

Zika virus

Market Spotlight



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CONTENTS

5 OVERVIEW

6 KEY TAKEAWAYS

7 DISEASE BACKGROUND

8 TREATMENT

8 Vaccines

8 Therapeutics

10 EPIDEMIOLOGY

12 PIPELINE DRUGS

15 KEY REGULATORY EVENTS

15 FDA Approves Roche Molecular Cobas Test As Zika Virus Blood Donor Screen

16 LICENSING AND ASSET ACQUISITION DEALS

16 Emergent BioSolutions gets global rights to Valneva's Zika vaccine technology

16 Sun Evaluating Plant-Based Candidates To Treat Zika

17 Spotlight Innovation gets license to FSURF's Zika candidates

17 Heat Biologics Gets Zika IP From University Of Miami

17 Takeda In Hot Pursuit Of Zika Vaccine With \$312m US Contract

17 GSK/NIH 'SAM' Strategy May Reap Benefits Beyond Zika

17 Sanofi Teams With US Military On Zika, But Not For The Profits

18 CLINICAL TRIAL LANDSCAPE

19 Clinical Trials

20 Sponsors by status

21 Sponsors by phase

22 BIBLIOGRAPHY

23 APPENDIX**LIST OF FIGURES**

- 12 Figure 1: Overview of pipeline drugs for Zika virus in the US
- 12 Figure 2: Pipeline drugs for Zika virus, by company
- 13 Figure 3: Pipeline drugs for Zika virus, by drug type
- 13 Figure 4: Pipeline drugs for Zika virus, by classifications
- 16 Figure 5: Licensing and asset acquisition deals in Zika virus, 2013–18
- 18 Figure 6: Clinical trials in Zika virus
- 19 Figure 7: Top 10 drugs for clinical trials in Zika virus
- 19 Figure 8: Top 10 companies for clinical trials in Zika virus
- 20 Figure 9: Zika virus trial locations
- 21 Figure 10: Zika virus trials status
- 21 Figure 11: Zika virus trials sponsors, by phase

LIST OF TABLES

- 10 Table 1: Recent epidemiological updates on Zika virus
- 11 Table 2: Zika virus cases timeline
- 14 Table 3: Pipeline drugs for Zika virus in the US

OVERVIEW

*****To view an accompanying slidepack for this report, please select the Slidepack Market Spotlight Summary option from the Tools menu, or [click here](#)*****

This Market Spotlight report covers the Zika virus market, comprising key pipeline therapies, clinical trials, and licensing and acquisition deals.

Data within this Market Spotlight report are sourced from across the Informa Pharma Intelligence suite of products, including Biomedtracker, Pharmaprojects, Trialrove, and Medtrack, as well as Datamonitor Healthcare. The report also features content from Scrip, Pink Sheet, and Medtech Insight. For more information on any of these services, please contact our client services team at clientservices@datamonitorhealthcare.com.

KEY TAKEAWAYS

- The Zika virus was first reported in continental South America in Brazil in May 2015. In February 2016, between 440,000 and 1,300,000 people were infected in Brazil. In the US, about 225 Zika virus cases were reported in August 2017. In addition, 554 cases were reported in people infected through local mosquito-borne transmission. Furthermore, autochthonous Zika virus transmission was reported in 25 countries in the Americas, Africa, and Asia.
- In 2016, it was estimated that there were between 508 and 1,778 imported cases in Europe, particularly in France, Portugal, and Italy.
- The majority of industry-sponsored drugs in active clinical development for Zika virus are in Phase I, with just a single product in Phase II.
- Therapies in early-to-mid-stage development for Zika virus focus on the immune system and viral antigens. Candidates comprise DNA vaccines such as the NIH's Zika Virus Vaccine and GeneOne's GLS-5700; Moderna's mRNA vaccine; and Themis Bioscience's recombinant viral vector vaccine, Imutex's AGS-v vaccine, Johnson & Johnson's Ad26.ZIKV.001 vaccine, Takeda's TAK-426 vaccine, and Valneva's ZIKV-VLA1601.
- There have been eight licensing and asset acquisition deals involving Zika virus drugs during 2013–18, all of which occurred in either 2016 or 2017. The exclusive 2017 agreement between Emergent BioSolutions and Valneva – worth \$58.3m – for the global rights to Valneva's Zika vaccine technology and ZIKV-VLA1601 was the largest deal.
- The distribution of clinical trials across Phases I–IV indicates that all trials for Zika virus have been in Phase I.
- The US leads the number of Zika virus clinical trials globally.
- The majority of industry-sponsored clinical trials are ongoing, with one trial each for Takeda, Emergent BioSolutions, and Valneva. Themis Bioscience has a completed trial in the Zika virus space.
- Emergent BioSolutions, Takeda, Themis Bioscience, and Valneva have each sponsored a single Phase I trial.

DISEASE BACKGROUND

Zika virus is caused by the bite of an infected *Aedes* mosquito, which can also transmit dengue, chikungunya, and yellow fever. The virus belongs to the genus *Flavivirus* of the family *Flaviviridae*. Other flaviviruses which are related to Zika include yellow fever virus, dengue virus, Japanese encephalitis virus, West Nile virus, Spondweni virus, and tick-borne encephalitis virus. Three lineages of Zika virus have been identified, namely East African, West African, and Asian. The most recent outbreak is clustered mostly around the Asian lineage.

Zika is an RNA virus made up of three structural proteins, namely capsid, pre-membrane, and envelope. An infected mosquito carries the virus in its saliva, and after a mosquito bite, the virus enters the human body and passes through the epidermal, dermal, and Langerhans cells of the skin. The virus first replicates in the dendritic cells near the site of the initial bite, before spreading further to the lymph nodes and bloodstream, finally reaching the organs and tissues. The primary target cells for infection include human epidermal keratinocytes, dermal fibroblasts, and immature dendritic cells.

The incubation period of Zika virus is 3–12 days after the mosquito bite. In addition to mosquito bites, Zika virus can also be spread through sexual transmission, blood transfusion, and from a pregnant woman to her fetus. People of all ages are prone to the disease, although the majority of those infected have mild or no symptoms. Where symptoms do occur, they commonly include fever, rash, headache, conjunctivitis, and joint and muscle pain, and will generally last for around a week. Other symptoms include anorexia, retro-orbital pain, edema, diarrhea, constipation, abdominal pain, dizziness, and pruritus. Blood and urine tests are generally performed to confirm the presence of the Zika virus. Risk factors include microcephaly and other brain defects, and there are also associations with Guillain-Barré syndrome, miscarriage, stillbirth, and other birth defects.

There are no US Food and Drug Administration (FDA)-approved diagnostic tests to detect Zika virus, and the development of such tests is challenging due to the serological cross-reactivity among flaviviruses. The FDA has granted Emergency Use Authorization to serologic and nucleic acid amplification tests including the Trioplex reverse transcription polymerase chain reaction, and the immunoglobulin M class capture enzyme-linked immunosorbent assay.

In 1947, the virus was first reported in a Rhesus monkey in Uganda, and then in 1948 it was identified in various *Aedes africanus* mosquitos. Later, in 1954, the virus was identified in humans during a yellow fever outbreak in Nigeria. In 2007, nearly 5,000 people were infected with Zika on the island of Yap in the western Pacific Ocean. During 2013, over 30,000 people were reported with the disease associated with neurological disorders such as Guillain-Barré syndrome. Furthermore, spread of the virus through sexual and vertical transmissions was first reported in 2014.

Zika virus was first reported in continental South America in Brazil in May 2015. In February 2016, between 440,000 and 1,300,000 people were infected in Brazil. In the US, about 225 Zika virus cases were reported in August 2017. Travelers who visited the affected areas constituted 223 cases, and two cases were reportedly due to sexual transmission. In addition, 554 cases were reported in people infected through local mosquito-borne transmission. Furthermore, autochthonous Zika virus transmission was reported in 25 countries in the Americas, Africa, and Asia. In Europe, it was estimated that in 2016 there were between 508 and 1,778 imported cases, particularly in France, Portugal, and Italy.

TREATMENT

No vaccines or medicines are currently approved for the treatment of Zika virus. However, many nucleoside analog drugs such as ribavirin and favipiravir; 2'-C-methylated nucleosides such as 2'-C-methylcytidine (2CMC) and 7-deaza-2'-C-methyladenosine (7DMA); and T-1105 have shown antiviral activity in cell cultures. Ribavirin and favipiravir are approved antiviral drugs for other diseases; however, they are less effective than 7DMA against Zika virus. Initially, 7DMA and 2CMC were developed to treat hepatitis C virus, which is not closely related to the Zika virus, but these compounds are also effective against other flaviviruses which are closely related to Zika such as dengue virus. The main considerations with the development of new treatments are that they should be active in nervous system cells, cross the blood-brain barrier and the placenta, and should be safe for pregnant women, their fetuses, and infants.

Many vaccines and drugs are being investigated for the prevention or treatment of Zika virus infection.

VACCINES

The development of an efficacious and safe vaccine against Zika virus infection is essential due to the rapid spread of the virus, as well as its associated outcomes. According to the WHO, there are about 45 Zika vaccine candidates, consisting of various vaccine platforms, at differing stages of development. The vaccines under development can be categorized into various subtypes:

- **DNA vaccines:** These vaccines contain a cloned gene sequence in a plasmid, which, when injected, allows the activation of antigen-presenting cells and expression of the plasmid-encoded genes, thereby generating the target antigens. Various DNA vaccine candidates which encode the prM-E genes of Zika virus are in Phase I clinical trials.
- **RNA vaccines:** RNA vaccines comprise an open reading frame which encodes an antigen that is translated by the host. RNA vaccines may be more beneficial than DNA vaccines, as RNA does not interact with the genome. Chahal et al. (2017) showed that an anti-Zika virus RNA vaccine candidate encoding prM and E proteins induced both CD8⁺ T-cell and antibody responses in C57BL/6 mice.
- **Recombinant viral vectors:** An anti-Zika virus vaccine containing a recombinant vesicular stomatitis virus has been recently studied in mice, with the study establishing maternal protective immunity in newborn mice born to a vaccinated mouse. Additionally, a small number of other recombinant viral vector anti-Zika virus vaccines are currently in the preclinical stages of development.
- **Inactivated whole organism vaccines:** Inactivated whole organism vaccines have several benefits, including non-replicating virus and multiple antigenic targets, which may improve their safety. Purified inactivated virus obtained from a Puerto Rican Zika virus strain was tested in BALB/c mice, with the vaccine being administered either via the intramuscular or subcutaneous route. The vaccine could induce Zika virus-specific neutralizing antibodies after the first immunization, and could also provide complete protection against the virus viremia in mice that received the vaccine through the intramuscular route. Yang et al. (2017) suggested the use of a cDNA clone-launched platform for large-scale production of inactivated Zika virus vaccine, which could reduce manufacturing costs and improve vaccine accessibility.
- **Other vaccines:** Other vaccine candidates in preclinical stages of development include peptide vaccines, live-attenuated vaccines, recombinant subunit vaccines, and Zika virus exosome vaccines.

THERAPEUTICS

As there are no approved therapies for Zika virus infection, the primary aim of drug development is to reduce the symptoms and viral load, and protect the fetus from neurological sequelae. In response to the public health threat posed by the Zika virus, researchers have been looking to repurpose previously approved or investigated small molecules in order to rapidly identify new treatments for the infection.

- **Repurposed drugs:** Scientists at the National Center for Advancing Translational Sciences have tested 6,000 compounds, including FDA-approved drugs and investigational drugs, in Zika-infected human cells. Of the compounds tested, 100 were considered to be promising. Compounds such as emricasan and niclosamide reduced brain cell death due to Zika virus infection either by reducing viral replication or by inhibiting caspases.

EPIDEMIOLOGY

Table 1: Recent epidemiological updates on Zika virus

Date	Update
September 2016	WHO concludes that Zika virus is a trigger of Guillain-Barré syndrome, and that Zika virus infection during pregnancy is a cause of congenital brain abnormalities, including microcephaly
October 2016	WHO includes congenital Zika virus syndrome, which includes a range of manifestations reported among newborns exposed to Zika virus in utero, on its fact sheet for microcephaly
October 2016	WHO launches the Zika Virus Research Agenda for global implementation to identify critical areas of research to support the need to generate evidence that can guide actions to limit the impact of Zika virus
October 2016	WHO issues first quarterly update of Zika Strategic Response Plan, which provides key information on the epidemiological situation and response for more than 60 Zika response partners
November 2016	WHO director general declares end of Public Health Emergency of International Concern regarding Zika virus and other neurological disorders (eg microcephaly and Guillain-Barré syndrome), as defined by the International Health Regulations

Source: Datamonitor Healthcare; WHO, 2017

- Zika virus infection and its associated consequences remain a substantial public health challenge, requiring long-term action.

Table 2: Zika virus cases timeline

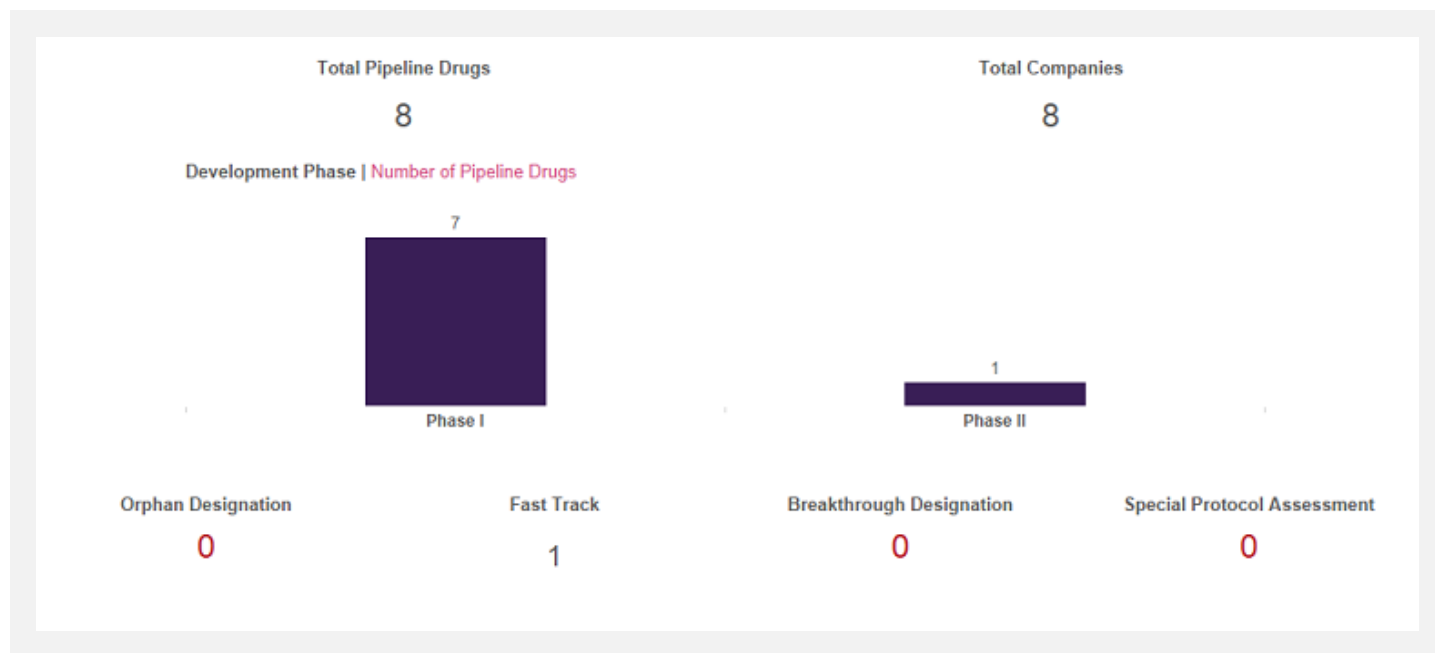
Date	Location	Cases
Prior to 2007	No outbreaks of Zika virus	Only 14 documented cases of human Zika worldwide
April 2007 to July 2007	Zika virus considered emergent since 2007 epidemic on Yap	About 73% of island residents infected; 185 suspected cases, 49 confirmed, 59 considered probable
2007 to 2013	Travelers in Thailand, Cambodia, and Indonesia	Sporadic cases reported
2008 to 2013	No further transmission reported until epidemic in French Polynesia	Three case reports and one surveillance study published
October 2013 to February 2014	Zika virus caused major French Polynesia epidemic	Approximately 10,000 cases registered, 70 severe
May 2015	Laboratory tests confirm Zika virus circulating in Brazil; alert issued	First report of locally acquired Zika virus in the Americas
October 2015	Colombia reports laboratory confirmed cases of Zika virus in 13 municipalities	156 cases
May 2015 to December 2015	Autochthonous Zika virus cases reported throughout the Americas	707,133 reported cases, 175,063 confirmed
April 2016	Vietnam reports first cases of locally acquired Zika virus	Two cases
November 2016 to present	No additional confirmed autochthonous cases of Zika virus in the Americas	See PAHO, 2017 source for updates

Source: Datamonitor Healthcare; Ikejezie et al., 2017; loos et al., 2014; PAHO, 2017; Paixao et al., 2016; WHO, 2017

PIPELINE DRUGS

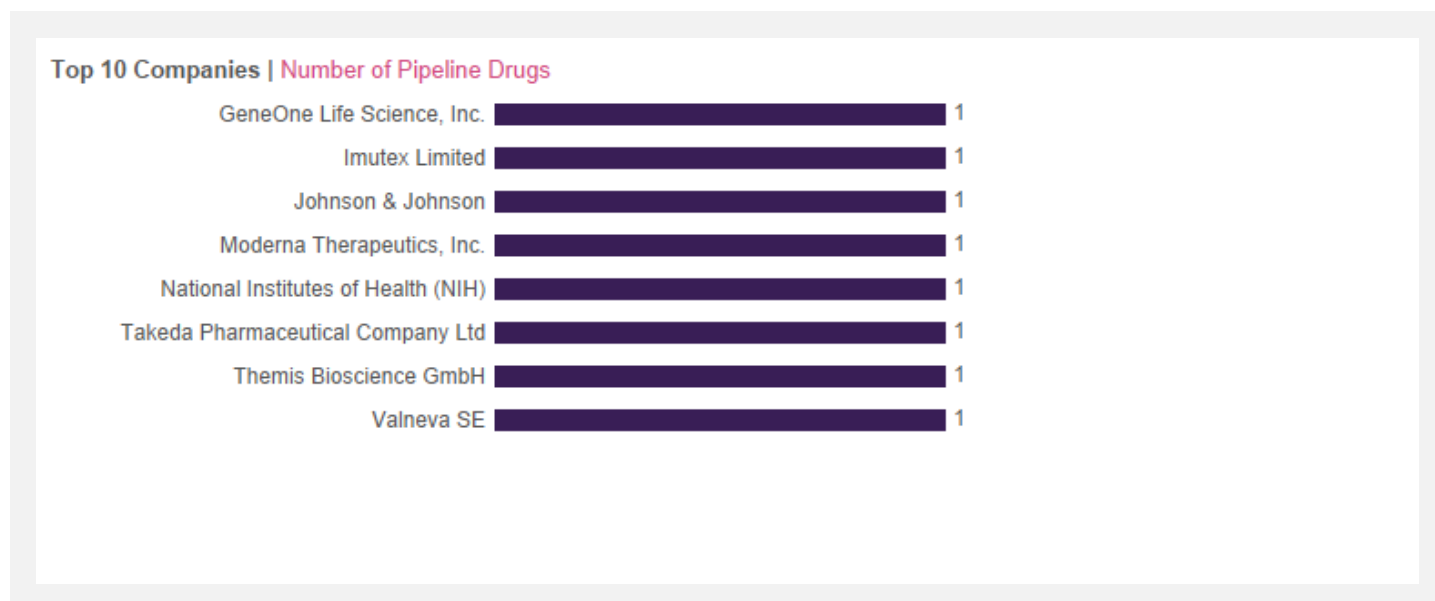
This is a snapshot of Phase I–III and New Drug Application (NDA) or Biologics License Application (BLA) candidate drugs in the Zika virus space in the curated Biomedtracker database. The majority of industry-sponsored drugs in active clinical development for Zika virus are in Phase I, with just a single product in Phase II. Preclinical, Investigator Initiated, and Investigational New Drug (IND) candidates are not included here. Phase I/II and Phase II/III are counted as Phase II and Phase III, respectively.

Figure 1: Overview of pipeline drugs for Zika virus in the US



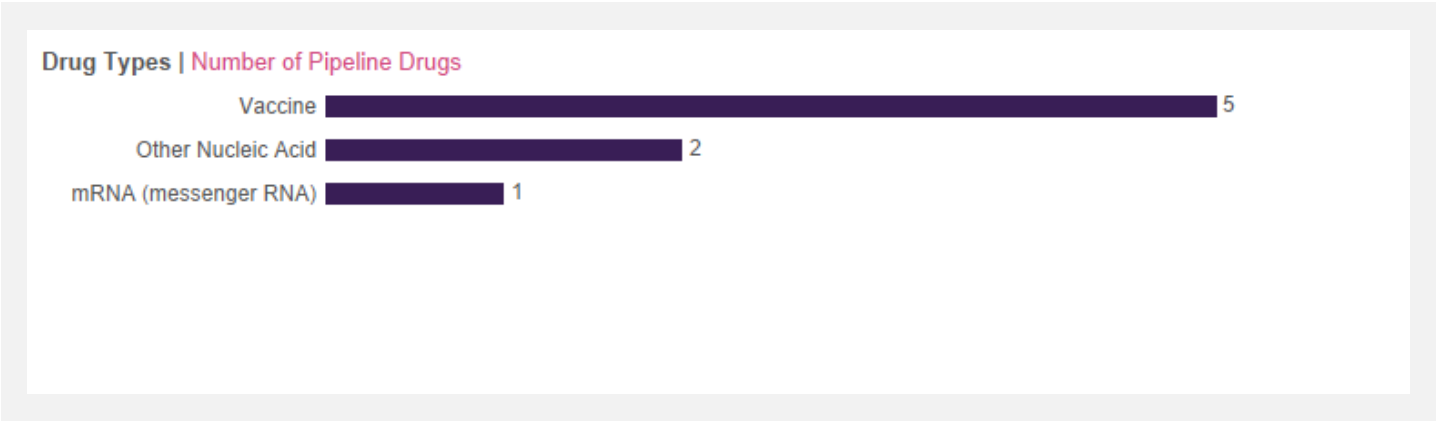
Source: Biomedtracker 4 May 2018

Figure 2: Pipeline drugs for Zika virus, by company



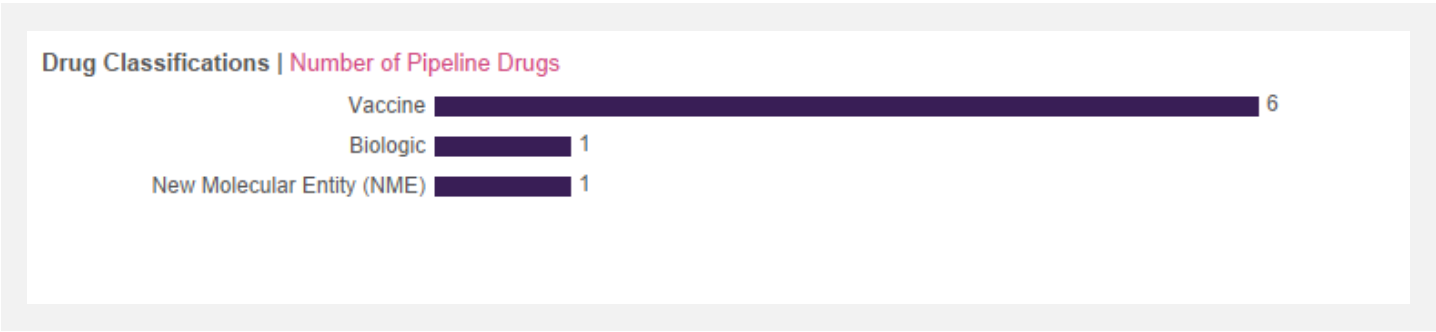
Source: Biomedtracker 4 May 2018

Figure 3: Pipeline drugs for Zika virus, by drug type



Source: Biomedtracker 4 May 2018

Figure 4: Pipeline drugs for Zika virus, by classifications



Source: Biomedtracker 4 May 2018

This is a snapshot of Phase I-III and NDA or BLA candidate drugs in the Zika virus space in the curated Biomedtracker database. Therapies in early-to-mid-stage development for Zika virus focus on the immune system and viral antigens. Candidates comprise DNA vaccines such as the NIH’s Zika Virus Vaccine and GeneOne’s GLS-5700; Moderna’s mRNA vaccine; and Themis Bioscience’s recombinant viral vector vaccine, Imutex’s AGS-v vaccine, Johnson & Johnson’s Ad26.ZIKV.001 vaccine, Takeda’s TAK-426 vaccine, and Valneva’s ZIKV-VLA1601.

Likelihood of Approval (LOA) refers to the chance of FDA approval of an NDA or BLA. The average chance of FDA approval for marketing in the US for the specified disease is based on the historical performance of drugs in the same development phase as per a 2003–13 analysis of the Biomedtracker database published in the peer-reviewed journal Nature Biotechnology. Biomedtracker analysts view the average approval chance as a starting point for analyzing specific data on the drug to arrive at the LOA. The difference from the average approval chance is indicated here in parentheses.

Table 3: Pipeline drugs for Zika virus in the US

Drug	Generic	Lead	Target(s)	Compound	Phase	LOA	Estimated Approval	Route of Administration
Zika Virus Vaccine		National Institutes of Health	Immune system, Viral antigens	Other Nucleic Acid	II	27%		Intramuscular
Ad26.ZIKV.001		Johnson & Johnson	Not specified	Vaccine	I	19%		Intramuscular
AGS-v		Imutex	Immune system, Viral antigens	Vaccine	I	19%		Intramuscular
GLS-5700		GeneOne	Immune system, Viral antigens	Other Nucleic Acid	I	19%		N/A
mRNA-1325		Moderna	Immune system, Viral antigens	mRNA (messenger RNA)	I	19%		N/A
TAK-426		Takeda	Immune system	Vaccine	I	19%		N/A
Zika Vaccine		Themis Bioscience	Immune system	Vaccine	I	19%		N/A
ZIKV-VLA1601		Valneva	Immune system, Viral Antigens	Vaccine	I	19%		N/A

Source: Biomedtracker 4 May 2018

KEY REGULATORY EVENTS

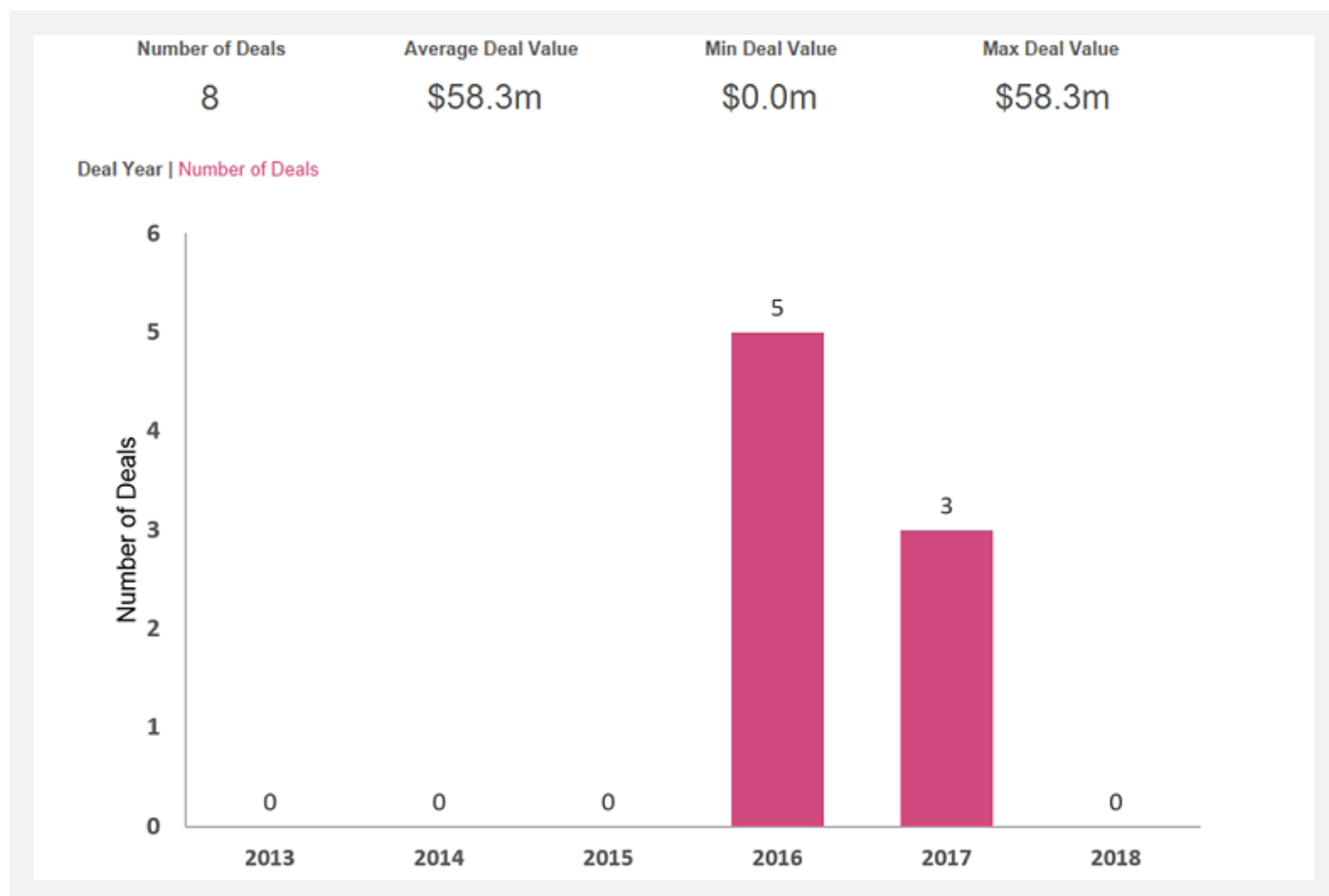
FDA APPROVES ROCHE MOLECULAR COBAS TEST AS ZIKA VIRUS BLOOD DONOR SCREEN

US FDA approved Roche Molecular Diagnostics' cobas Zika virus test to screen plasma specimens from blood and organ donors. Medtech Insight October 2017

LICENSING AND ASSET ACQUISITION DEALS

This is a snapshot of partnership deals involving drugs in the Zika virus space in the curated Medtrack database.

Figure 5: Licensing and asset acquisition deals in Zika virus, 2013–18



Source: Medtrack 4 May 2018

There have been eight licensing and asset acquisition deals involving Zika virus drugs during 2013–18, all of which occurred in either 2016 or 2017. The exclusive 2017 agreement between Emergent BioSolutions and Valneva – worth \$58.3m – for the global rights to Valneva's Zika vaccine technology and ZIKV-VLA1601 was the largest deal.

EMERGENT BIOSOLUTIONS GETS GLOBAL RIGHTS TO VALNEVA'S ZIKA VACCINE TECHNOLOGY

In its third deal in a month, Emergent BioSolutions Inc licensed exclusive worldwide rights to Valneva SE's ZIKV Zika vaccine technology and know-how related to Zika drug development. Emergent will pay \$1.17m (€1m) up front. Scrip July 2017

SUN EVALUATING PLANT-BASED CANDIDATES TO TREAT ZIKA

India's largest pharmaceutical company, Sun Pharmaceutical Industries Ltd, says plant-based drug candidates to treat Zika will be studied as part of a new alliance with the National Institute of Virology. Under the agreement, the institute is going to test potential medicines developed by Sun to combat mosquito-borne viruses like Zika, chikungunya, and dengue. Scrip July 2017

SPOTLIGHT INNOVATION GETS LICENSE TO FSURF'S ZIKA CANDIDATES

The Florida State University Research Foundation licensed Spotlight Innovation Inc exclusive global rights to develop and commercialize compounds aimed at treating viral infections, including Zika virus. Scrip February 2017.

HEAT BIOLOGICS GETS ZIKA IP FROM UNIVERSITY OF MIAMI

The University of Miami licensed Heat Biologics Inc a portfolio of patents to use in developing heat shock protein gp96-based vaccines aimed at Zika virus and other infectious diseases including HIV, West Nile, dengue, and yellow fever. Heat has concurrently formed Zolovax Inc as a wholly owned subsidiary to focus exclusively on developing the infectious disease vaccines. Scrip October 2016.

TAKEDA IN HOT PURSUIT OF ZIKA VACCINE WITH \$312M US CONTRACT

Takeda Pharmaceutical Co Ltd has jumped fully into development of a Zika vaccine after landing a US government contract worth up to \$312m that will fund the Japanese biopharmaceutical firm's efforts. Takeda has banked \$19.8m from the US Biomedical Advanced Research and Development Authority (BARDA) to get the ball rolling on the preclinical and clinical development of an experimental inactivated, adjuvanted whole Zika virus vaccine and carry it through Phase I testing. Scrip September 2016.

GSK/NIH 'SAM' STRATEGY MAY REAP BENEFITS BEYOND ZIKA

GlaxoSmithKline and NIH's National Institute of Allergy and Infectious Diseases (NIAID) Vaccine Research Center have joined together under a cooperative research and development agreement to develop a Zika vaccine based on the London-based company's novel self-amplifying mRNA (SAM) technology, which the firm acquired as part of its 2015 asset swap with Novartis. Scrip July 2016.

SANOFI TEAMS WITH US MILITARY ON ZIKA, BUT NOT FOR THE PROFITS

Sanofi Pasteur has entered into an agreement with the US Walter Reed Army Institute of Research, part of the Department of Defense, to develop a Zika vaccine. The company had decided in February that it would take on Zika and pursue a vaccine based on the live chimeric vaccine technology it used for its dengue shot, Dengvaxia, and its product against Japanese encephalitis – two viruses that belong to the same family as Zika, known as flaviviruses. Under their cooperative research and development agreement, WRAIR will take the vaccine candidate into Phase I development, which it is doing with the NIAID. After the Phase I results are known, Sanofi will pick up development from there and take the product into Phase II and III studies. The company will be responsible for creating a clinical development and regulatory strategy. Scrip July 2016.

CLINICAL TRIAL LANDSCAPE

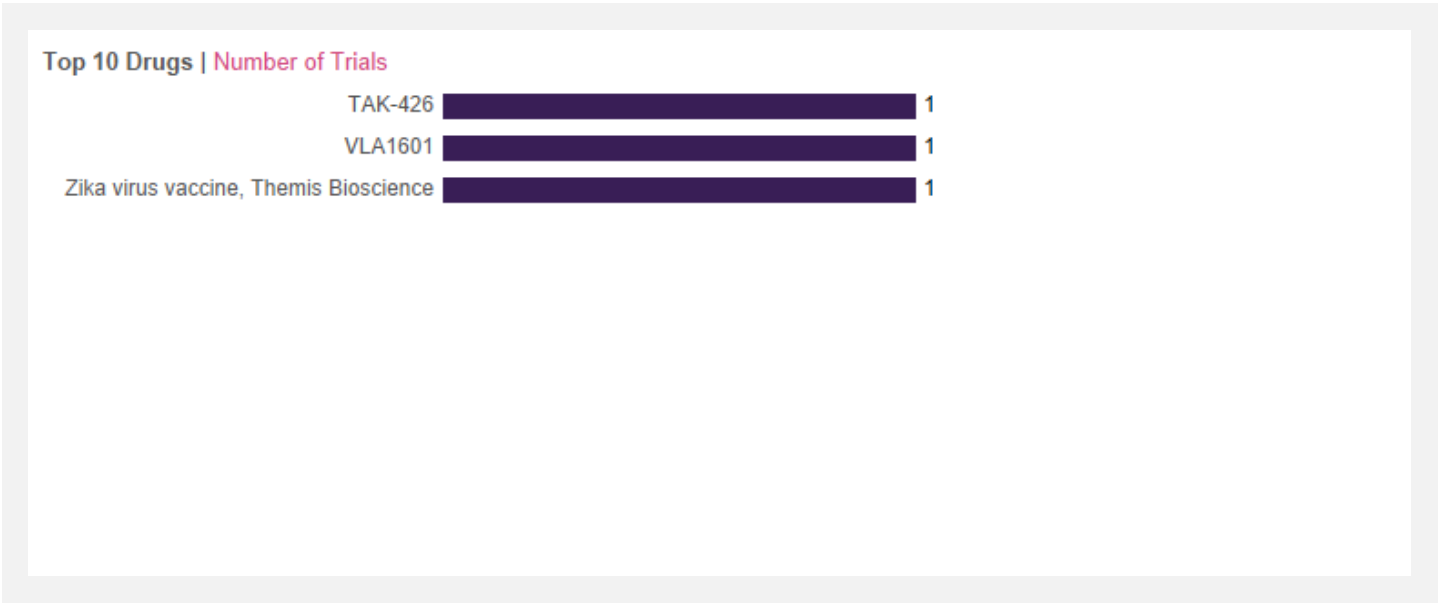
This is a snapshot of Phase I-IV clinical trials for primary investigational drugs with at least one industry sponsor in the Zika virus space in the curated Trialtrove database. The distribution of clinical trials across Phases I-IV indicates that all trials for Zika virus have been in Phase I. Phase I/II and Phase II/III trials are counted as Phase II and Phase III, respectively.

Figure 6: Clinical trials in Zika virus



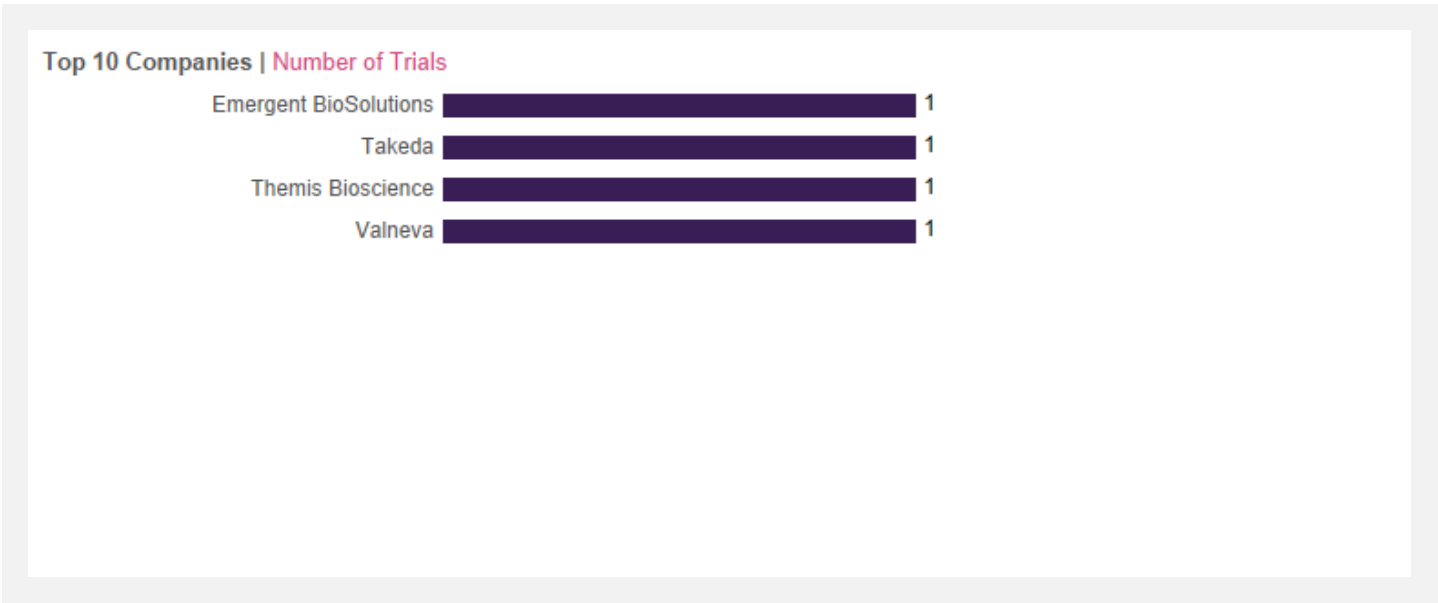
Source: Trialtrove 4 May 2018

Figure 7: Top 10 drugs for clinical trials in Zika virus



Source: Trialtrove 4 May 2018

Figure 8: Top 10 companies for clinical trials in Zika virus

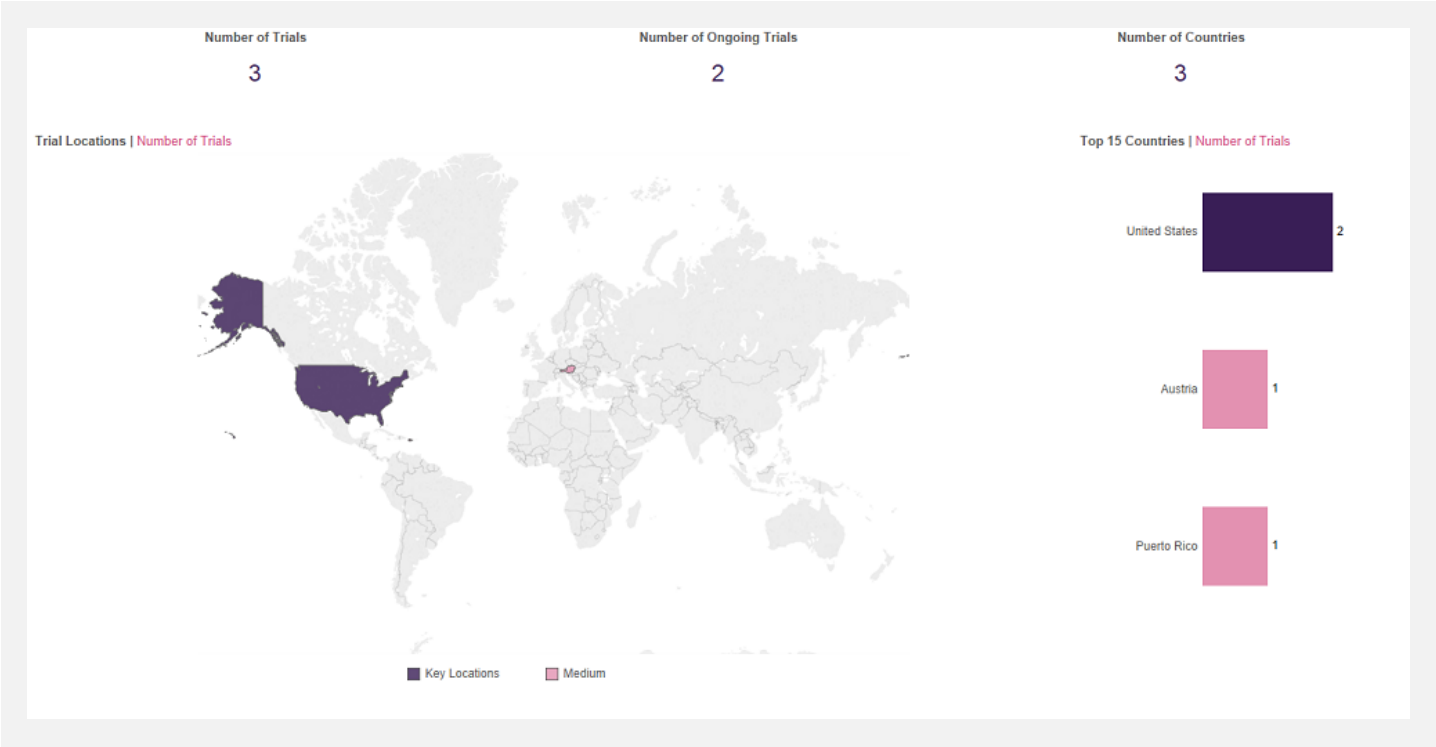


Source: Trialtrove 4 May 2018

CLINICAL TRIALS

This is a snapshot of Phase I-IV clinical trials for primary investigational drugs with at least one industry sponsor in the Zika virus space in the curated Trialtrove database. The US leads the number of Zika virus clinical trials globally.

Figure 9: Zika virus trial locations

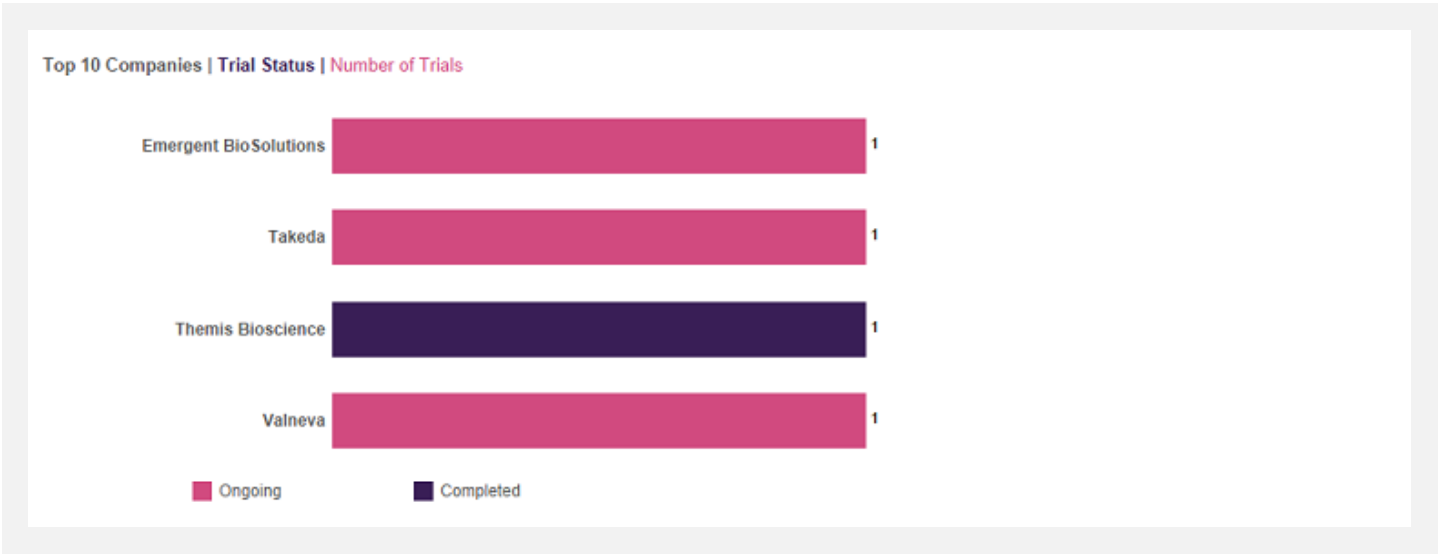


Source: Trialtrove 4 May 2018

SPONSORS BY STATUS

This is a snapshot of Phase I–IV clinical trials for primary investigational drugs with at least one industry sponsor in the Zika virus space in the curated Trialtrove database. The majority of industry-sponsored clinical trials are ongoing, with one trial each for Takeda, Emergent BioSolutions, and Valneva. Themis Bioscience has a completed trial in the Zika virus space.

Figure 10: Zika virus trials status



Source: Trialtrave 4 May 2018

SPONSORS BY PHASE

This is a snapshot of Phase I-IV clinical trials for primary investigational drugs with at least one industry sponsor in the Zika virus space in the curated Trialtrave database. Emergent BioSolutions, Takeda, Themis Bioscience, and Valneva have each sponsored a single Phase I trial.

Figure 11: Zika virus trials sponsors, by phase



Source: Trialtrave 4 May 2018

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APPENDIX

- Biomedtracker tracks impactful future catalysts; analyzes these commercial, clinical, and regulatory activities when they happen; and presents them in an easily searchable interface to help you stay on top of your game. Biomedtracker analysts attend medical and investor meetings that matter to you, to bring not just the news, but also industry-acclaimed insight to you faster. Biomedtracker's team of expert analysts monitors companies, trials, deals, and regulatory meetings to capture the most critical events so that you can spend more time making the right decisions for your business. Biomedtracker's Likelihood of Approval analyses are informed by these events and showcase the "bottom-line" of the news's impact on a drug's future.
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