Halozyme Therapeutics, Inc.	HALO	PEGPH20	Pancreatic Cancer	III	Trial Data - Top-Line Results	Phase III HALO-301 - Top-Line Results	Halozyme announced continued progress screening and enrolling patients in the HALO-301 study of PEGPH20 in combination with ABRAXANE (nab-paclitaxel) and gemcitabine in first line metastatic pancreas cancer patients with high levels of tumor hyaluronan (HA-High). An interim analysis will be conducted for the first primary endpoint of progression-free survival when the target number of events has been reached which the company projects will be in the fourth quarter of 2018.	Date Range Refined (01/09/2019) - Halozyme Therapeutics anticipates top-line results from the Phase III study of PEGPH20 for the treatment of pancreatic cancer in the second half of 2019.	137883
01/09/2019-12/31/2019	Hutchison MediPharma Limited	HCM	Epitinib	Brain Cancer (Malignant Glioma; AA and glioblastoma (GBM))	Development Outside U.S.	Trial Announcement - Initiation	Phase III - Trial to Start	ChiMed announced that based on further data from the Phase Ib study the Company is preparing to initiate a Phase III pivotal study of epitinib in EGFR mutant NSCLC patients with brain metastasis in China in 2018.	Date Range Delayed (01/09/2019) - Hutchison currently lists Epitinib for the treatment of glioblastoma in early clinical development in its pipeline. We await an update through 2019 for the advancement of clinical development.	141022
10/01/2019-12/31/2019	Hutchison MediPharma Limited	HCM	Sulfatinib	Neuroendocrine Tumors (NET)	I/II	Trial Data - Top-Line Results	Phase III - SANET-p - Top-Line Results	Hutchison China MediTech announced that approximately 195 patients will be enrolled in SANET-p and is expected to start by the end of 2015 with top-line results expected in 2017.	Date Range Refined (01/09/2019) - Hutchison expects to have interim data from its Phase III study of surufatinib for pancreatic NET in late 2019.	117517

Biomedtracker JPM Updated Catalysts - Day 3

Expected Date Range	Company	Symbol	Drug	Indication	Phase	Expected Catalyst	Catalyst Title	Analysis	Updated Analysis	Link
01/09/2019-12/31/2019	Idera Pharmaceuticals, Inc.	IDRA	Tilsotolimod	Solid Tumors	I	Trial Announcement - Initiation	Phase II ILLUMINATE 206 Trial to Start	Idera expects to initiate a Phase II combination trial of IMO-2125 in multiple refractory solid tumors during the second half of 2017.	Date Range Refined (01/09/2019) - Idera Pharmaceuticals plans to initiate the ILLUMINATE 206 study of tilsotolimod combined with one or more immunotherapy agents for the treatment of solid tumors in 2019.	129571
07/01/2019-12/31/2019	Inventiva S.A.	IVA	Odiparcil	Mucopolysaccharidosis VI (MPS VI)	II	Trial Data - Top-Line Results	Phase IIa - iMProveS - Top-Line Results	Inventiva announced the enrollment of the first patient in its Phase IIa iMProveS (improve MPS treatment) trial targeting mucopolysaccharidosis VI patients (MPS VI). Results from the Phase IIa study are expected during the first semester of 2019.	Date Range Delayed (01/09/2019) - Results from the iMProveS Phase IIa trial of odiparcil in MPS VI are expected in the second half of 2019.	139204
Now-12/31/2019	Jounce Therapeutics, Inc.	JNCE	JTX-2011	Solid Tumors	I/II	Trial Announcement - Initiation	Additional Combination - Trials to Start	Jounce expects to initiate new JTX-2011 combination studies in 2018.	Date Range Delayed (01/09/2019) - Jounce expects additional Phase II combination trials of JTX-2011 with CTLA-4i and PD-1/monotherapy to be initiated in 2019.	139697
10/01/2019-12/31/2019	MorphoSys AG	MOR	MOR208	Diffuse Large B-Cell Lymphoma (DLBCL) - NHL	II/III	Regulatory - NDA/BLA Filing	BLA Filing	MorphoSys announced that they tentatively expect to file a BLA submission to the U.S. FDA in the second half of 2019 for MOR208 for the treatment of diffuse large B-cell lymphoma (DLBCL). This will largely depend on the outcome of the upcoming regulatory meeting with the FDA planned for the first quarter of 2018.	New Information (03/13/2018) - MorphoSys continues to have discussions with the FDA under the current breakthrough therapy designation on the path to market for MOR208 including the possibility of an expedited regulatory submission and approval for MOR208 based primarily on the L-MIND study.Date Range Refined (01/09/2019) - Morphosys announced that it plans to file a BLA application for MOR208 for diffuse large B-cell lymphoma based on results from the Phase II L-MIND trial in the fourth quarter of 2019.	139687
07/01/2019-12/31/2019	Novavax, Inc.	NVAX	NanoFlu	Seasonal Influenza Vaccines	II	Trial Announcement - Initiation	Phase III - Pivotal Trial to Start	Novavax announced the initiation of a Phase II dose and formulation confirmation clinical trial in older adults of NanoFlu its nanoparticle seasonal influenza vaccine candidate. Top-line immunogenicity and safety data are expected in the first quarter of 2019. The Phase II results will support meeting with the U.S. Food and Drug Administration (FDA) in an End of Phase II meeting and Phase III clinical trial design. A pivotal Phase III clinical trial is expected to initiate in the second half of 2019.	Date Range Delayed (01/09/2019) - Novavax expects to initiate a Phase III trial with NanoFlu in Q4 2019.	145719
01/09/2019-12/31/2019	NovoCure Limited	NVCR	Optune	Mesothelioma	HDE	Regulatory - HDE Approval Decision	Optune Humanitarian Device Exemption Approval	Novocure announced positive top-line results from its STELLAR phase II pilot trial in mesothelioma demonstrating clinically meaningful improvements in overall survival and progression free survival among patients who received Tumor Treating Fields plus standard of care chemotherapy pemetrexed and cisplatin or carboplatin compared to historical control data of patients who received standard of care chemotherapy alone. Based on this data the Company plans to submit a Humanitarian Device Exemption application to the FDA for approval. We await an update in the time frame above.	New Information (01/09/2019) - Novocure announced that it expects to receive HDE FDA approval for Optune for unresectable malignant pleural mesothelioma in 2019. The company has received initial comments from the FDA on its October 2018 Humanitarian Device Exemption (HDE) application for approval in malignant pleural mesothelioma and is currently preparing its response.	142127
01/09/2019-12/31/2019	NovoCure Limited	NVCR	Optune	Gastric Cancer	Development Outside U.S.	Trial Announcement - Initiation (Emerging Markets)	Phase II Pilot Study to Start	Novocure and Zai Labs announced that Zai Lab will conduct a Phase II pilot trial to investigate Tumor Treating Fields in gastric cancer in China. The Companies did not provide a time frame for the initiation of the trial therefore we anticipate an update in the time frame listed above.	Date Range Delayed (01/09/2019) - Novocure announced that Zia Labs expects to start the Phase II pilot trial in Gastric Cancer in 2019.	145414
Now-12/31/2019	Orchard Therapeutics Limited	ORTX	OTL-200	Metachromatic Leukodystrophy	III	Trial Data - Top-Line Results	Clinical Data Readout	GlaxoSmithKline announced that they expect a clinical data readout from their metachromatic leukodystrophy program before the end of 2018. We await an update in the time frame listed above.	Date Range Delayed (01/09/2019) - Orchard Therapeutics plans to release two and three-year follow-up data in 20 patients from the fresh formulation registrational trial of OTL-200 for metachromatic leukodystrophy (MLD) in 2019 as well as engraftment data in the first three patients from the cryopreserved formulation clinical trial of OTL-200 for MLD.	129420
Now-12/31/2019	Orchard Therapeutics Limited	ORTX	OTL-102	Chronic Granulomatous Disease	Development Outside U.S.	Regulatory - Meeting with FDA	Meeting w/Regulatory Authorities	In 2019 Orchard intends to meet with regulatory authorities to discuss the clinical development path forward for the OTL-102 program in patients with X-Linked Chronic Granulomatous Disease (X-CGD).	New Information (01/09/2019) - Orchard Therapeutics plans to design and engage regulators on a registrational trial for OTL-102 in X-linked chronic granulomatous disease (X-CGD) which recently achieved clinical proof-of-concept in 2019.	147402
07/01/2019-12/31/2019	Supernus Pharmaceuticals, Inc.	SUPN	SPN-810	Attention Deficit Hyperactivity Disorder (ADHD)	III	Trial Data - Top-Line Results	Phase III CHIME 1 - Top-Line Results	Supernus announced that the Company expects Phase III data for SPN-810 for the treatment of impulsive aggression in ADHD to be available by mid 2017.	Date Range Delayed (01/10/2018) - Supernus announced they anticipate the top-line results for their Phase III study of SPN-810 for the treatment of ADHD in the first quarter of 2019.Date Range Delayed (01/09/2019) - Supernus expects to have Phase III P301 data for SPN-810 in the second half of 2019.	120089
07/01/2019-12/31/2019	TherapeuticsMD, Inc.	TXMD	Annovera	Contraception	Approved	Progress Update - Product Launch (U.S.)	Product Launch (US)	TherapeuticsMD currently estimates Annovera will be commercially available as early as the third quarter of 2019 and commercially launched as early as the fourth quarter of 2019 or first quarter of 2020.	Date Range Refined (01/09/2019) - TherapeuticsMD announced that the company plans to launch the contraceptive product Annovera in the second half of 2019.	144631
01/01/2020-03/31/2020	Akebia Therapeutics, Inc.	AKBA	Vadadustat	Anemia Due to Chronic Renal Failure, Dialysis-Dependent	III	Trial Data - Top-Line Results	Phase III INNO2VATE - Top-Line Results	Akebia anticipates releasing data from the Phase III INNO2VATE study of vadadustat during the first half of 2019.	Date Range Delayed (01/09/2019) - Akebia anticipates to have top-line results for the Phase III INNO2VATE trial in the first quarter of 2020.	134402
01/01/2020-04/30/2020	AstraZeneca PLC	AZN	Savolitinib	Non-Small Cell Lung Cancer (NSCLC)	II	Regulatory - Filing for Approval (Emerging Markets)	Chinese NDA Filing - MET Exon 14	Subject to positive Phase II outcomes Chi Med intends to submit a China NDA for savolitinib in 2020.	Date Range Refined (01/09/2019) - Hutchison will potentially file the Savolitinib NDA for the treatment of MET Exon 14 NSCLC in China in early 2020.	147719
01/01/2020-06/30/2020	Inventiva S.A.	IVA	Lanifibranor	Non-Alcoholic Steatohepatitis (NASH)	IIb	Trial Data - Top-Line Results	Phase IIb NATIVE - Top-Line Results	Inventiva announced that results from the IVA-337 SSc clinical trial are expected in the second half of 2018 while those of the NASH trial are due for early 2019.	Date Range Delayed (01/09/2019) - Inventiva announced the last visit by the last patient in its Phase IIb FASST (For A Systemic Sclerosis Treatment) trial as well as the second positive review of the Data Safety Monitoring Board (DSMB) in its Phase IIb NATIVE (NASH Trial to Validate IVA337 Efficacy) trial both conducted with lanifibranor. The results of the second DSMB meeting regarding the NATIVE study are encouraging and headline results are expected for the first half of 2020.	136384
07/01/2019-06/30/2020	Puma Biotechnology, Inc.	PBYI	Nerlynx	Breast Cancer	Approved	Regulatory - Approval Decision (Emerging Markets)	Chinese Approval Decision	Puma Biotechnology has been advised that its licensing partner CANbridge Pharmaceutical received confirmation that China's National Medical Products Administration (NMPA) has accepted its New Drug Application (NDA) for NERLYNX (neratinib) for the extended adjuvant treatment of adult patients with early stage HER2-positive breast cancer following adjuvant trastuzumab based-therapy. Based on an internal analysis of the Chinese approval procedure we estimate an approval decision for this drug for this indication will be granted in approximately 1 to 2 years.	Date Range Expedited (01/09/2019) - Puma expects to receive approval of Nerlynx in breast cancer in China in the second half of 2019 if priority review first half of 2020 if standard review.	145875
01/01/2020-12/31/2020	NovoCure Limited	NVCR	Optune	Non-Small Cell Lung Cancer (NSCLC)	IDE	Trial Data - Top-Line Results	Phase III - LUNAR - Top-Line Results	NovoCure announced it expects to release top-line results from its Phase III LUNAR trial in NSCLC in 2021.	Date Range Expedited (01/09/2019) - Novocure announced that the interim analysis of the Phase III pivotal LUNAR trial in NSCLC is expected to be announced in 2020.	132776
01/01/2020-12/31/2020	Orchard Therapeutics Limited	ORTX	OTL-200	Metachromatic Leukodystrophy	III	Regulatory - MAA Submission (Europe)	MAA Filing	GlaxoSmithKline announced that they plan to file for regulatory approval for their metachromatic leukodystrophy (MLD) drug candidate before the end of 2018.	Date Range Delayed (01/09/2019) - Orchard expects to submit a MAA for OTL-200 for MLD in 2020 followed by a BLA.	129413
07/01/2020-06/30/2021	Orchard Therapeutics Limited	ORTX	OTL-200	Metachromatic Leukodystrophy	III	Regulatory - NDA/BLA Filing	BLA Filing	GlaxoSmithKline announced that they plan to file for regulatory approval for their metachromatic leukodystrophy (MLD) drug candidate before the end of 2018.	Date Range Refined (01/09/2019) - Orchard expects to submit a MAA for OTL-200 for MLD in 2020 followed by a BLA.	129412

Biomedtracker JPM Updated Catalysts - Day 3

Expected Date Range	Company	Symbol	Drug	Indication	Phase	Expected Catalyst	Catalyst Title	Analysis	Updated Analysis	Link
10/01/2020-06/30/2021	Rigel Pharmaceuticals, Inc.	RIGL	Tavalisse	Anemia	II	Trial Data - Top-Line Results	Pivotal Phase III Trial - Top-Line Results	Rigel expects to start enrolling patients in the first half of 2019 for a randomized control trial of Fostamatinib for AIHA. Topline results are expected in the first half of 2021.	Date Range Expedited (01/09/2019) - Rigel anticipates top-line results for the Phase III pivotal study of Fostamatinib for AIHA at the end of 2020 to early 2021.	145980
01/01/2021-12/31/2021	NovoCure Limited	NVCR	Optune	Pancreatic Cancer	IDE	Trial Data - Top-Line Results	Phase III PANOVA-3 - Top-Line Results	NovoCure expects to release data from the Phase III Pivotal Pancreatic Cancer Trial 18 months following the last patient enrollment.	Date Range Expedited (01/09/2019) - Optune announced that the interim analysis of the Phase III Pivotal PANOVA-3 trial in locally advanced pancreatic cancer is expected to be reported in 2021.	128387
01/01/2021-12/31/2021	NovoCure Limited	NVCR	Optune	Brain Cancer (Secondary; Metastases)	IDE	Trial Data - Top-Line Results	IDE - METIS - Top-Line Results	NovoCure announced it expects to release top-line results from its IDE METIS study in 2020.	Date Range Delayed (01/09/2019) - Novocure announced that data from the Phase III pivotal METIS trial in brain metastases is expected in 2021.	132775
01/01/2021-12/31/2021	Orchard Therapeutics Limited	ORTX	OTL-103	Thrombocytopenia	III	Regulatory - MAA Submission (Europe)	MAA Filing	Orchard anticipates submitting regulatory applications for the MLD program next year and the WAS program in 2020 or 2021.	Date Range Refined (01/09/2019) - Orchard Therapeutics expects to submit a BLA and MAA for OTL-103 for WAS in 2021.	142280