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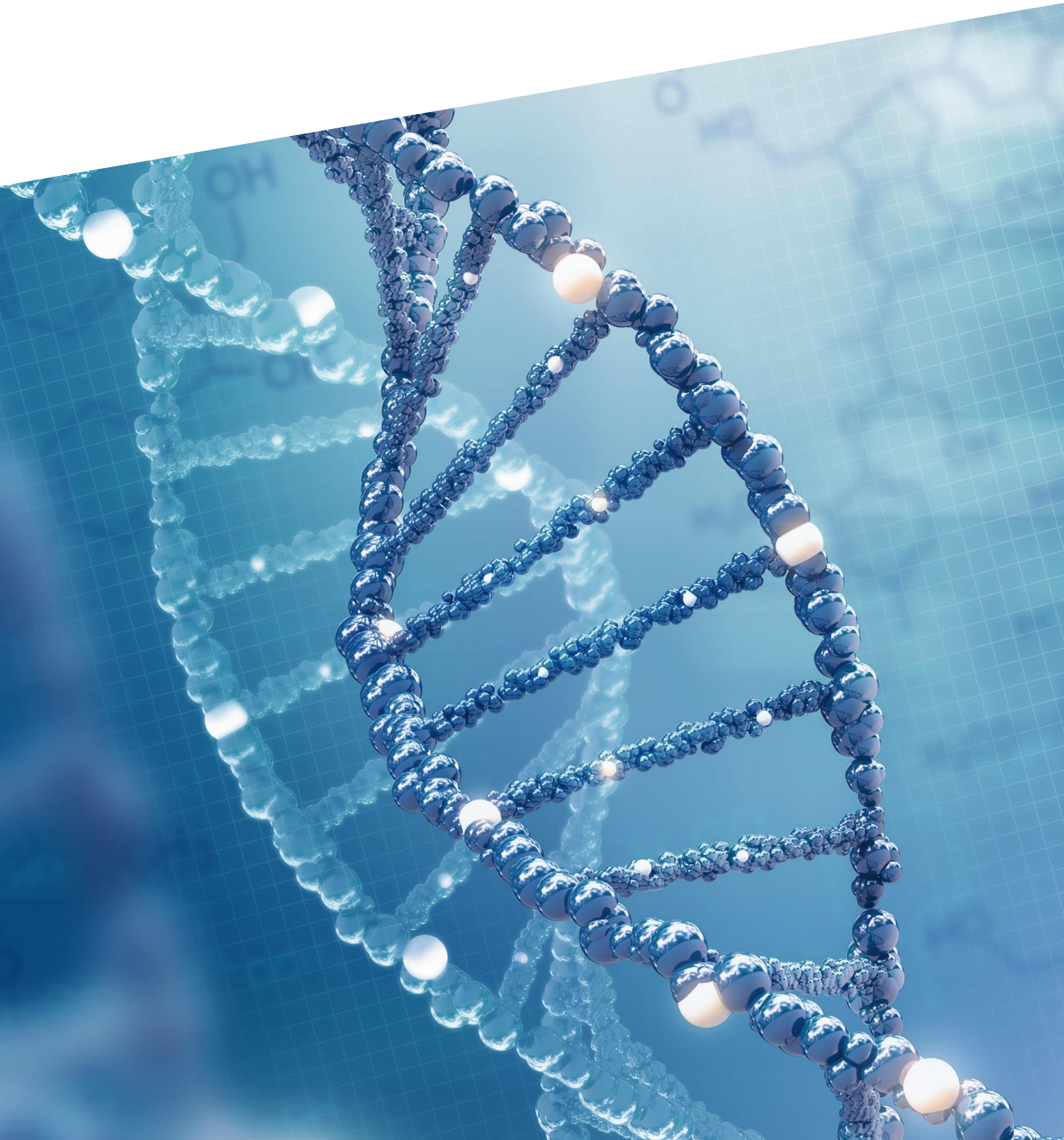
2019 JP MORGAN HEALTHCARE CONFERENCE: DAY 4



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 4

Mid Cap Companies

- Arena Pharmaceutical's (ARNA) presentation outlined their four products, however, unsurprisingly the main focus was on etrasimod and olorinab. They began the presentation outlining their best-in-class S1P receptor modulator Etrasimod for the treatment of ulcerative colitis (UC) and Chron's disease (CD). Officials claimed that there is a $3-4b market opportunity in UC and CD with etrasimod. They also pointed out that although some think this is an already crowded market it is estimated to be worth $23b in 2026 as the prevalence of the disease is continuously increasing. The CDC NHIS household survey indicate that prevalence could reach 3.1m in the EU. Additionally, officials explained that only 40% of responders on biologics achieve remission at 1year. Etrasimod recently released positive data from a Phase II OASIS open-label extension study, which demonstrated that 39% of patients achieved long-term clinical remission at both 12 and 46 weeks. Arena further summarised recently released data, which shows that etrasimod has rapid onset and offset action, competitive efficacy in UC and demonstrated a consistent reduction in lymphocytes with an improved clinical response. They explained that etrasimod's highly selective properties enable it to have a good safety and tolerability profile with no SAEs and most significantly there were no cases of sinoatrial arrest, which has been observed in competing compounds. Officials also highlighted the response of 100 GI physicians in a quantitative conjoint study, which indicated that etrasimod was likely to be preferred in the future compared to JAK inhibitors and ozanimod. Arena stated that a Phase III UC study and Phase II/III CD study will be initiated in 2019. They said the Phase III study, which is an expedited trial design, aims to drive rapid enrollment through patient referrals and a high-touch engagement using their internal field-based team.

  Arena then switched its focus on exploring etrasimod for atopic dermatitis, which has a prevalence of 22m in the US. They said that there is a severe impact on quality of life with 86% of patients not satisfied with current treatment options. Officials reiterated that early clinical results were positive in reducing wounds caused by pyoderma gangrenosum. A Phase II trial is expected to initiate in 2019.

  In addition, officials highlighted old data from olorinab for treatment of IBS and IBD. They noted that olorinab was a non-opioid that could address GI pain, which is a current unmet need. Arena summarised successful results from Phase IIa, which showed that olorinab significantly reduced abdominal pain over 8 weeks in patients with Chron's disease. They stated that olorinab was a $1-3b opportunity and confirmed plans to initiate Phase IIb IBS and IBD studies in 2019.

  Officials very briefly mentioned ralinepag, which is a selective prostacyclin receptor agonist for pulmonary arterial hypertension. They highlighted their global license agreement with United

Therapeutics who will receive exclusive worldwide rights. This strengthens their strategic position to advance etrasimod and olorinab.

Arena concluded the presentation with a summary of APD418 for decompensated heart failure. They confirmed that this therapy improved cardiac function without any hemodynamic changes in animals, which is an advantage over other inotrope therapies such as Dobutamine. Officials stated that they are preparing an IND submission for 2019.

- Outlining their strategy of teaming up with top academic labs to identify novel antibody targets, argenx (ARGX) noted that they are focused on treating orphan disease conditions with high unmet need. Lead product, efgartigimod, targets the neonatal Fc receptor (FcRn) and is being developed in several autoimmune disorders. The company is hailing this candidate as a first-in-class, best-in-class, and pipeline-in-a-product opportunity. Differentiating the drug using data on the safety and tolerability profile, with no headache or gastrointestinal toxicity, and fast onset of clinical benefit, the small size of this natural ligand of FcRn enables convenient subcutaneous dosing, a formulation being considered for development in immune thrombocytopenia and chronic inflammatory demyelinating polyneuropathy.

  A Phase III trial evaluating efgartigimod was recently initiated what they noted as being the largest myasthenia gravis trial and one which uniquely includes anti-acetylcholine receptor antibody negative patients, whose disease is driven primarily by MuSK and LRP4 autoantibodies. Favorable outcomes on secondary endpoints for this sub-set of patients may provide a competitive edge for the product's label over drugs approved exclusively for anti-acetylcholine receptor antibody positive patients. A Phase III trial with the intravenous formulations is planned for immune thrombocytopenia in the second half of 2019 while an ongoing Phase II trial evaluating efgartigimod in pemphigus vulgaris has been modified so that the third cohort, to start enrollment in the first half of 2019, can evaluate clinical remission.

  The company recently entered into an alliance with Janssen for cusatuzumab, an anti-CD70 product being evaluated for the treatment of acute myeloid leukemia. As part of the deal, argenx received a total of $500 million upfront, which includes a $200 million equity investment, and retains the right to co-promote cusatuzumab in the US and share economics 50-50 on a royalty basis, with no cap on the commercial upside. Strategically, this would allow argenx to establish an acute myeloid leukemia sales force that could also work to promote efgartigimod in immune thrombocytopenia.

  CEO Tim Van Hauwermeiren made a point during the presentation to call out the primary academic researchers critical to the development of their products. Likewise, he mentioned that they are working with a leading global expert in complement on ARGX-117, to be discussed further at the company's R&D day in May. Out-licensed products include IL-22 receptor targeting ARGX-122, from which argenx receives milestones from LEO Pharma, and which will be developed for atopic dermatitis; GARP-targeting ARGX-115 moving forward with AbbVie; and a partnership with Staten Bio to develop an anti-APOC3, ARGX-116, for dyslipidemia. Cash at year end 2018 was estimated at 582.3m Euros (+$500m from the Janssen deal).

- Evotec (EVT) focused on their strategic business model, rather than their product pipeline, which aims to create a high degree of efficiency with financial reward so that innovation can continue to grow. They described their business approach as unique due to their one core platform, which

they apply to different business models on a fee for service basis. Officials noted their action plan 2022, which aims to increase their co-owned pipeline and grow their platform further. Evotec indicated that their main focus going forward were small molecules and new modalities as these are efficient and cost effective.

Officials summarized their one fully integrated platform that contains two types of partnered drug discovery and development programs. Firstly, they described Evotec Execute, which is used when their scientists work on intellectual property (IP) that belongs to their partners. Officials noted their top quality and fully integrated R&D services with a comprehensive service panel used for external innovation. They mentioned a few examples of Evotec executive alliances, including their partnership with Roche focused on oncology.

Secondly, officials spoke about their Evotec Innovate business, which is used when their scientists generate IP and subsequently work with external partners. They briefly recalled some of their main partners for this including Sanofi for diabetes and Celgene for oncology. Evotec highlighted their platform used in the drug discovery paradigm that leads to better translation. The platform starts with medical records and patient induced pluripotent stem cell (iPSC) lines, it then moves on to holistic profiles with large data sets and AI technology.

To conclude, Evotec moved on to financials where they showed a consistent increase in total group revenue, R&D expenses and EBITDA over the past 3 years. They also announced that there will be a dense flow of clinical news in 2019 from preclinical data to Phase II data from their alliances including that with Bayer for chronic cough. In addition, there will be more news regarding the $14m payment from Celgene for the advancement of a program using Evotec's iPSC screening platform.

- Immunomedics (IMMU) is on the cusp of its first approval with the PDUFA date for sacituzumab govitecan in metastatic triple negative breast cancer (mTNBC) set for 18 January 2019. As a small company handling its first launch, management were keen to show that they are "launch ready", discussing the company's operations and supply chain as well as partnerships it has made with Samsung Biologics, Johnson Matthey, and BSP Pharmaceuticals to enable supply in case of growing demand due to subsequent approvals. Immunomedics is in a strong cash position with $583m cash and no long-term debt.

  In terms of sacituzumab govitecan's potential in mTNBC, the company outlined strong Phase II data in which the therapy provided an overall response rate (ORR) of 33% and a progression-free survival of 5.5 months, which compare well to data from other therapies for similar patient groups. Head-to-head trial data is not yet available, though a Phase III comparative trial is underway. Sacituzumab govitecan is under regulatory review for the treatment of mTNBC patients who have received two prior therapies; this is a patient group who have few options and where sacituzumab govitecan will likely be well-received. Indeed, the company stated its intention to make sacituzumab govitecan the standard of care for third-line treatment.

  The majority of the company's remaining pipeline activity comprises of investigating sacituzumab govitecan in other indications. A pivotal Phase II trial in advanced urothelial cancer was initiated in June 2018, a pivotal Phase III trial in HR+/HER- breast cancer is planned for the first half of 2019, and a non-pivotal basket study investigating sacituzumab govitecan for refractory non-small cell lung cancer, small cell lung cancer, head and neck squamous cell carcinoma,

endometrial cancer, and hepatocellular carcinoma is planned for the second half of 2019. With a likely launch and a busy clinical program, 2019 should be a good year for Immunomedics.

Small Cap Companies

- Dynavax (DVAX) began the presentation talking about its first commercialized product Heplisav-B, which received FDA approval for adults with hepatitis B infection in November 2017 and was launched in Q1 2018. The drug demonstrated higher seroprotection rates with its one-month, two-dose regimen compared with GlaxoSmithKline's Engerix-B with a six-month, three-dose regimen. Heplisav-B is expected to be profitable by year end and is positioned to be the standard of care hepatitis B adult vaccine in the US. Gross peak US sales could reach $500m. It is currently available in all Sam's Club pharmacy locations and Dynavax will work with pharmacy chains across the US to make the drug more available. Other clients for Heplisav-B include department of corrections facilities and the Department of Defense. CEO Eddie Gray pointed out that since there is no cure for hepatitis B, effective vaccination is critical.

  The company went on to talk about its lead clinical program SD-101/pembrolizumab combination that consistently provides significantly higher and more durable responses than monotherapy. The combo therapy is in Phase II trials for melanoma (resistant and refractory), head and neck cancer (naïve), and breast cancer (naïve). In 47 patients who received 2 mg/lesion of SD-101 in combination with pembrolizumab the overall response rate was 70%. Dynavax looks to explore SD-101 in other tumor indications and find potential partners to allow the therapy to reach its fullest potential.

  Dynavax's pipeline also includes DV281, currently being studied in Phase I for NSCLC in combination with nivolumab (anti-PD-1). Upcoming 2019 catalysts are safety and biomarker data from the Phase I study and initiation of a Phase II study, both anticipated in the first quarter. The company is continuing to advance its preclinical programs. Dynavax closed the presentation by announcing its strong financial position with cash and equivalents of $180.2m as of the end of September 2018. It looks forward to a busy and exciting year ahead.

- Having been mired in legal issues concerning former company executives and opioid kickback schemes in the last few years, Saeed Motahari, CEO of Insys Therapeutics (INYS) since 2017, began his presentation by emphasizing the transformation of the company and the rebuilding of its reputation. Key priorities included resolving government investigations, strengthening the leadership team and board members, and establishing a new organizational culture of compliance. Mr. Motahari highlighted that there was new leadership within the company and that more than two-thirds of the Board is new since April 2017. The aim of new management is to change the company's focus to pharmaceutical cannabinoids and spray technology, and strategically divest their opioid assets.

  The Company provided updates on their pipeline activities focusing on pharmaceutical cannabinoids and sprays. Oral Cannabidiol which is in Phase 2 for childhood absence epilepsy has an expected first data readout in Q1 2019. Insys has also initiated a proof-of-concept study for oral cannabidiol in Prader-Willi Syndrome and first data readouts are expected in the last quarter of this year. The drug is also in Phase III development for infantile spasms, however, management admitted that the Company was having difficulty enrolling the Phase III trial due to the nature of

the infants being registered. They will therefore be revisiting the protocol and/or adding more enrolment sites.

Having released positive data from a dose-finding pharmacokinetic study for epinephrine nasal spray for the treatment of anaphylaxis on January 9, management touted their positive outlook in this space. As epinephrine products are currently all injectables, the intranasal formulation provides a convenient and attractive non-invasive alternative. Importantly, the PK data demonstrated that the intranasal formulation provided a rapid drug absorption with similar bioavailability as compared to intramuscular injection of EpiPen® (0.3mg). Planned pivotal studies this year will include nasal allergen challenged patients with seasonal allergies, as well as in healthy volunteers. Insys will be presenting further results at the AAAAI Annual Meeting in February 2019, with a planned NDA filing date in Q4 2019.

Management addressed the declining financials for Insys since 2015 and reinforced that they had no debt but had financial obligations regarding DOJ settlements and other legal spending. In addition, their goals are to manage operational costs without compromising their clinical development program. More details surrounding financials will be delivered in the Company's upcoming investor call.

- Heading into 2019, the pivotal UNITY-NHL will be of upmost importance for **TG Therapeutics (TGTX)** as it moves closer to transitioning into a commercial phase company. The trial is now fully enrolled, and the company expects a top-line ORR release for the marginal zone lymphoma (MZL) and follicular lymphoma (FL) cohorts mid-2019, with a potential NDA filing in 2H 2019. Look for further updates from UNITY-NHL at the end of the year, at ASH 2019. In addition, the UNITY-CLL trial, also testing the ublituximab/umbralisib ("U2") combination but in chronic lymphocytic leukemia, is making good progress, with enrollment complete and a top-line PFS readout expected in 2H 2019.

  Looking ahead, the excellent tolerability profile of umbralisib compared to other PI3K inhibitors enables the drug to be developed in various other combinations. For example, TG Therapeutics announced that a Phase Ib in hematological cancers will begin in Q1 2019, testing U2 in combination with TG-1501, the company's proprietary PD-L1 inhibitor. In addition, U2 is being tested with the company's BTK inhibitor TG-1701 in mantle cell lymphoma and Waldenstrom's macroglobulinemia. The company also suggested further trials featuring U2-based triple and quadruple combinations may be on the horizon.

  TG Therapeutics concluded the talk by discussing its Phase III ULTIMATE trial testing ublituximab in multiple sclerosis. This pivotal trial is also fully enrolled, and an initial data release is currently slated for mid-2020.

- Newly appointed Elizabeth Barrett, who less than a week ago took the helm as **UroGen's (URGN)** president and CEO, discussed the company's uro-oncology-focused pipeline, mostly highlighting lead candidate UGN-101 (mitomycin gel), which has FDA Fast-Track, Breakthrough, and Orphan designations for low-grade upper tract urothelial cancer (LG UTUC; a rare malignant cancer of the cells lining the urinary tract, which affects a US patient population of about 6-8k). Because LG UTUC most commonly presents in the elderly, who often have co-morbidities, and the current standard of care in 78% of the cases requires kidney and/or ureter removal surgery, Ms. Barrett emphasized the advantage of a non-surgical treatment option.

The company recently announced positive results of UGN-101 from the ongoing pivotal Phase III OLYMPUS trial in which 57% patients achieved a complete response rate, all of whom were evaluated remained disease free at 6 months. In December, the company initiated a rolling submission for FDA approval, which is anticipated in the first half of 2020. UGN-101, as well as UroGen's two other uro-oncology pipeline candidates (UGN-102 and UGN-201), are driven by UroGen's RTGel sustained release, hydrogel-based formulation platform; a reverse thermal gel that liquefies upon instillation at body temperature, enabling longer exposure of mitomycin to urinary tract tissue, thereby providing a non-surgical tumor treatment option. Both for bladder cancer, UGN-102 addresses a low-grade non-muscle invasive bladder cancer (NMIBC) US patient population of about 80k, while UGN-201, for the high-grade form of the disease (CIS; carcinoma in situ), addresses a US market of about 2k patients. For UGN-102, a Phase IIb trial in NMIBC was initiated in August 2018 with interim data expected during 1H 2019. Phase Ib data for UGN-201 in CIS suggests preliminary efficacy with the company evaluating future clinical trials.

An additional candidate, BotuGel, is partnered via a 2016 deal potentially worth up to $225m with Allergan, which is using the RTGel platform with its neurotoxins to treat overactive bladder. Phase II data is expected in 2H 2019. The potential applications of the RTGel platform, including other UTUC and bladder cancer uses, as well as gastroenterology, women's health, weight loss, and enteral feeding indications, were also highlighted. Ms. Barrett closed the presentation stressing that 2019 will be a defining year for UroGen on the eve of the anticipated commercialization of its first product (UGN-101) in 2020.

- Claus Moller, CEO of Y-mAbs Therapeutics (YMAB), highlighted three of the company's most advanced candidates in today's presentation. The company plans to submit Biologics License Applications (BLAs) for naxitamab and omburtamab in 2019, and to submit an Investigational New Drug (IND) application for two bispecific antibodies (BsAb).

  For naxitamab, which is currently in Phase II trials for relapsed/refractory high-risk neuroblastoma and osteosarcoma, the CEO stressed the therapy's potential for addressing unmet needs due to the modest toxicity of the drug, shorter infusion time, and ability to be administered in an outpatient setting. Following the submission of the BLA in 2019, the company plans to commercialize the product in the US, if approved.

  As there are no approved therapies for patients with relapsed/refractory neuroblastoma suffering from CNS/leptomeningeal metastases, there is a wide market opportunity for omburtamab. Based on clinical studies in which the drug demonstrated an improvement in the overall survival rate of patients, the company plans to submit a BLA in 2019.

  The company's BsAb platform was also briefly mentioned, which includes two antibodies targeting GD2- and CD33-positive cancers, huGD2-BsAb, which is in a Phase I study for GD2-positive solid tumours, and huCD33-BsAb for hematological malignancies, with a potential IND submission planned for Q1 2020.

  The presentation concluded with a brief overview of the company's financial position. Y-mAbs Therapeutics has raised $230m through a series of financing rounds with key investors such as HBM, Scopia Captial, Sofinnova, and Nasdaq. The priorities for investment are going to be the

two pivotal stage candidates, their respective approvals and potential commercialization, as well as continuing the expansion of potential indications for the lead candidates in ongoing studies.

Micro Cap Companies

- Adverum's (ADVM) presentation primarily focused on promoting its Phase I gene therapy asset, ADVM-022, which is in development for the treatment of wet age-related macular degeneration (wAMD). ADVM-022 comprises of a proprietary AAV2.7m8 vector that transduces retinal cells and expresses the anti-vascular endothelial growth factor (VEGF) protein aflibercept, which has established efficacy in the treatment of wAMD.

  CEO Leone Patterson reiterated the preclinical data generated for ADVM-022 to date, which showed durable expression of anti-VEGF protein at therapeutic levels for over a year after a single intravitreal injection in non-human primates. ADVM-022's efficacy in reducing grade IV lesions (induced by laser) was also shown to be comparable to aflibercept when administered 13 months prior to lesion induction, providing a promising proof of concept of long-term efficacy. Patterson also highlighted how ADVM-022's potential to provide durable efficacy after a single dose could address a major limitation of current standard of care anti-VEGF agents, which require patients to visit retinal specialists for intraocular injections every 4–8 weeks. The company presented real-world data showing that only approximately half of the recommended annual injections of anti-VEGF agents are typically administered in clinical practice, with this poor compliance resulting in substantially lower effectiveness than observed in registrational trials. Patterson also touted ADVM-022's ease of use as a key USP, as it can be administered by any retinal specialist capable of delivering current anti-VEGF therapies in the outpatient setting (i.e. more complex sub-retinal surgery is not required).

  Adverum's presentation also highlighted key upcoming catalysts for the company, including the Q1 2020 release of interim data from the first three cohorts of the Phase I OPTIC study, which enrolled its first patient in November 2018. The study is enrolling wAMD patients who are responsive to anti-VEGF treatment with safety as the primary endpoint. Adverum also intends to provide an update on its preclinical rare disease programs for hereditary angioedema and alpha-1 antitrypsin deficiency (A1AD) in H1 2019, and its progress in scaling up its manufacturing process for ADVM-022 in H2 2019. Finally, the company noted its ongoing partnerships with Editas and Regeneron, which have collectively identified 13 potential candidates to investigate in a range of eye disorders, and its cash reserves of ~$200m, which should power the company through to at least H1 2020.

- Pavan Cheruvu, Axovant Sciences' (AXON) CEO as of early 2018, led with the announcement of a 2019 packed with clinical catalysts that is delivering on his promise last year to build a leading gene therapy company with a rich pipeline. Cheruvu highlighted Axovant's recent additions to its leadership team and its cultivation of an experienced scientific advisory board, bringing a wealth of gene therapy experience to the table. Delivering on four clinical programs that span diverse patient populations, from children with rare diseases to adults, constitutes the company's main focus for 2019. These include AXO-AAV-GM1 for GM1 gangliosidosis, AXO-AAV-GM2 for GM2 gangliosidosis, AXO-LENTI-PD for Parkinson's disease (PD), and AXO-AAV-OPMD for oculopharyngeal muscular dystrophy (OPMD).

Axovant's two newest clinical programs are the first to target gangliosidosis. There is critical unmet need for treatments in this space, considering that existing options are palliative. GM1 and GM2 gangliosidoses represent a 600-800 patient opportunity across the US and EU. Cheruvu emphasized the sound and well-characterized neurobiology of these diseases that makes them attractive targets for gene therapy. Positive preclinical data were reiterated, with AXO-AAV-GM1 appearing to prolong survival, revitalize enzyme activity, and maintain normal brain architecture, while AXO-AAV-GM2 has shown dose-dependent increases in the activity of the Hex A enzyme that translates to survival in mouse models. AXO-AAV-GM1 and AXO-AAV-GM2 are on track for interim data readouts during the first quarter of 2019 and the second half of 2019, respectively.

AXO-LENTI-PD was developed by Axovant as an improved version of ProSavin, with up to 10-fold increases in potency, which was in-licensed from Oxford BioMedica in 2018. AXO-LENTI-PD uses a lentiviral vector that is differentiated in allowing the delivery of multiple genes in a single construct. Axovant is positioning AXO-LENTI-PD to address troublesome motor fluctuations with dyskinesia in PD and minimize the need for exogenous levodopa. Cheruvu recapped the six-year clinical data on ProSavin that importantly is being accepted by the FDA as part of a single pivotal clinical program encompassing both AXO-LENTI-PD and ProSavin data. The first two patients in the SUNRISE trial were dosed in 2018 and, since the dose tested is in the lower range of the ProSavin doses previously studied, the primary focus of AXO-LENTI-PD's trial is upon safety, tolerability, and dosing. The trial is set to generate an interim data readout in March 2019. Axovant Sciences is building scalable cGMP manufacturing capacity through strategic partnerships to ensure the availability of its products. Manufacturing of its products is ongoing and they are moving towards suspension-based production at Oxford BioMedica for AXO-LENTI-PD.

In the second half of 2019, Axovant is further initiating a clinical program investigating AXO-AAV-OPMD for OPMD, which is an underserved patient population with an absence of approved therapies. AXO-AAV-OPMD will be the first gene therapy using Silence-and-Replace technology in a single vector to reach the clinic. The company aims to address the issue of aspiration pneumonia (a leading cause of death in OPMD), by designing their product for direct injection into the muscles that control swallowing.

- David Veitch, CEO of Basilea Pharmaceutica (BSLN), gave a "whistle-stop" overview of the company, including plans for the portfolio of two commercial stage assets and three oncology products in the pipeline, as well as the financial position of the company going into 2019. With a stronger than expected preliminary revenue in 2018, the company is in a good financial position to focus on their goals of expanding the oncology and anti-infectives pipeline, including multiple clinical oncology products and ceftobiprole - a fifth generation cephalosporin.

  The company's strong 2018 performance was mainly driven by the continued uptake of Cresemba and Zevtera. Cresemba's in-market sales amounted to $145m as of Q3 2018, and Basilea intends on launching Cresemba in 40 additional markets over the next three years. With clinical studies demonstrating non-inferiority of Cresemba to the standard of treatment, voriconazole, while showing a superior safety profile and broader action spectrum, the company hopes to increase the US market share of Cresemba in the upcoming years. The increase in market share is expected to be further powered by the ECIL-6 guidance for the use of Cresemba in first-line treatment of aspergillosis in leukemia and hematopoietic stem cell transplant patients due to its safety profile. Zevtera, which is indicated for use in hospital- and community-acquired

pneumonia, is marketed in the major EU markets, Canada, and several other markets in South America and Asia. In its anti-infective pipeline, the company plans to gain market approval for ceftobiprole in 2022 for the treatment of acute bacterial skin and skin structure infections, as well as Staphylococcus aureus bacteraemia, following the completion of two ongoing supportive Phase III studies in the US.

In the presentation of the oncology portfolio, the CEO mentioned three main agents: BAL10153 for recurrent or progressive glioblastoma and platinum-resistant ovarian cancer, BAL3833 for patients with solid tumors including metastatic melanoma, and an in-licensed pan-FGFR kinase inhibitor, derazantinib, for intrahepatic cholangiocarcinoma. Derazantinib, which is Basilea's lead oncology compound, is currently in a registrational Phase II study with interim results expected in H1 2019. The CEO disclosed that the interim analysis of the Phase II study shows encouraging results, which mirrors the achievements seen from a Phase I study, including an increased objective response rate and improved disease control rate.

Veitch briefly mentioned BAL10153 and BAL3833. He highlighted that BAL10153, with its ability to penetrate the blood brain barrier, is being investigated in three ongoing studies in patients with newly diagnosed and recurrent glioblastoma. Data from two of the studies is expected in 2019. BAL3833 has completed one Phase I study to date, but with the maximum tolerated dose not identified during the trial, the company will further explore the use of the drug in solid tumor treatment.

About the Author

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Product Updates from Biomedtracker/Meddevicetracker

Aurinia (AUPH)

Voclosporin Ophthalmic Solution (VOS) for Dry Eye (Ophthalmology)

Event Date:	12/20/2018
Event Type:	Trial Announcement - Trial Progressing (Clinical Analysis)
Trial Name:	Phase IIa - vs. Restasis
Market Group:	Ophthalmology
Lead Company:	Lux Biosciences
Partner Companies:	Aurinia (AUPH)
Phase:	II
Change to Likelihood of Approval:	0%
Likelihood of Approval:	24% (Same As Avg.)
Average Approval:	24%

Analysis:

Aurinia announced that the database locked for the Phase IIa trial of Voclosporin Ophthalmic Solution (VOS) for subjects with mild to moderate dry eye disease on December 20, 2018, with data to be available before the end of January 2019.

Source:

J.P. Morgan Healthcare Conference 01/10/2019 (AUPH)

Axovant Sciences, Inc. (AXON)

AXO-AAV-ALS for Amyotrophic Lateral Sclerosis (ALS)

Event Date:	01/10/2019
Event Type:	Progress Update (Clinical Analysis)
Trial Name:	N/A
Market Group:	Neurology
Lead Company:	Axovant Sciences, Inc. (AXON)

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

Analysis:

Axovant lists AXO-AAV-ALS in preclinical development for the treatment of ALS in its pipeline.

Source:

J.P. Morgan Healthcare Conference 01/10/2019 (AXON, Slide 4)

AXO-AAV-FTD for Dementia

Event Date:	01/10/2019
Event Type:	Progress Update (Clinical Analysis)
Trial Name:	N/A
Market Group:	Neurology
Lead Company:	Axovant Sciences, Inc. (AXON)
Partner Companies:	Benitec Biopharma (BNTC)
Phase:	Preclinical
Change to Likelihood of Approval:	0%
Likelihood of Approval:	0% (Same As Avg.)
Average Approval:	N/A

Analysis:

Axovant lists AXO-AAV-FTD in preclinical development for the treatment of frontotemporal dementia in its pipeline.

Source:

J.P. Morgan Healthcare Conference 01/10/2019 (AXON, Slide 4)

Basilea Pharmaceutica AG (BSLN:SW)

BAL3833 for Solid Tumors

Event Date:	01/10/2019
Event Type:	Trial Data - Top-Line Results (Clinical Analysis)
Trial Name:	Phase I - PanRAF
Market Group:	Oncology
Lead Company:	Basilea Pharmaceutica AG (BSLN:SW)
Partner Companies:	N/A
Phase:	I
Change to Likelihood of Approval:	0%
Likelihood of Approval:	6% (Same As Avg.)
Average Approval:	6%

Analysis:

Basilea announced that the Phase I dose-escalation study of BAL3833 was completed.

Results
Broad dose range was investigated, but maximum tolerated dose (MTD) was not defined.

Conclusion
Pre-clinical activities to explore alternative formulations are being initiated.

Source:

J.P. Morgan Healthcare Conference 01/10/2019 (Basilea, Slide 28)

Dynavax Technologies Corporation (DVAX)

Heplisav-B for Hepatitis B Prevention (Vaccines, Antiviral)

Event Date:	01/08/2019
Event Type:	Reimbursement - Progress Update (Clinical Analysis)
Trial Name:	N/A
Market Group:	Infectious disease
Lead Company:	Dynavax Technologies Corporation (DVAX)
Partner Companies:	Pfizer (PFE)

Phase:	Approved
Change to Likelihood of Approval:	0%
Likelihood of Approval:	100% (Same As Avg.)
Average Approval:	100%

Analysis:

Dynavax and Sam's Club announced the companies collaborated to introduce HEPLISAV-B into Sam's Club retail pharmacies nation-wide where pharmacists can immunize patients. HEPLISAV-B is indicated for prevention of infection caused by all known subtypes of hepatitis B virus in adults age 18 years and older.

Source:

Press Release 01/08/2019
J.P. Morgan Healthcare Conference 01/10/2019 (DVAX, Slide 7)

DV281 for Non-Small Cell Lung Cancer (NSCLC)

Event Date:	01/10/2019
Event Type:	Trial Announcement - Trial Completed (Clinical Analysis)
Trial Name:	Phase Ib - Dose Escalation
Market Group:	Oncology
Lead Company:	Dynavax Technologies Corporation (DVAX)
Partner Companies:	N/A
Phase:	I
Change to Likelihood of Approval:	0%
Likelihood of Approval:	6% (Same As Avg.)
Average Approval:	6%

Analysis:

Dynavax announced that the Phase I dose escalation study in combination with an anti-PD-1 in patients with non-small cell lung cancer is completed and initial safety data should be available in the spring.

Source:

J.P. Morgan Healthcare Conference 01/10/2019 (DVAX)

INSYS Therapeutics, Inc. (INSY)

Epinephrine Nasal Spray for Anaphylaxis

Event Date:	01/10/2019
Event Type:	Trial Announcement - Trial Completed (Clinical Analysis)
Trial Name:	Phase I - Dose Finding
Market Group:	Allergy
Lead Company:	INSYS Therapeutics, Inc. (INSY)
Partner Companies:	N/A
Phase:	II
Change to Likelihood of Approval:	0%
Likelihood of Approval:	24% (Same As Avg.)
Average Approval:	24%

Analysis:

Insys announced that the dose-finding bioavailability study evaluating Epinephrine nasal spray for anaphylaxis in healthy volunteers has been completed, and the company expects a top-line data readout in the first quarter of 2019.

Source:

J.P. Morgan Healthcare Conference 01/10/2019 (INSY, Slide 17)

Epinephrine Nasal Spray for Anaphylaxis

Event Date:	01/10/2019
Event Type:	Trial Announcement (Clinical Analysis)
Trial Name:	Phase I - Seasonal Allergies
Market Group:	Allergy
Lead Company:	INSYS Therapeutics, Inc. (INSY)
Partner Companies:	N/A
Phase:	II
Change to Likelihood of Approval:	0%

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

Analysis:

Insys announced that the company plans to initiate a study of Epinephrine nasal spray for nasal allergan challenged patients with seasonal allergies and another study of replicate design in healthy volunteers in the first half of 2019.

Source:

J.P. Morgan Healthcare Conference 01/10/2019 (INSY, Slide 17)

MacroGenics, Inc. (MGNX)

MGD009 for Solid Tumors

Event Date:	12/31/2018
Event Type:	Regulatory - Progress Update (Clinical Analysis)
Trial Name:	N/A
Market Group:	Oncology
Lead Company:	MacroGenics, Inc. (MGNX)
Partner Companies:	N/A
Phase:	I
Change to Likelihood of Approval:	0%
Likelihood of Approval:	6% (Same As Avg.)
Average Approval:	6%

Analysis:

In December 2018, MacroGenics submitted a response to the U.S. Food and Drug Administration (FDA) in regards to the partial clinical hold that has been placed on its Phase I monotherapy study of MGD009 as well as on a combination study of MGD009 and MGA012 (anti-PD-1).

Source:

J.P. Morgan Healthcare Conference 01/10/2019 (MGNX, Slide 17)

MGC018 for Solid Tumors

Event Date:	01/10/2019

Event Type:	Trial Announcement - Initiation (Clinical Analysis)
Trial Name:	Phase I/II - CP-MGC018-01
Market Group:	Oncology
Lead Company:	MacroGenics, Inc. (MGNX)
Partner Companies:	Synthon Biopharmaceuticals
Phase:	II
Change to Likelihood of Approval:	10%
Likelihood of Approval:	10% (Same As Avg.)
Average Approval:	10%

Analysis:

MacroGenics reported that the Phase I/II, first-in-human, open-label, dose-escalation study of MGC018 (anti-B7-H3 antibody drug conjugate) alone and in combination with MGA012 (anti-PD-1 antibody) in patients with advanced solid tumors has been initiated. The trial is expected to enroll 193 participants.

Source:

www.clinicaltrials.gov
J.P. Morgan Healthcare Conference 01/10/2019 (MGNX, Slide 17)

MeiraGTx (MGTX)

AAV-CNGB3 for Other Congenital Blindness Indications

Event Date:	12/31/2018
Event Type:	Trial Announcement - Dosing Completed (Clinical Analysis)
Trial Name:	Phase I/II - CNGB3
Market Group:	Ophthalmology
Lead Company:	Athena Vision
Partner Companies:	MeiraGTx (MGTX)
Phase:	II
Change to Likelihood of Approval:	0%
Likelihood of Approval:	24% (Same As Avg.)
Average Approval:	24%

Analysis:

MeiraGTx announced it completed dosing in both pediatric and adult patients in the Phase I/II trial of AAV-CNGB3 in December 2018. The company has treated 11 adults and 9 patients.

Source:

J.P. Morgan Healthcare Conference 01/10/2019 (MGTX)

AAV-RPGR for Retinitis Pigmentosa (RP) (Ophthalmology)

Event Date:	01/10/2019
Event Type:	Trial Announcement - Trial Progressing (Clinical Analysis)
Trial Name:	Phase I/II - MGT009
Market Group:	Ophthalmology
Lead Company:	Athena Vision
Partner Companies:	MeiraGTx (MGTX)
Phase:	II
Change to Likelihood of Approval:	0%
Likelihood of Approval:	24% (Same As Avg.)
Average Approval:	24%

Analysis:

MeiraGTx announced it completed the adult dose escalation portion of the Phase I/II MGT009 trial. The company has also treated 1 pediatric patient. Results from study are expected in mid-2019.

Source:

J.P. Morgan Healthcare Conference 01/10/2019 (MGTX)

AAV-RPE65 for Leber's Congenital Amaurosis (Ophthalmology)

Event Date:	01/10/2019
Event Type:	Trial Announcement - Trial Completed (Clinical Analysis)
Trial Name:	Phase I/II - OPTIRPE65
Market Group:	Ophthalmology
Lead Company:	Athena Vision

Partner Companies:	MeiraGTx (MGTX)
Phase:	II
Change to Likelihood of Approval:	0%
Likelihood of Approval:	24% (Same As Avg.)
Average Approval:	24%

Analysis:

MeiraGTx announced it completed its Phase I/II trial of AAV-RPE65. The company expects to release top line data from the study in the next few months.

Source:

J.P. Morgan Healthcare Conference 01/10/2019 (MGTX)

Ophthotech Corporation (OPHT)

AAV2-hBest1 Gene Therapy (Ophthotech) for Other Retinopathy (Ophthalmology)

Event Date:	01/10/2019
Event Type:	Progress Update (Clinical Analysis)
Trial Name:	N/A
Market Group:	Ophthalmology
Lead Company:	Ophthotech Corporation (OPHT)
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:

Ophthotech announced the development of a gene therapy that targets Best disease or Best Vitelliform macular dystrophy, an orphan inherited retinal disease caused by mutations in the BEST1 gene.

Proof of concept has been established in naturally occurring canine models. IND enabling studies

and natural history studies are planned. A Phase I/II clinical trial is planned to initiate by 2021.

Source:

J.P. Morgan Healthcare Conference 01/10/2019 (OPHT, Slide 13-16)

Otonomy, Inc. (OTIC)

OTO-6XX for Hearing Loss - General

Event Date:	01/10/2019
Event Type:	Progress Update - Development Review (Clinical Analysis)
Trial Name:	N/A
Market Group:	ENT/Dental
Lead Company:	Otonomy, Inc. (OTIC)
Partner Companies:	N/A
Phase:	Preclinical
Change to Likelihood of Approval:	0%
Likelihood of Approval:	0% (Same As Avg.)
Average Approval:	N/A

Analysis:

Otonomy announced that it has selected a development candidate for the OTO-6XX program.

Source:

J.P. Morgan Healthcare Conference 01/10/2019 (OTIC, Slide 4)

OTO-510 for Hearing Loss - Chemotherapy-Induced

Event Date:	01/10/2019
Event Type:	Progress Update - Development Review (Clinical Analysis)
Trial Name:	N/A
Market Group:	ENT/Dental
Lead Company:	Otonomy, Inc. (OTIC)

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

Analysis:

Otonomy announced the selection of a development candidate for its OTO-5XX program. The company lists OTO-510 as the candidate, and will be initiating IND enabling studies with the candidate. OTO-510 will be initially targeting children receiving Cisplatin.

Source:

J.P. Morgan Healthcare Conference 01/10/2019 (OTIC, Slide 4, 23)

Retrophin (RTRX)

CNSA-001 for Phenylketonuria (PKU)

Event Date:	01/07/2019
Event Type:	Trial Announcement - Trial Progressing (Clinical Analysis)
Trial Name:	Phase II - 001
Market Group:	Metabolic
Lead Company:	Censa Pharmaceuticals Inc.
Partner Companies:	Retrophin (RTRX)
Phase:	II
Change to Likelihood of Approval:	0%
Likelihood of Approval:	24% (Same As Avg.)
Average Approval:	24%

Analysis:

Retrophin announced the Phase II proof-of-concept study evaluating CNSA-001 in patients with phenylketonuria (PKU) continues to progress, and top-line data are expected to be available in the first half of 2019. Retrophin also anticipates the potential to begin registrational study pending positive readout from Phase II PoC.

CNSA-001 is advancing under a joint development and option agreement with Censa, and Retrophin expects to make a determination on its option to acquire Censa following the data readout.

Source:

Press Release 01/07/2019
J.P. Morgan Healthcare Conference 01/10/2019 (RTRX, Slide 6)

Syros Pharmaceuticals (SYRS)

SY-1425 for Acute Myelogenous Leukemia (AML)

Event Date:	01/06/2019
Event Type:	Trial Announcement - Trial Progressing (Clinical Analysis)
Trial Name:	Phase II - AML/MDS
Market Group:	Oncology
Lead Company:	Syros Pharmaceuticals (SYRS)
Partner Companies:	Nippon Shinyaku (4516:JP) CytRx Corporation (CYTR) TMRC
Phase:	II
Change to Likelihood of Approval:	0%
Likelihood of Approval:	10% (Same As Avg.)
Average Approval:	10%

Analysis:

Syros announced that the company has made a portfolio prioritization decision to not pursue further development of SY-1425 in combination with daratumumab beyond completion of the ongoing pilot cohort in the Phase II - AML/MDS trial.

Source:

Press Release 01/06/2019 (SYRS)
J.P. Morgan Healthcare Conference 01/10/2019 (SYRS)

SY-1425 for Myelodysplastic Syndrome (MDS)

Event Date:	01/06/2019
Event Type:	Trial Announcement - Trial Progressing (Clinical Analysis)
Trial Name:	Phase II - AML/MDS
Market Group:	Oncology

Lead Company:	Syros Pharmaceuticals (SYRS)
Partner Companies:	Nippon Shinyaku (4516:JP) CytRx Corporation (CYTR) TMRC
Phase:	II
Change to Likelihood of Approval:	0%
Likelihood of Approval:	10% (Same As Avg.)
Average Approval:	10%

Analysis:

Syros announced that the company has made a portfolio prioritization decision to not pursue further development of SY-1425 in combination with daratumumab beyond completion of the ongoing pilot cohort in the Phase II - AML/MDS trial.

Source:

Press Release 01/06/2019 (SYRS)
J.P. Morgan Healthcare Conference 01/10/2019 (SYRS)

SY-5609 for Solid Tumors

Event Date:	01/10/2019
Event Type:	Trial Announcement (Clinical Analysis)
Trial Name:	Phase I - Oncology
Market Group:	Oncology
Lead Company:	Syros Pharmaceuticals (SYRS)
Partner Companies:	N/A
Phase:	Preclinical
Change to Likelihood of Approval:	0%
Likelihood of Approval:	0% (Same As Avg.)
Average Approval:	N/A

Analysis:

Syros announced that the company plans to complete IND-enabling studies of SY-5609 to support the initiation of a Phase I oncology trial in early 2020.

Source:

Press Release 01/06/2019 (SYRS)
J.P. Morgan Healthcare Conference 01/10/2019 (SYRS, Slide 7)

TG Therapeutics, Inc. (TGTX)

TG-1501 for Hematologic Cancer

Event Date:	01/10/2019
Event Type:	Trial Announcement - Initiation (Clinical Analysis)
Trial Name:	Phase I - Australia (Solid Tumors)
Market Group:	Oncology
Lead Company:	TG Therapeutics, Inc. (TGTX)
Partner Companies:	N/A
Phase:	I
Change to Likelihood of Approval:	6%
Likelihood of Approval:	6% (Same As Avg.)
Average Approval:	6%

Analysis:

TG Therapeutics announced in a Phase I solid tumor study conducted in Australia, 800 mg every 2 weeks was selected as the dose for TG1501.

Source:

J.P. Morgan Healthcare Conference 01/10/2019 (TGTX, Slide 16)

TGR-1202 for Indolent Non-Hodgkin's Lymphoma (Including Follicular Lymphoma) - NHL

Event Date:	01/10/2019
Event Type:	Trial Announcement - Patient Enrollment Completed (Clinical Analysis)
Trial Name:	Phase II/III - UNITY-NHL
Market Group:	Oncology
Lead Company:	TG Therapeutics, Inc. (TGTX)

Partner Companies:	Rhizen Pharmaceuticals
Phase:	III
Change to Likelihood of Approval:	0%
Likelihood of Approval:	35% (Same As Avg.)
Average Approval:	35%

Analysis:

TG Therapeutics announced that it completed enrollment in the UNITY NHL program. Data from the trial is expected in mid-2019.

Source:

J.P. Morgan Healthcare Conference 01/10/2019 (TGTX, Slide 11)

TG-1303 for Chronic Lymphocytic Leukemia (CLL)/Small Cell Lymphocytic Lymphoma (SLL) - NHL

Event Date:	01/10/2019
Event Type:	Trial Announcement - Patient Enrollment Completed (Clinical Analysis)
Trial Name:	Phase II/III - UNITY-NHL
Market Group:	Oncology
Lead Company:	TG Therapeutics, Inc. (TGTX)
Partner Companies:	N/A
Phase:	III
Change to Likelihood of Approval:	0%
Likelihood of Approval:	33% (2% Below Avg.)
Average Approval:	35%

Analysis:

TG Therapeutics announced that it completed enrollment in the UNITY NHL program. Data from the trial is expected in mid-2019.

Source:

J.P. Morgan Healthcare Conference 01/10/2019 (TGTX, Slide 11)

TG-1303 for Diffuse Large B-Cell Lymphoma (DLBCL) - NHL

Event Date:	01/10/2019
Event Type:	Trial Announcement - Patient Enrollment Completed (Clinical Analysis)
Trial Name:	Phase II/III - UNITY-NHL
Market Group:	Oncology
Lead Company:	TG Therapeutics, Inc. (TGTX)
Partner Companies:	N/A
Phase:	III
Change to Likelihood of Approval:	0%
Likelihood of Approval:	37% (2% Above Avg.)
Average Approval:	35%

Analysis:

TG Therapeutics announced that it completed enrollment in the UNITY NHL program. Data from the trial is expected in mid-2019.

Source:

J.P. Morgan Healthcare Conference 01/10/2019 (TGTX, Slide 11)

TG-1303 for Indolent Non-Hodgkin's Lymphoma (Including Follicular Lymphoma) - NHL

Event Date:	01/10/2019
Event Type:	Trial Announcement - Patient Enrollment Completed (Clinical Analysis)
Trial Name:	Phase II/III - UNITY-NHL
Market Group:	Oncology
Lead Company:	TG Therapeutics, Inc. (TGTX)

Partner Companies:	N/A
Phase:	III
Change to Likelihood of Approval:	0%
Likelihood of Approval:	35% (Same As Avg.)
Average Approval:	35%

Analysis:

TG Therapeutics announced that it completed enrollment in the UNITY NHL program. Data from the trial is expected in mid-2019.

Source:

J.P. Morgan Healthcare Conference 01/10/2019 (TGTX, Slide 11)

TG-1303 for Mantle Cell Lymphoma - NHL

Event Date:	01/10/2019
Event Type:	Trial Announcement - Patient Enrollment Completed (Clinical Analysis)
Trial Name:	Phase II/III - UNITY-NHL
Market Group:	Oncology
Lead Company:	TG Therapeutics, Inc. (TGTX)
Partner Companies:	N/A
Phase:	III
Change to Likelihood of Approval:	0%
Likelihood of Approval:	35% (Same As Avg.)
Average Approval:	35%

Analysis:

TG Therapeutics announced that it completed enrollment in the UNITY NHL program. Data from the trial is expected in mid-2019.

Source:

J.P. Morgan Healthcare Conference 01/10/2019 (TGTX, Slide 11)

TG-1303 for Marginal Zone Lymphoma - NHL

Event Date:	01/10/2019
Event Type:	Trial Announcement - Patient Enrollment Completed (Clinical Analysis)
Trial Name:	Phase II/III - UNITY-NHL
Market Group:	Oncology
Lead Company:	TG Therapeutics, Inc. (TGTX)
Partner Companies:	N/A
Phase:	III
Change to Likelihood of Approval:	0%
Likelihood of Approval:	35% (Same As Avg.)
Average Approval:	35%

Analysis:

TG Therapeutics announced that it completed enrollment in the UNITY NHL program. Data from the trial is expected in mid-2019.

Source:

J.P. Morgan Healthcare Conference 01/10/2019 (TGTX, Slide 11)

TGR-1202 for Chronic Lymphocytic Leukemia (CLL)/Small Cell Lymphocytic Lymphoma (SLL) - NHL

Event Date:	01/10/2019
Event Type:	Trial Announcement - Patient Enrollment Completed (Clinical Analysis)
Trial Name:	Phase II/III - UNITY-NHL
Market Group:	Oncology
Lead Company:	TG Therapeutics, Inc. (TGTX)
Partner Companies:	Rhizen Pharmaceuticals

Phase:	III
Change to Likelihood of Approval:	0%
Likelihood of Approval:	35% (Same As Avg.)
Average Approval:	35%

Analysis:

TG Therapeutics announced that it completed enrollment in the UNITY NHL program. Data from the trial is expected in mid-2019.

Source:

J.P. Morgan Healthcare Conference 01/10/2019 (TGTX, Slide 11)

TGR-1202 for Diffuse Large B-Cell Lymphoma (DLBCL) - NHL

Event Date:	01/10/2019
Event Type:	Trial Announcement - Patient Enrollment Completed (Clinical Analysis)
Trial Name:	Phase II/III - UNITY-NHL
Market Group:	Oncology
Lead Company:	TG Therapeutics, Inc. (TGTX)
Partner Companies:	Rhizen Pharmaceuticals
Phase:	III
Change to Likelihood of Approval:	0%
Likelihood of Approval:	35% (Same As Avg.)
Average Approval:	35%

Analysis:

TG Therapeutics announced that it completed enrollment in the UNITY NHL program. Data from the trial is expected in mid-2019.

Source:

J.P. Morgan Healthcare Conference 01/10/2019 (TGTX, Slide 11)

TGR-1202 for Mantle Cell Lymphoma - NHL

Event Date:	01/10/2019
Event Type:	Trial Announcement - Patient Enrollment Completed (Clinical Analysis)
Trial Name:	Phase II/III - UNITY-NHL
Market Group:	Oncology
Lead Company:	TG Therapeutics, Inc. (TGTX)
Partner Companies:	Rhizen Pharmaceuticals
Phase:	III
Change to Likelihood of Approval:	0%
Likelihood of Approval:	35% (Same As Avg.)
Average Approval:	35%

Analysis:

TG Therapeutics announced that it completed enrollment in the UNITY NHL program. Data from the trial is expected in mid-2019.

Source:

J.P. Morgan Healthcare Conference 01/10/2019 (TGTX, Slide 11)

TGR-1202 for Marginal Zone Lymphoma - NHL

Event Date:	01/10/2019
Event Type:	Trial Announcement - Patient Enrollment Completed (Clinical Analysis)
Trial Name:	Phase II/III - UNITY-NHL
Market Group:	Oncology
Lead Company:	TG Therapeutics, Inc. (TGTX)
Partner Companies:	Rhizen Pharmaceuticals
Phase:	III
Change to Likelihood of Approval:	0%

Likelihood of Approval:	35% (Same As Avg.)
Average Approval:	35%

Analysis:

TG Therapeutics announced that it completed enrollment in the UNITY NHL program. Data from the trial is expected in mid-2019.

Source:

J.P. Morgan Healthcare Conference 01/10/2019 (TGTX, Slide 11)

TG-1701 for Hematologic Cancer

Event Date:	01/10/2019
Event Type:	Trial Data (Clinical Analysis)
Trial Name:	Phase I -101 (Australia)
Market Group:	Oncology
Lead Company:	TG Therapeutics, Inc. (TGTX)
Partner Companies:	Hengrui Medicine (600276:SS)
Phase:	Development Outside U.S.
Change to Likelihood of Approval:	0%
Likelihood of Approval:	0% (Same As Avg.)
Average Approval:	N/A

Analysis:

TG Therapeutics announced results from the first cohort in the Australian Phase I trial of TG-1701.

Data from this trial were previously seen in November 2018.

Results

The first two cohorts evaluating TG-1701 at a dose of 100 mg once-daily have been fully enrolled. Results from the first cohort (3 patients at 100mg) include:

- MCL - Partial Response
- WM - Partial Response
- DLBCL - Discontinued (PD)

Source:

J.P. Morgan Healthcare Conference 01/10/2019 (TGTX, Slide 17)

UroGen Pharma, Ltd. (URGN)

MitoGel for Bladder Cancer

Event Date:	01/08/2019
Event Type:	Trial Data - Updated Results (Clinical Analysis)
Trial Name:	Phase III - OLYMPUS
Market Group:	Oncology
Lead Company:	UroGen Pharma, Ltd. (URGN)
Partner Companies:	N/A
Phase:	NDA/BLA
Change to Likelihood of Approval:	0%
Likelihood of Approval:	82% (Same As Avg.)
Average Approval:	82%

	Treatment
Treatment Description	UGN-101
Number of Patients	71
Number of Evaluable Patients	61
Complete Response (Endpoint=Primary)	57.000 %
Disease Free at 6 Months	100.000 %

Analysis:

UroGen announced topline results from the ongoing pivotal Phase III OLYMPUS clinical trial of UGN-101 (mitomycin gel) for instillation, an investigational mitomycin formulation for the non-surgical treatment of low-grade upper tract urothelial cancer (UTUC).

Data from this study were last seen in May 2018.

Context

UroGen intends to seek regulatory approval of UGN-101 in LG UTUC based on data from all 71 patients and initiated its rolling submission of the New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) in December 2018. The FDA previously granted Orphan Drug, Fast Track, and Breakthrough Therapy Designations to UGN-101 for the treatment of UTUC.

Design

This international, multi-center trial completed enrollment with 71 patients in December 2018. Of the

71 patients enrolled in the trial, 61 patients have been evaluated for the primary endpoint which was a CR as defined as a negative ureteroscopic evaluation and a negative wash cytology. The remaining 10 patients are awaiting PDE evaluation.

Endpoints
The primary endpoint was complete response (CR) rate at their primary disease evaluation (PDE, or the primary endpoint) which was conducted four to six weeks after completion of UGN-101 treatment. Durability is a key secondary endpoint for the trial.

Results
This analysis showed that on an intent-to-treat basis, 57 percent of patients achieved a complete response (CR) rate at their primary disease evaluation. All evaluated patients in CR remain disease free at six months. Approximately 45 percent of tumors treated were categorized as unresectable by surgery at baseline. Of the patients who achieved CR, UroGen now has six-month durability on half of these patients.

Most Common Adverse Events
The safety profile of UGN-101 continues to be acceptable with most treatment-emergent adverse events characterized as mild or moderate and transient and in line with ureteral procedures. These included ureteral narrowing and hydronephrosis, urinary tract infection, flank pain and creatinine elevation.

Source:

Press Release 01/08/2019 (URGN)
J.P. Morgan Healthcare Conference 01/10/2019 (URGN)

Vectura Group plc (VEC:LN)

VR410 DPI for Drug Delivery Technology

Event Date:	01/10/2019
Event Type:	Partnership - Cancellation (Clinical Analysis)
Trial Name:	N/A
Market Group:	Not Specified
Lead Company:	Vectura Group plc (VEC:LN)
Partner Companies:	N/A
Phase:	Development
Change to Likelihood of Approval:	0%
Likelihood of Approval:	0% (Same As Avg.)
Average Approval:	N/A

Analysis:

Vectura announced that, following a review of the company's genetic pipeline, Vectura and Pulmatrix have mutually agreed to terminate the agreement and cease further development of this project.

Source:

J.P. Morgan Healthcare Conference 01/10/2019 (Vectura, Slide 10)

VR647 for Asthma

Event Date:	01/10/2019
Event Type:	Progress Update - Development Review (Clinical Analysis)
Trial Name:	N/A
Market Group:	Respiratory
Lead Company:	Vectura Group plc (VEC:LN)
Partner Companies:	N/A
Phase:	II
Change to Likelihood of Approval:	0%
Likelihood of Approval:	18% (Same As Avg.)
Average Approval:	18%

Analysis:

Vectura announced that partnering options are actively being explored for 2019. Vectura plans to initiate the Phase III program in 2019, following consultation with the U.S. Food and Drug Administration (FDA) and pharmaceutical dose development and device manufactures.

Source:

J.P. Morgan Healthcare Conference 01/10/2019 (Vectura, Slide 18)

Y-mAbs Therapeutics Inc.

huGD2-BsAb for Solid Tumors

Event Date:	12/31/2018
Event Type:	Trial Announcement - Initiation (Clinical Analysis)
Trial Name:	Phase I - Study 18-034 (Refractory GD2 Positive Solid Tumors)
Market Group:	Oncology

Lead Company:	Y-mAbs Therapeutics Inc.
Partner Companies:	N/A
Phase:	I
Change to Likelihood of Approval:	6%
Likelihood of Approval:	6% (Same As Avg.)
Average Approval:	6%

Analysis:

Y-Mabs announced that its huGD-BsAb bispecific antibody has started clinical testing in December 2018.

Source:

J.P. Morgan Healthcare Conference 01/10/2019 (YMAB, Slide 26)

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

Event Date:	01/10/2019
Event Type:	Regulatory - Meeting with FDA (Clinical Analysis)
Trial Name:	N/A
Market Group:	Oncology
Lead Company:	Y-mAbs Therapeutics Inc.
Partner Companies:	Memorial Sloan-Kettering Cancer Center
Phase:	II
Change to Likelihood of Approval:	0%
Likelihood of Approval:	10% (Same As Avg.)
Average Approval:	10%

Analysis:

Y-Mabs announced a regulatory update on naxitamab, an anti-GD2 antibody for neuroblastoma and osteosarcoma. Based on the discussion with the FDA, the company believes that naximatab may qualify for accelerated approval if it can demonstrate 30% ORR with a minimum of 12-week duration of response. Pending comparability, data from both study 12-230 and study 201 may be pooled to form the primary basis of a BLA submission, expected in 2019.

Source:

J.P. Morgan Healthcare Conference 01/10/2019 (YMAB, Slide 11)

^{177}Lu-omburtamab-DTPA for Solid Tumors

Event Date:	01/10/2019
Event Type:	Progress Update (Clinical Analysis)
Trial Name:	N/A
Market Group:	Oncology
Lead Company:	Y-mAbs Therapeutics 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:

Y-Mabs announced that animal toxicity studies of 177Lu-omburtamab-DTPA is completed on GLP material, and cGMP production is established. The company expects to file an IND for 177Lu-omburtamab-DTPA for treatment of B7-H3 positive LM from solid tumors in first half of 2019.

Source:

J.P. Morgan Healthcare Conference 01/10/2019 (YMAB, Slide 24)

huCD33-BsAb for Hematologic Cancer

Event Date:	01/10/2019
Event Type:	Progress Update (Clinical Analysis)
Trial Name:	N/A
Market Group:	Oncology
Lead Company:	Y-mAbs Therapeutics 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:

Y-Mabs currently lists huCD33-BsAb in preclinical development for the treatment of hematological malignancies expressing CD33 in its pipeline.

Source:

J.P. Morgan Healthcare Conference 01/10/2019 (YMAB, Slide 7)

ZIOPHARM Oncology, Inc. (ZIOP)

Ad-RTS-hIL-12 for Brain Cancer (Malignant Glioma; AA and glioblastoma (GBM))

Event Date:	01/10/2019
Event Type:	Trial Announcement - Trial Progressing (Clinical Analysis)
Trial Name:	Phase I - w/Veledimex (Grade III)
Market Group:	Oncology
Lead Company:	ZIOPHARM Oncology, Inc. (ZIOP)
Partner Companies:	Intrexon (XON)
Phase:	I
Change to Likelihood of Approval:	0%
Likelihood of Approval:	9% (3% Above Avg.)
Average Approval:	6%

Analysis:

Ziopharm Oncology announced the company has completed patient enrollment for the expansion cohort of monotherapy and guidance for low dose of the Phase I study of Ad-RTS-hIL-12 plus 20mg of veledimex.

Source:

J.P. Morgan Healthcare Conference 01/10/2019 (ZIOP, Slide 17)

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Expected Date Range	Company	Symbol	Drug	Indication	Phase	Expected Catalyst	Catalyst Title	Analysis	Link
1/17/2019	MacroGenics, Inc.	MGNX	Margetuximab	Gastric Cancer	I/II	Trial Data - Updated Results	Phase Ib/II w/Pembrolizumab - Updated Results at ASCO GI	Macrogenics reported that data from the gastric cancer (HER2 3+) cohort of the Phase II study of margetuximab in combination with pembrolizumab will be presented at ASCO GI on January 17 2019. The abstract is entitled Antitumor activity of margetuximab (M) plus pembrolizumab (P) in patients (pts) with advanced HER2+ (IHC3+) gastric carcinoma (GC).	148603
1/18/2019	Kura Oncology, Inc.	KURA	Tipifarnib (Oncology)	Pancreatic Cancer	Suspended	Trial Data - Other	Retrospective Data at ASCO GI	Kura announced that a poster entitled Patient reported abdominal pain as a surrogate of the clinical benefit of tipifarnib in pancreatic cancer patients will be presented at the ASCO GI symposium on January 18 2019.	148561
01/10/2019-01/31/2019	MacroGenics, Inc.	MGNX	MGD009	Solid Tumors	Program Hold	Regulatory - FDA Response	FDA Response - Partial Hold Decision	In December 2018 MacroGenics submitted a response to the U.S. Food and Drug Administration (FDA) in regards to the partial clinical hold that has been placed on its Phase I monotherapy study of MGD009 as well as on a combination study of MGD009 and MGA012 (anti-PD-1). The Company expects to hear from the FDA by the end of January 2019.	148609
02/14/2019-02/16/2019	Kura Oncology, Inc.	KURA	Tipifarnib (Oncology)	Head and Neck Cancer	II	Trial Data - Updated Results	Phase II - Updated Results at ASCO GU	Kura anticipates providing additional data on Tipifarnib for HRAS mutations at the ASCO GU conference in February 14-16 2019.	148555
01/10/2019-03/31/2019	argenx N.V.	ARGX	Efgartigimod	Immune Thrombocytopenic Purpura (ITP)	II	Regulatory - Progress Update	Meeting with PMDA	Argenx reported that the End of Phase II meeting with the FDA/EMA/PMDA for Efgartigimod in ITP is expected in the first quarter of 2019.	148568
01/10/2019-03/31/2019	argenx N.V.	ARGX	Efgartigimod	Immune Thrombocytopenic Purpura (ITP)	II	Regulatory - Meeting with FDA	Meeting with FDA	Argenx reported that the End of Phase II meeting with the FDA/EMA/PMDA for Efgartigimod in ITP is expected in the first quarter of 2019.	148570
01/10/2019-03/31/2019	argenx N.V.	ARGX	Efgartigimod	Immune Thrombocytopenic Purpura (ITP)	II	Regulatory - Meeting with European Medicines Agency	Meeting with EMA	Argenx reported that the End of Phase II meeting with the FDA/EMA/PMDA for Efgartigimod in ITP is expected in the first quarter of 2019.	148569
01/10/2019-03/31/2019	Immunomedics, Inc.	IMMU	Sacituzumab Govitecan	Breast Cancer	BLA	Progress Update - Product Launch (U.S.)	Product Launch (US)	Immunomedics announced that Sacituzumab is launch ready is planned to be launched in the US in the first quarter of 2019 pending approval on January 18 2019.	148542
Now-03/31/2019	INSYS Therapeutics, Inc.	INSY	Epinephrine Nasal Spray	Anaphylaxis	II	Trial Data - Top-Line Results	Phase I - Dose Finding Top-Line Results	Insys announced that the dose-finding bioavailability study evaluating Epinephrine nasal spray for anaphylaxis in healthy volunteers has been completed and the company expects a top-line data readout in the first quarter of 2019.	148601
01/10/2019-03/31/2019	Ophthotech Corporation	OPHT	Zimura	Stargardt Disease (Ophthalmology)	IIb	Trial Announcement - Patient Enrollment Completed	Phase IIb - Patient Enrollment Completed	Ophthotech expects to complete enrollment of its Phase IIb Zimura study of Stargardt disease in the first quarter of 2019.	148567
01/10/2019-03/31/2019	TG Therapeutics, Inc.	TGTX	TG-1501	Hematologic Cancer	I	Trial Announcement - Initiation	Phase Ib - Trial to Start	TG Therapeutics expects to commence its Phase Ib study of TG1501 in hematologic cancers in the first quarter of 2019.	148598
01/10/2019-04/30/2019	Chimerix, Inc.	CMRX	Brincidofovir (Oral)	Smallpox	I	Trial Announcement - Trial Completion	Rabbitpox Study to Complete	Chimerix lists that a rabbitpox virus study of oral brincidofovir for the treatment of smallpox is anticipated to be completed in early 2019.	148585
5/16/2019	argenx N.V.	ARGX				Company - Analyst/R&D Update	R&D Day	Argenx announced that its R&D Day will be hosted on May 16 2019.	148575
01/10/2019-06/30/2019	argenx N.V.	ARGX	Efgartigimod	Pemphigus Vulgaris	II	Trial Announcement - Other	Phase II - Cohort 3 to Start	Argenx reported that cohort 3 of its Phase II trial of efgartigimod in pemphigus vulgaris is expected to start in the first half of 2019.	148576
01/10/2019-06/30/2019	Athena Vision		AAV-RPE65	Leber's Congenital Amaurosis (Ophthalmology)	I/II	Trial Data - Top-Line Results	Phase I/II OPTIRPE65 - Top-Line Results	MeiraGTx announced its expects data from the Phase I/II OPTIRPE65 study of AAV-RPE65 in the coming months. We await an update in the time frame above.	148584
01/10/2019-06/30/2019	Basilea Pharmaceutica AG	BSLN:SW	BAL101553	Brain Cancer (Malignant Glioma; AA and glioblastoma (GBM))	I/II	Trial Announcement - Trial Completion	Phase I/IIa Oral Formulation Trial Completion	Basilea anticipates the completion of the Phase I dose escalation (daily oral) of BAL101553 in patients with recurrent glioblastoma in the first half of 2019.	148548
01/10/2019-06/30/2019	Chimerix, Inc.	CMRX	Brincidofovir (Oral)	Antiviral - Other Treatments	III	Regulatory - Meeting with FDA	Type C Meeting w/FDA	Chimerix plans to hold a Type C meeting with the U.S. FDA regarding brincidofovir for the treatment of Adenovirus in the first half of 2019.	148578
01/10/2019-06/30/2019	Chimerix, Inc.	CMRX	Brincidofovir (Oral)	Smallpox	I	Trial Data - Other	Pivotal Rabbitpox Study Data	Chimerix lists that pivotal rabbitpox study data of oral brincidofovir for the treatment of smallpox are anticipated in the first half of 2019.	148580
Now-06/30/2019	Dynavax Technologies Corporation	DVAX	Heplisav-B	Hepatitis B Prevention (Vaccines, Antiviral)	Approved	Regulatory - MAA Submission (Europe)	MAA Filing	Dynavax anticipates a potential MAA submission for Heplisav-B in the first half of 2019.	148577
04/01/2019-06/30/2019	Dynavax Technologies Corporation	DVAX	DV281	Non-Small Cell Lung Cancer (NSCLC)	I	Trial Data - Updated Results	Phase I - Updated Results	Dynavax anticipates readout from the Phase I dose escalation results in the second quarter of 2019.	148596
01/10/2019-06/30/2019	Grace Therapeutics, LLC.		GTX-104	Subarachnoid Hemorrhage	Preclinical	Trial Announcement - Initiation	Pivotal PK Trial to Start	Grace plans to initiate a pivotal trial of GTX-104 in the first half of 2019.	148602
01/10/2019-06/30/2019	Immunomedics, Inc.	IMMU	Sacituzumab Govitecan	Breast Cancer	BLA	Trial Announcement - Initiation	Phase III - HER+/HER2- Trial to Start	Immunomedics plans to initiate a Phase III study of Sacituzumab for the treatment of HR+/HER2- metastatic breast cancer in the first half of 2019.	148543
01/10/2019-06/30/2019	Infinity Pharmaceuticals, Inc.	INFI	IPI-549	Solid Tumors	I	Trial Announcement - Initiation	Phase I/Ib w/AB928 + Chemo - Trial to Start	Infinity Pharmaceuticals lists that they plan to initiate a triple therapy study of IPI-549 with AB928 and chemotherapy in patients with advanced TNBC in the first half of 2019.	148560
Now-06/30/2019	INSYS Therapeutics, Inc.	INSY	Epinephrine Nasal Spray	Anaphylaxis	II	Trial Announcement - Initiation	Phase I - Seasonal Allergies Study to Start	Insys announced that the company plans to initiate a study of Epinephrine nasal spray for nasal allergan challenged patients with seasonal allergies and another study of replicate design in healthy volunteers in the first half of 2019.	148605
Now-06/30/2019	INSYS Therapeutics, Inc.	INSY	Dronabinol Inhalation Device	Chemotherapy Induced Nausea and Vomiting (CINV)	Development	Regulatory - Meeting with FDA	FDA Advisory Board Meeting	Insys announced that the company is planning to meet with an FDA advisory board to discuss the drug candidate Dronabinol (THC) for anorexia in cancer in the first half of 2019.	148610
01/10/2019-06/30/2019	United Therapeutics Corporation	UTHR	Ralinepag	Pulmonary Arterial Hypertension (PAH) and Pulmonary Hypertension (PH)	III	Trial Announcement - Initiation	PAH Differentiation - Trial to Start	Arena Pharmaceuticals lists that a study of ralinepag in PAH differentiation is anticipated to start in the first half of 2019.	148552
01/10/2019-06/30/2019	UroGen Pharma, Ltd.	URGN	VesiGel	Bladder Cancer	IIb	Trial Data - Top-Line Results	Phase IIb - Interim Results	UroGen announced that an interim data analysis for the Phase IIb study of UGN-102 for LG NMIBC is expected in the first half of 2019.	148597
Now-06/30/2019	Y-mAbs Therapeutics Inc.		¹⁷⁷Lu-omburtamab-DTPA	Solid Tumors	Preclinical	Regulatory - IND Filing	IND Filing	Y-Mabs expects to file an IND for 177Lu-omburtamab-DTPA for treatment of B7-H3 positive LM from solid tumors in first half of 2019.	148571
04/01/2019-06/30/2019	ZIOPHARM Oncology, Inc.	ZIOP	Ad-RTS-hIL-12	Brain Cancer (Malignant Glioma; AA and glioblastoma (GBM))	I	Trial Announcement - Patient Enrollment Completed	Phase I w/Veledimex + Nivolumab - Patient Enrollment Completed	Ziopharm anticipates the Phase I trial of controlled IL-12 incombination with the PD-1 antibody nivolumab to treat patients with rGBM to complete patient enrollment in the second quarter of 2019.	148559

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Expected Date Range	Company	Symbol	Drug	Indication	Phase	Expected Catalyst	Catalyst Title	Analysis	Link
04/01/2019-09/30/2019	Arena Pharmaceuticals, Inc.	ARNA	Olorinab	Pain Indications	II	Trial Announcement - Initiation	Phase IIb IBD/IBS Pain - Trial Initiation	Arena Pharmaceuticals plans to initiate a Phase IIb study of olorinab in IBD/IBS pain in mid-2019.	148551
04/01/2019-09/30/2019	Athena Vision		AAV-RPGR	Retinitis Pigmentosa (RP) (Ophthalmology)	I/II	Trial Data - Top-Line Results	Phase I/II - Top-Line Results	MeiraGTx announced it expects top-line results from the Phase I/II study of AAV-RPGR in mid-2019.	148588
07/01/2019-09/30/2019	Athena Vision		AAV-CNGB3	Other Congenital Blindness Indications	I/II	Trial Data - Top-Line Results	Phase I/II - Trial to Start	MeiraGTx announced it expects top-line results from the Phase I/II study of AAV-CNGB3 in the third quarter of 2019.	148589
07/01/2019-09/30/2019	Grace Therapeutics, LLC.		GTX-104	Subarachnoid Hemorrhage	Preclinical	Regulatory - NDA/BLA Filing	NDA Filing	Grace plans to submit an NDA for GTX-104 in the third quarter of 2019.	148604
04/01/2019-09/30/2019	Immunomedics, Inc.	IMMU	Sacituzumab Govitecan	Bladder Cancer	II	Trial Data - Top-Line Results	Phase II TROPHY U-01 - Top-Line Results	Immunomedics expects to have an interim analysis from its Phase II TROPHY U-01 study of Sacituzumab in mid-2019.	148545
04/01/2019-09/30/2019	Syros Pharmaceuticals	SYRS	SY-1425	Acute Myelogenous Leukemia (AML)	II	Trial Announcement - Other	Phase II - AML/MDS Cohort Enrollment Completion	Syros announced that the company plans to complete enrollment in mid-2019 in the ongoing Phase II study cohort evaluating the safety and efficacy of SY-1425 in combination with azacytidine in RARA and IFRA biomarker-positive patients with newly diagnosed acute myeloid leukemia (AML) who are not suitable candidates for standard chemotherapy.	148557
12/07/2019-12/10/2019	TG Therapeutics, Inc.	TGTX	TG-1303	Marginal Zone Lymphoma - NHL	II/III	Trial Data - Updated Results	Phase II/III UNITY-NHL - Updated Results at ASH	TG Therapeutics announced the company plans to provide an update on UNITY NHL at ASH 2019.	148619
01/10/2019-12/31/2019	Angion Biomedica Corp.		BB3	Delayed Graft Function (DGF)	III	Trial Announcement - Initiation (Emerging Markets)	Clinical Trials to Start (China)	Sinovant lists the initiation of a BB3 clinical program in China as a near term catalyst for the company. We await the start of clinical trials in China through 2019.	148554
10/01/2019-12/31/2019	argenx N.V.	ARGX	ARGX-117	Autoimmune Disorders	Preclinical	Regulatory - Progress Update	CTA Filing	Argenx reported that the CTA filing for ARGX-117 is expected in the fourth quarter of 2019.	148573
Now-12/31/2019	Avanos Medical, Inc.	AVNS	COOLIEF Cooled RF	Arthritis Pain	Approved	Trial Data - Published Results	COOLIEF for Knee Pain - Published Results	Avanos announced that the company plans to accelerate clinical evidence trials of COOLIEF for knee pain and plans to publish 6-month clinical evidence and economic knee and SI health studies in 2019.	148553
07/01/2019-12/31/2019	Basilea Pharmaceutica AG	BSLN:SW	BAL101553	Solid Tumors	II	Trial Data - Top-Line Results	Phase I/IIa IV Formulation - Top-Line Results	Basilea anticipates top-line results of the Phase IIa expansion (weekly 48-hour I.V.) of BAL101553 in patients with recurrent glioblastoma or platinum-resistant ovarian cancer in the second half of 2019.	148547
07/01/2019-12/31/2019	Basilea Pharmaceutica AG	BSLN:SW	Zeftera	Skin and Skin-Structure Infections (Antibacterial)	III	Trial Data - Top-Line Results	Phase III - Top-Line Results	Basilea expects to have top line results from its Phase III study of Ceftobiprole for ABSSSI in the second half of 2019.	148549
07/01/2019-12/31/2019	Chimerix, Inc.	CMRX	Brincidofovir (Oral)	Smallpox	I	Trial Data - Other	Pivotal Mouse Study Preliminary Data	Chimerix lists that pivotal mouse study preliminary data of oral brincidofovir for the treatment of smallpox are anticipated in the second half of 2019.	148582
01/10/2019-12/31/2019	Chimerix, Inc.	CMRX	Brincidofovir (Oral)	Smallpox	I	Trial Announcement - Trial Completion	Mousepox Study to Complete	Chimerix lists that a mousepox study of oral brincidofovir for the treatment of smallpox is anticipated to be completed in 2019.	148586
01/10/2019-12/31/2019	Enzyvant Therapeutics, Inc.		RVT-802	Primary Immunodeficiencies	BLA	Regulatory - Filing for Approval (Emerging Markets)	Filing for Approval - China	Sinovant lists a submission of a RVT-802 NDA to the NMPA (China) as a near-term catalyst in its pipeline. We await the NDA filing through 2019.	148564
07/01/2019-12/31/2019	Immunomedics, Inc.	IMMU	Sacituzumab Govitecan	Non-Small Cell Lung Cancer (NSCLC)	I/II	Trial Announcement - Initiation	Phase II Trop-2 Enriched Basket Study to Start	Immunomedics plans to initiate a Phase II basket study of Sacituzumab for the treatment of refractory NSCLC SCLC HNSCC Endometrial and HCC in the second half of 2019.	148544
07/01/2019-12/31/2019	Infinity Pharmaceuticals, Inc.	INFI	IPI-549	Solid Tumors	I	Trial Announcement - Initiation	Front-Line Combination - Trial to Start	Infinity Pharmaceuticals lists that they plan to initiate a combination study of IPI-549 in front-line advanced cancer patients in the second half of 2019.	148562
07/01/2019-12/31/2019	Infinity Pharmaceuticals, Inc.	INFI	IPI-549	Solid Tumors	I	Trial Announcement - Patient Enrollment Completed	Phase I/Ib MARIO-1 - Patient Enrollment Complete	Infinity Pharmaceuticals plans to complete enrollment of MARIO-1 seven combination expansion cohorts investigating IPI-549 in the second half of 2019.	148563
Now-12/31/2019	INSYS Therapeutics, Inc.	INSY	Naloxone Nasal Spray	Substance Use Disorder	I	Trial Data - Updated Results	Phase I - PK Study Updated Results	Insys announced that the company plans to present abstracts on the Phase I-PK Study of Naloxone at the American Society of Addiction Medicine (ASAM) 2019 and College on Problems of Drug Dependence (CPDD) 2019.	148595
01/10/2019-12/31/2019	Iovance Biotherapeutics, Inc.	IOVA	Contego	Melanoma	II	Trial Data - Updated Results	Phase II C-144-01 Cohort 2 - Updated Results	Iovance anticipates to present updated data for cohort 2 in the Phase II C-144-01 trial for melanoma in 2019.	148587
01/10/2019-12/31/2019	Iovance Biotherapeutics, Inc.	IOVA	LN-145	Cervical Cancer	II	Trial Data - Updated Results	Phase II C-145-04 - Updated Results	Iovance anticipates to present updated data for the Phase II C-145-04 trial in 2019.	148591
01/10/2019-12/31/2019	MacroGenics, Inc.	MGNX	Margetuximab	Breast Cancer	III	Regulatory - NDA/BLA Filing	BLA Filing	Macrogenics reported that a BLA submission for margetuximab in metastatic breast cancer is expected in 2019.	148594
01/10/2019-12/31/2019	MacroGenics, Inc.	MGNX	MGD013	Solid Tumors	I	Progress Update - Development Review	Development Review	MacroGenics expects to provide clinical update on MGD013 by year-end 2019.	148611
01/10/2019-12/31/2019	MeiraGTx Holdings Plc	MGTX	AAV-AQP1	Xerostomia (Dry Mouth)	I	Trial Announcement - Initiation	Phase I/II - Trial to Start	MeiraGTx announced that it expects to initiate a Phase I/II trial of AAV-AQP1 with the Memorial Sloan Kettering Cancer Center in 2019.	148592
01/10/2019-12/31/2019	Nabriva Therapeutics plc	NBRV	Lefamulin	Community Acquired Pneumonia (CAP) (Antibacterial)	NDA	Trial Announcement - Initiation (Emerging Markets)	Pivotal Clinical Trials to Start (China)	Sinovant lists the initiation of a Lefamulin registrational program in China as a near term catalyst for the company. We await the start of clinical trials in China through 2019.	148556
10/01/2019-12/31/2019	Retrophin, Inc.	RTRX	Fosmetpantotenate	Pantothenate Kinase-associated Neurodegeneration (PKAN)	III	Regulatory - MAA Submission (Europe)	MAA Filing	Retrophin expects potential NDA and MAA filings pending positive results from the pivotal Phase III FORT study of fosmetpantotenate. We await an update on the European regulatory filing in the time frame above.	148581
01/10/2019-12/31/2019	Roivant Sciences, Inc.		Vibegron	Overactive Bladder (OAB)	III	Trial Announcement - Initiation (Emerging Markets)	Clinical Trials to Start (China)	Sinovant lists the initiation of a Vibegron clinical program in China as a near term catalyst for the company. We await the start of clinical trials in China through 2019.	148565
01/10/2019-12/31/2019	SI-BONE, Inc.	SIBN	iFuse Implant System	Bone Fractures and Mechanical Defects	Approved	Reimbursement - Reimbursement Decision (Japan)	Reimbursement Coverage – Japan	SI-BONE announced that it expects to receive reimbursement coverage in Japan. The company did not provide timing details therefore we look for an update through 2019.	148593
07/01/2019-12/31/2019	Syros Pharmaceuticals	SYRS	SY-1425	Acute Myelogenous Leukemia (AML)	II	Trial Data - Updated Results	Phase II - AML/MDS Updated Results	Syros announced that the company plans to report updated clinical data in the second half of 2019 from the ongoing Phase II study cohort evaluating SY-1245 in combination with azacitidine.	148558

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Expected Date Range	Company	Symbol	Drug	Indication	Phase	Expected Catalyst	Catalyst Title	Analysis	Link
10/01/2019-12/31/2019	Syros Pharmaceuticals	SYRS	SY-1365	Solid Tumors	I	Trial Data - Updated Results	Phase I - Updated Results	Syros announced that the company plans to report initial clinical trial data in the fourth quarter of 2019 from the expansion portion of the ongoing Phase I trial which is assessing SY-1365 as a single agent and in combination with standard of care therapies in multiple ovarian and breast cancer populations.	148579
07/01/2019-12/31/2019	TG Therapeutics, Inc.	TGTX	TG-1303	Marginal Zone Lymphoma - NHL	II/III	Regulatory - NDA/BLA Filing	NDA Filing (UNITY-NHL)	TG Therapeutics announced a potential NDA filing based off the UNITY-NHL study of TG-1303 + TG-1202 in H2 2019.	148614
07/01/2019-12/31/2019	TG Therapeutics, Inc.	TGTX	TG-1303	Indolent Non-Hodgkin's Lymphoma (Including Follicular Lymphoma) - NHL	II/III	Regulatory - NDA/BLA Filing	NDA Filing	TG Therapeutics announced a potential NDA filing based off the UNITY-NHL study of TG-1303 + TG-1202 in H2 2019.	148615
07/01/2019-12/31/2019	TG Therapeutics, Inc.	TGTX	TGR-1202	Indolent Non-Hodgkin's Lymphoma (Including Follicular Lymphoma) - NHL	II/III	Regulatory - NDA/BLA Filing	NDA Filing	TG Therapeutics announced a potential NDA filing based off the UNITY-NHL study of TG-1303 + TG-1202 in H2 2019.	148616
07/01/2019-12/31/2019	TG Therapeutics, Inc.	TGTX	TGR-1202	Marginal Zone Lymphoma - NHL	II/III	Regulatory - NDA/BLA Filing	NDA Filing	TG Therapeutics announced a potential NDA filing based off the UNITY-NHL study of TG-1303 + TG-1202 in H2 2019.	148617
07/01/2019-12/31/2019	UroGen Pharma, Ltd.	URGN	VesiGel	Bladder Cancer	IIb	Trial Announcement - Patient Enrollment Completed	Phase IIb - Enrollment Complete	UroGen announced that enrollment is expected to complete in the second half of 2019 for the Phase IIb study of UGN-102 for LG NMIBC.	148600
07/01/2019-12/31/2019	UroGen Pharma, Ltd.	URGN	BotuGel	Overactive Bladder (OAB)	II	Trial Data - Top-Line Results	Phase II - Top-Line Results	UroGen expects data from the Phase II trial of BotuGel UroGen's RTGel in combination with BOTOX for the treatment of overactive bladder in the second half of 2019.	148608
01/10/2019-12/31/2019	Vectura Group plc	VEC:LN	VR647	Asthma	II	Trial Announcement - Initiation	Phase III Trial to Start	Vectura announced that partnering options are actively being explored for 2019. Vectura plans to initiate the Phase III program in 2019 following consultation with the U.S. Food and Drug Administration (FDA) and pharmaceutical dose development and device manufacturers.	148572
01/01/2020-03/31/2020	Y-mAbs Therapeutics Inc.		huCD33-BsAb	Hematologic Cancer	Preclinical	Regulatory - IND Filing	IND Filing	Y-Mabs anticipates a potential IND submission for huCD33-BsAb in Q1 2020.	148574
01/01/2020-04/30/2020	Syros Pharmaceuticals	SYRS	SY-5609	Solid Tumors	Preclinical	Trial Announcement - Initiation	Phase I - Oncology Trial to Start	Syros announced that the company plans to complete IND-enabling studies of SY-5609 to support the initiation of a Phase I oncology trial in early 2020.	148583
01/01/2020-12/31/2020	Arena Pharmaceuticals, Inc.	ARNA	Etrasimod	Atopic Dermatitis (Eczema)	Preclinical	Trial Data - Top-Line Results	Phase II - Top-Line Results	Arena Pharmaceuticals plans to initiate a Phase II study of etrasimod in atopic dermatitis in 2019 with top-line data expected in 2020.	148550
01/01/2020-12/31/2020	Chimerix, Inc.	CMRX	Brincidofovir (Oral)	Antiviral - Other Treatments	III	Regulatory - NDA/BLA Filing	NDA Filing	Chimerix announced that top-line data from the Phase II AdAPT study of oral brincidofovir are anticipated in 2020. Regulatory submissions are anticipated shortly after the Phase II data. As such we await a filing update in the 2020 time frame.	148590
01/01/2020-12/31/2020	UroGen Pharma, Ltd.	URGN	VesiGel	Bladder Cancer	IIb	Trial Data - Updated Results	Phase IIb - CR/Durability Data	UroGen announced that an analysis to evaluate the CR and durability of the Phase IIb study of UGN-102 for LG NMIBC is expected in 2020.	148599
01/01/2021-03/31/2021	Grace Therapeutics, LLC.		GTX-102	Neurology - Other	Preclinical	Regulatory - NDA/BLA Filing	NDA Filing	Grace plans to file an NDA for GTX-102 in the first quarter of 2021.	148607
10/01/2021-12/31/2021	Grace Therapeutics, LLC.		GTX-101	Postherpetic Neuralgia (PHN)	Preclinical	Regulatory - NDA/BLA Filing	NDA Filing	Grace plans to file an NDA for GTX-101 in the fourth quarter of 2021.	148606
01/01/2021-12/31/2021	Ophthotech Corporation	OPHT	AAV2-hBest1 Gene Therapy (Ophthotech)	Other Retinopathy (Ophthalmology)	Preclinical	Trial Announcement - Initiation	Phase I/II to Start	Ophthotech announced the development of a gene therapy that targets Best disease or Best Vitelliform macular dystrophy an orphan inherited retinal disease caused by mutations in the BEST1 gene. A Phase I/II clinical trial is planned to initiate by 2021.	148566

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Expected Date Range	Company	Symbol	Drug	Indication	Phase	Expected Catalyst	Catalyst Title	Analysis	Updated Analysis	Link
Now-03/31/2019	Dynavax Technologies Corporation	DVAX	DV281	Non-Small Cell Lung Cancer (NSCLC)	I	Trial Data - Top-Line Results	Phase Ib - Top-Line Results	Dynavax announced that it expects results from the Phase Ib study of DV281 for the treatment of non-small cell lung cancer in the fourth quarter of 2018.	Date Range Delayed (01/10/2019) - Dynavax anticipates safety and biomarker data from the Phase I study of DV281 in the first quarter of 2019.	139804
01/10/2019-03/31/2019	TG Therapeutics, Inc.	TGTX	TG-1801	Hematologic Cancer	Preclinical	Trial Announcement - Initiation	Clinical Trial to Start	TG-1801 is expected to go into clinical trials later this year or early in 2019.	Date Range Delayed (01/10/2019) - TG Therapeutics expects a Phase I trial with TG-1801 to commence in the first quarter of 2019.	143672
01/10/2019-06/30/2019	argenx N.V.	ARGX	Efgartigimod	Immune Thrombocytopenic Purpura (ITP)	II	Trial Announcement - Initiation	Phase II SC Efgartigimod - Trial to Start	Based on Phase II data argenx plans to initiate a Phase II trial in ITP using a subcutaneous formulation of efgartigimod. As such we await an update in the time frame above.	Date Range Delayed (01/10/2019) - Argenx plans to initiate a Phase II trial in ITP using a subcutaneous formulation of efgartigimod in the first half of 2019.	145543
Now-06/30/2019	Censa Pharmaceuticals Inc.		CNSA-001	Phenylketonuria (PKU)	II	Trial Data - Top-Line Results	Phase II - Top-Line Results	Retrophin expects results from a Phase II proof-of-concept study of CSNA-001 to be available in early 2019.	Date Range Delayed (01/10/2019) - Retrophin expects results from a Phase II proof-of-concept study of CNSA-001 to be available in the first half of 2019.	139397
01/10/2019-06/30/2019	Chimerix, Inc.	CMRX	Brincidofovir (IV)	Antiviral - Other Treatments	II	Trial Data - Top-Line Results	Phase II - Top-Line Results	Chimerix announced that data from the open-label Phase II IV BCV studies in adult patients are expected in late 2018 to early 2019.	Date Range Refined (01/10/2019) - Chimerix lists that interim Phase II data of IV brincidofovir for the treatment of Adenovirus are anticipated in the first half of 2019.	146314
Now-06/30/2019	Dynavax Technologies Corporation	DVAX	SD-101 (Dynavax)	Melanoma	I/II	Trial Announcement - Initiation	Phase III - Trial to Start	Dynavax announced that it expects to start a Phase III study of SD101 for the treatment of melanoma by the end of 2018.	Date Range Delayed (01/10/2019) - Dynavax anticipates a decision to start registrational study of SD-101 in melanoma refractory/resistant patients in the first half of 2019. We continue to await an update in the Phase III study initiation in the same time frame.	139766
01/10/2019-06/30/2019	Immunomedics, Inc.	IMMU	Sacituzumab Govitecan	Breast Cancer	BLA	Trial Announcement - Patient Enrollment Completed	Phase III - Patient Enrollment Completed	Immunomedics expects to complete patient enrollment of the Phase III study of sacituzumab govitecan in TNBC in the fourth quarter of 2018.	Date Range Delayed (01/10/2019) - Immunomedics expects to complete enrollment of its Phase III ASCENT study of Sactiuzumab for breast cancer in the first half of 2019.	139844
04/01/2019-06/30/2019	Kura Oncology, Inc.	KURA	KO-539	Hematologic Cancer	Preclinical	Trial Announcement - Initiation	Phase I - Trial to Start	Kura announced the nomination of KO-539 an orally-available small molecule inhibitor of the menin-MLL interaction as a development candidate for the treatment of mixed lineage leukemias a genetically-defined subset of the two most common forms of acute leukemia acute myeloid leukemia and acute lymphoblastic leukemia.The company's goal for its menin-MLL inhibitor program is to initiate a Phase I clinical trial in 2018.	Date Range Delayed (01/10/2019) - Kura plans to file an IND for KO-539 in the first quarter of 2019 and initiate the trial in the second quarter of 2019.	128867
01/10/2019-06/30/2019	TG Therapeutics, Inc.	TGTX	Ublituximab	Chronic Lymphocytic Leukemia (CLL)/Small Cell Lymphocytic Lymphoma (SLL) - NHL	III	Trial Announcement - Other	Phase I/II - Protocol Amendment	TG Therapeutics announced the ublituximab data presented at ASH sets the stage for the commencement of the combination of U2 plus TG-1501 in the coming months. As such we await the initiation of this trial through April 2019.	Date Range Delayed (01/10/2019) - TG Therapeutics expects to amend its Phase I/II U2 + pembro study to replace pembro with TG-1501 in H1 2019.	147363
04/01/2019-09/30/2019	TG Therapeutics, Inc.	TGTX	TG-1303	Diffuse Large B-Cell Lymphoma (DLBCL) - NHL	II/III	Trial Data - Top-Line Results	Phase IIb UNITY-DLBCL - Top-Line Results	TG Therapeutics announced that they anticipate a first interim analysis from the Phase IIb UNITY-DLBCL study of TGR-1202 and ublituximab for the treatment of diffuse large B-cell lymphoma (DLBCL) in mid-2017. Pending the results of UNITY-DLBCL the Company expects to drop TGR-1202 as "futile" and continue the TGR-1303 arm in approximately 100 patients. TG Therapeutics would then replace the TGR-1202 arm with TGR-1303 in combination with Benda.	Date Range Delayed (01/10/2019) - TG Therapeutics announced that pivotal data are expected from the ongoing UNITY-NHL registration program in mid-2019.	129748
04/01/2019-09/30/2019	TG Therapeutics, Inc.	TGTX	TG-1303	Mantle Cell Lymphoma - NHL	II/III	Trial Data - Top-Line Results	Phase II/III UNITY-NHL - Top-Line Results	TG Therapeutics announced that pivotal data are expected from the ongoing UNITY-NHL registration directed program in the first half of 2019.	Date Range Delayed (01/10/2019) - TG Therapeutics announced that pivotal data are expected from the ongoing UNITY-NHL registration program in mid-2019.	147380
04/01/2019-09/30/2019	TG Therapeutics, Inc.	TGTX	TGR-1202	Chronic Lymphocytic Leukemia (CLL)/Small Cell Lymphocytic Lymphoma (SLL) - NHL	II/III	Trial Data - Top-Line Results	Phase II/III UNITY-NHL - Top-Line Results	TG announced that if all goes as planned it should be able to have topline data available for all three cohorts of the UNITY-NHL study in the first half of 2019.	Date Range Delayed (01/10/2019) - TG Therapeutics announced that pivotal data are expected from the ongoing UNITY-NHL registration program in mid-2019.	141762
04/01/2019-09/30/2019	TG Therapeutics, Inc.	TGTX	TGR-1202	Diffuse Large B-Cell Lymphoma (DLBCL) - NHL	II/III	Trial Data - Top-Line Results	Phase II/III UNITY-NHL - Top-Line Results	TG announced that if all goes as planned it should be able to have topline data available for all three cohorts of the UNITY-NHL study in the first half of 2019.	Date Range Delayed (01/10/2019) - TG Therapeutics announced that pivotal data are expected from the ongoing UNITY-NHL registration program in mid-2019.	141764
04/01/2019-09/30/2019	TG Therapeutics, Inc.	TGTX	TGR-1202	Mantle Cell Lymphoma - NHL	II/III	Trial Data - Top-Line Results	Phase II/III UNITY-NHL - Top-Line Results	TG Therapeutics announced that pivotal data are expected from the ongoing UNITY-NHL registration directed program in the first half of 2019.	Date Range Delayed (01/10/2019) - TG Therapeutics announced that pivotal data are expected from the ongoing UNITY-NHL registration program in mid-2019.	147381
04/01/2019-09/30/2019	TG Therapeutics, Inc.	TGTX	TG-1303	Chronic Lymphocytic Leukemia (CLL)/Small Cell Lymphocytic Lymphoma (SLL) - NHL	III	Trial Data - Top-Line Results	Phase II/III UNITY-NHL - Top-Line Results	TG Therapeutics announced that pivotal data are expected from the ongoing UNITY-NHL registration directed program in the first half of 2019.	Date Range Delayed (01/10/2019) - TG Therapeutics announced that pivotal data are expected from the ongoing UNITY-NHL registration program in mid-2019.	147379
Now-12/31/2019	Arena Pharmaceuticals, Inc.	ARNA	Etrasimod	Atopic Dermatitis (Eczema)	Preclinical	Trial Announcement - Initiation	Phase II - Trial to Start	Arena Pharmaceuticals announced that it is planning a Phase II/III study of etrasimod in atopic dermatitis. The Phase II/III trial is expected to initiate in 2019.	New Information (01/10/2019) - Arena Pharmaceuticals plans to initiate a Phase II study of etrasimod in atopic dermatitis in 2019 with top-line data expected in 2020.	145978
01/10/2019-12/31/2019	Arena Pharmaceuticals, Inc.	ARNA	APD418	Acute Decompensated Heart Failure	Preclinical	Regulatory - IND Filing	IND Filing	Arena Pharmaceuticals is currently developing APD418 a first-in-class calcium-independent myofilament derepressor (CMD) for decompensated heart failure. APD418 targets a novel mechanism that improves contractility without adverse hemodynamic changes that would put stress on the heart. An IND filing for APD418 is anticipated in the fourth quarter of 2019.	Date Range Refined (01/10/2019) - Arena Pharmaceuticals plans to file an IND for APD418 in decompensated heart failure (DHF) in 2019.	145972
07/01/2019-12/31/2019	argenx N.V.	ARGX	Efgartigimod	Immune Thrombocytopenic Purpura (ITP)	II	Trial Announcement - Initiation	Phase III (IV) - Trial to Start	Based on Phase II data argenx plans to advance efgartigimod (IV) to Phase III development in ITP. As such we await the start of a Phase III trial in the time frame above.	Date Range Delayed (01/10/2019) - Argenx plans to initiate the Phase III trial of efgartigimod (IV) in ITP in the second half of 2019.	145542
07/01/2019-12/31/2019	argenx N.V.	ARGX	Efgartigimod	Chronic Inflammatory Demyelinating Polyneuropathy (CIDP)	Preclinical	Trial Announcement - Initiation	Phase II - Trial to Start	argenx announced plans to initiate a Phase II proof-of-concept trial of efgartigimod (IV) in chronic inflammatory demyelinating polyneuropathy (CIDP) in the first half of 2019.	Date Range Delayed (01/10/2019) - Argenx plans to initiate a Phase II trial of efgartigimod (IV) in chronic inflammatory demyelinating polyneuropathy (CIDP) in the second half of 2019.	145545
07/01/2019-12/31/2019	Chimerix, Inc.	CMRX	Brincidofovir (Oral)	Antiviral - Other Treatments	III	Trial Announcement - Patient Enrollment Completed	Phase II AdAPT - Patient Enrollment Complete	Chimerix announced that patient enrollment in the Phase II AdAPT study of brincidofovir is estimated to complete in 2019.	Date Range Refined (01/10/2019) - Chimerix announced that patient enrollment in the Phase II AdAPT study of oral brincidofovir is estimated to complete in the second half of 2019.	139266
07/01/2019-12/31/2019	Chimerix, Inc.	CMRX	Brincidofovir (IV)	Antiviral - Other Treatments	II	Trial Announcement - Initiation	Phase IIb - BKV Treatment - Trial to Start	Chimerix expects to initiate a Phase IIb study of IV Brincidofovir for BKV Treatment in late 2017.	Date Range Delayed (01/10/2019) - Chimerix lists that a proof-of-concept Phase II study of IV brincidofovir for the treatment of BKV is anticipated to initiate in the second half of 2019.	129531
07/01/2019-12/31/2019	Grace Therapeutics, LLC.		GTX-102	Neurology - Other	Preclinical	Trial Announcement - Initiation	Phase III - Trial to Start	Grace Therapeutics anticipates starting a Phase III clinical trial with GTX-102 for the treatment of ataxia telangiectasia in the second half of 2018.	Date Range Delayed (01/10/2019) - Grace plans to initiate a Phase III trial of GTX-102 in the second half of 2019.	139198
07/01/2019-12/31/2019	Grace Therapeutics, LLC.		GTX-101	Postherpetic Neuralgia (PHN)	Preclinical	Trial Announcement - Initiation	Phase II - Trial to Start	Grace Therapeutics anticipates starting a Phase III clinical trial with GTX-101 for the treatment of pain associated with postherpetic neuralgia in the second half of 2018.	Date Range Delayed (01/10/2019) - Grace plans to initiate a Phase II study of GTX-101 in the second half of 2019.	139197
01/10/2019-12/31/2019	Kura Oncology, Inc.	KURA	KO-947	Solid Tumors	I	Trial Data - Top-Line Results	Phase I Non-Hematological Malignancies - Top-Line Results	Kura Oncology announced data from the KO-947 Phase I trial in non-hematological malignancies is expected in 2018.	Date Range Delayed (12/19/2018) - According to the company website Kura Oncology is currently conducting a Phase I clinical trial of KO-947 in patients with locally advanced unresectable or metastatic relapsed and/or refractory non-hematological malignancies. The company did not provide an update on when results are expected therefore we continue to await an update.Date Range Delayed (01/10/2019) - Kura anticipates having Phase I clinical data of KO-947 in 2019.	137927
07/01/2019-12/31/2019	MacroGenics, Inc.	MGNX	Margetuximab	Gastric Cancer	I/II	Trial Announcement - Initiation	Phase II Combo - Trial to Start	Zai Lab and MacroGenics intend to initiate a global study using combination regimens containing margetuximab in order to maximize potential clinical benefit in gastric cancer. We await an update in the time frame above.	Date Range Delayed (01/10/2019) - MacroGenics plans to initiate a Phase II combination study of margetuximab with a checkpoint inhibitor in gastric cancer in the second half of 2019.	147269
01/10/2019-12/31/2019	MacroGenics, Inc.	MGNX	Flotetuzumab	Acute Myelogenous Leukemia (AML)	I	Trial Data - Updated Results	Phase I - Updated Results (Expansion Cohort)	MacroGenics expects to present full expansion cohort data for flotetuzumab in the second half of 2018.	Date Range Delayed (12/31/2018) - We await an update.Date Range Delayed (01/10/2019) - MacroGenics expects to present expansion cohort data for flotetuzumab in AML in 2019.	139839

Biomedtracker JPM Updated Catalysts - Day 4

Expected Date Range	Company	Symbol	Drug	Indication	Phase	Expected Catalyst	Catalyst Title	Analysis	Updated Analysis	Link
09/01/2019-12/31/2019	MacroGenics, Inc.	MGNX	Flotetuzumab	Acute Myelogenous Leukemia (AML)	I	Trial Announcement - Initiation	Combination Study w/MGA012 to Start	MacroGenics intends to initiate a combination study with the anti-PD-1 mAb MGA012 in the coming months while it continues to enroll the AML and MDS dose expansion cohorts in the Phase I study of Flotetuzumab.	Date Range Delayed (01/10/2019) - MacroGenics intends to commence enrollment of a combination study of flotetuzumab with MGA012 in AML in late 2019.	138806
07/01/2019-12/31/2019	TG Therapeutics, Inc.	TGTX	TG-1303	Chronic Lymphocytic Leukemia (CLL)/Small Cell Lymphocytic Lymphoma (SLL) - NHL	III	Trial Data - Top-Line Results	Phase III UNITY-CLL - Top-Line Results	TG Therapeutics plans to release an interim analysis of single agent arms from the Phase III UNITY-CLL study of TG-1303 for the treatment of chronic lymphocytic leukemia (CLL) in the second half of 2017.	Date Range Refined (01/10/2019) - TG Therapeutics expects results from the Phase III UNITY-CLL study of TG-1303 in H2 2019.	129750
Now-12/31/2019	Y-mAbs Therapeutics Inc.		Naxitamab	Brain Cancer (Malignant Glioma; AA and glioblastoma (GBM))	II	Regulatory - NDA/BLA Filing	BLA Filing	YmAbs expects to initiate a rolling BLA filing for Hu3F8 in front line NB in 2017.	Date Range Delayed (01/10/2019) - Y-Mabs expects to submit a BLA for Naxitamab for relapsed/refractory high-risk neuroblastoma in pediatric population in 2019.	129503
Now-12/31/2019	Y-mAbs Therapeutics Inc.		Omburtamab	Brain Cancer (Malignant Glioma; AA and glioblastoma (GBM))	II	Regulatory - NDA/BLA Filing	BLA Filing	YmAbs expects to initiate a rolling BLA filing in Q2 2017 with an expected completion by Q4 2017.	Date Range Delayed (01/10/2019) - Y-Mabs expects to submit a BLA for omburtamab for treatment of patients with CNS/LM from neuroblastoma in 2019.	129498
09/01/2019-04/30/2020	Y-mAbs Therapeutics Inc.		Omburtamab	Brain Cancer (Malignant Glioma; AA and glioblastoma (GBM))	II	Regulatory - sNDA/sBLA Filing	sBLA Filing - DIPG and DSRCT	YmAbs expects to file a BLA expansion in 2018 for Diffuse Pontine Gliomas and Desmoplastic Small Round Cell Tumor.	Date Range Delayed (01/10/2019) - Y-Mabs announced that the company may qualify for a sBLA for omburtamab in DIPG and DSRCT assuming positive pivotal data. As such we assume the sBLA filing to occur after the initial BLA filing for omburtamab in patients with CNS/LM from neuroblastoma and await an update in the time frame above.	129500
01/01/2020-12/31/2020	Chimerix, Inc.	CMRX	Brincidofovir (Oral)	Antiviral - Other Treatments	III	Trial Data - Top-Line Results	Phase II AdAPT Study - Top-Line Results	Chimerix projects that data from the Phase II AdAPT study of oral Brincidofovir for the treatment of Adenovirus disease after Allogeneic Pediatric Transplantation will be available in early 2019.	Date Range Delayed (01/10/2019) - Chimerix announced that top-line data from the Phase II AdAPT study of oral brincidofovir are anticipated in 2020.	133256
01/01/2020-12/31/2020	Chimerix, Inc.	CMRX	Brincidofovir (Oral)	Smallpox	I	Regulatory - MAA Submission (Europe)	MAA Filing	Chimerix announced that it is in the process of preparing for a marketing application submission to EMA in early 2019. Chimerix intends to submit a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) contingent upon the results of animal efficacy studies to be conducted in 2018.	Date Range Delayed (01/10/2019) - Chimerix lists that regulatory submissions in the U.S. and Europe for oral brincidofovir for the treatment of smallpox are anticipated in 2020.	139270
01/01/2020-12/31/2020	Chimerix, Inc.	CMRX	Brincidofovir (Oral)	Smallpox	I	Regulatory - NDA/BLA Filing	NDA Filing	Chimerix intends to submit a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) contingent upon the results of animal efficacy studies to be conducted in 2018. We await an update in the time frame above.	Date Range Delayed (02/20/2018) - Chimerix announced that regulatory submissions for marketing approval of oral BCV for smallpox are planned for 2019. Date Range Delayed (01/10/2019) - Chimerix lists that regulatory submissions in the U.S. and Europe for oral brincidofovir for the treatment of smallpox are anticipated in 2020.	139302
01/01/2020-12/31/2020	Chimerix, Inc.	CMRX	Brincidofovir (Oral)	Antiviral - Other Treatments	III	Regulatory - MAA Submission (Europe)	MAA Submission	Chimerix projects that data from the Phase II AdAPT study of oral Brincidofovir for the treatment of Adenovirus disease after Allogeneic Pediatric Transplantation will be available in early 2019 which will facilitate an application and European approval in 2020.	New Information (01/10/2019) - Chimerix announced that top-line data from the Phase II AdAPT study of oral brincidofovir are anticipated in 2020. Regulatory submissions are anticipated shortly after the Phase II data. As such we continue to await a filing update in the 2020 time frame.	133259
07/01/2020-12/31/2020	Ophthotech Corporation	OPHT	Zimura	Stargardt Disease (Ophthalmology)	IIb	Trial Data - Top-Line Results	Phase IIb - Top-Line Results	Ophthotech expects top-line results from the Phase IIb trial of Zimura in Stargardt disease to be available in 2020.	Date Range Refined (01/10/2019) - Ophthotech expects to have Phase IIb topline data on Zimura for Stargardt disease in the second half of 2020.	137980