

# Tychan's first-in-class Zika monoclonal antibody therapeutics ready for human trial after 9 month's development

- *Tychan establishes Joint-Partnership with Wuxi Biologics to develop Therapeutics in three areas including Zika Virus*
- *Focused on developing quick and effective response against deadly infectious diseases*

**Singapore –7 FEBURARY, 2018** – Tychan, a Singapore clinical-stage biotechnology company, announced today that its first-in-class monoclonal antibody therapeutics for Zika, Tyzivumab, is now ready for human trials. Developed in a record time of 9 months and having proven safe and effective in animals, the first patient dose in a Phase 1a clinical trial will take place on 8<sup>th</sup> February 2018, following a regulatory authorisation by the Health Sciences Authority, Singapore. Two further phases of clinical trials will typically follow before the therapeutics could be applied to patients.

Lack of timely intervention during infectious disease outbreaks results in millions of fatalities every year. The short development cycle of the Zika therapeutics is made possible by a technology platform developed by Dr. Ram Sasisekharan, Alfred H. Caspary Professor of Biological Engineering and Health Sciences & Technology, Department of Biological Engineering, Koch Institute for Integrative Cancer Research of Massachusetts Institute of Technology (MIT) and Singapore-MIT Alliance for Research and Technology (SMART); and Professor Ooi Eng Eong, Deputy Director, Emerging Infectious Diseases Programme, Duke-NUS Medical School, Singapore and Co-Director, Viral Research and Experimental Medicine Centre@SingHealth Duke-NUS (ViREMiCS), with the basic research funded by National Research Foundation (NRF), Singapore. Temasek Foundation Ecosperity also provided funding support to help start the quick development capability in line with its objective to enhance livability of Singapore and other cities.

Tychan believes that its platform can shorten the required timeline to bring a candidate therapy from design to clinical trials from months to weeks. It intends to do this using a staged approach that integrates innovative drug development and bio-manufacturing processes. With this integrated approach, Tychan puts Singapore on the map to address and manage emerging pathogens that impact local and global economies. Tychan is founded by Drs. Sasisekharan and Ooi with funding from Tychan's major shareholder, Temasek - a Singapore headquartered investment company.

*"The current paradigm of taking years to bring a drug from discovery to the clinic does not allow us to effectively deal with outbreaks of emerging diseases", said Teo Ming Kian, Chairman of the Board, Tychan.*

*"These outbreaks are often explosive and claim many lives within a few months. The SARS episode is a painful reminder. To make a difference to outbreak interventions, research discovery must be translated into medicines within such timelines. The development of Tyzivumab is a first step in this direction", Teo added.*

## **Joint Partnership with Wuxi Biologics**

The joint partnership with Wuxi Biologics enabled the Zika therapeutics to be produced within the 9 month record timeline. Tychan is expanding the collaboration with WuXi Biologics on two other infectious diseases of global importance. WuXi Biologics will set up a biologics manufacturing facility in Singapore, with the support of Economic Development Board (EDB), Singapore.

*"We are very excited to have participated in this important venture of filing and obtaining approval for an IND in world record time. WuXi-Tychan joint partnership will help produce important medicines for deadly infectious diseases; and we look forward to the journey ahead" said Chris Chen, CEO WuXi Biologics.*

*Dr Beh Swan Gin, Chairman EDB added, "Tychan is an exciting new local biotech firm that is working to address an important global health issue. Entering human trials is a significant development and we are pleased to see the company reach such an important milestone. Tychan's progress is illustrative of the growing biotech ecosystem in Singapore and another sign that the Government's patient investment to build*

*up our scientific capabilities in Biomedical Sciences is starting to bear fruit. We look forward to more of such success stories”.*

### ***Enabling quick response to infectious diseases***

With globalisation and Singapore as a transport hub, the risk of pandemics caused by rapidly mutating and acceleratingly virulent viruses will increase. Stocking drugs developed for infectious diseases that may not be effective against subsequent mutations even if they had been effective against earlier forms is expensive and not the right strategy. Having a development capability and manufacturing facility that can quickly respond to emerging infectious diseases provides greater assurance of defence against such deadly diseases.

The scientific discovery and resulting technology platform and manufacturing process will enable quick response to deadly infectious disease pandemics caused by deadly viruses like SARS, Ebola and Zika.

*“The discovery and development of Tyzivumab is not just a story about scientific advance, but also of how collaborative efforts between key parties, many of whom are based here in Singapore, can produce results that fundamentally change the way the world thinks about drug development. SMART’s contribution to this first-in-class human testing of this important antibody via licensing relevant intellectual property is consistent with MIT and SMART’s mission of research for impact,” said, Professor Daniel Hastings, CEO and Director of SMART.*

*“Finding an effective therapeutics for infectious diseases in a timely manner has proven to be one of the biggest scientific challenges in recent years,” said Professor Patrick Casey, Senior Vice Dean of Research, Duke-NUS Medical School. “The launch of Tyzivumab’s first-in-human clinical trials is a significant step towards realising Duke-NUS’s mission of transforming medicine and improving lives through innovative research. Our partnership in this journey with partners like MIT/ SMART as well as Tychan and WuXi has placed us with those who share our commitment to address this unmet medical need.”*

To derive full advantage of the technologies that shorten the development and production cycle, and the in-depth data made available, Tychan is also working with local partners and HSA on innovations to shorten clinical trials that would otherwise take several years. This will enable therapeutics and prophylactics to be made available quickly to patients in a pandemic to minimise human suffering and economic loss.

*“This ‘first-in-man’ clinical trial shows this potential Zika therapeutics has reached an important milestone in the drug development pathway. Zika virus is one of the rapidly emerging infectious disease with public health importance globally and this clinical trial will be important to us”, Associate Professor Teoh Yee Leong, Public Health Physician and CEO of Singapore Clinical Research Institute.*

The outcome of such innovations would be tremendously impactful; as every day saved to advance the delivery of therapeutics, without compromising on the safety while establishing the efficacy to patients, would save many lives in pandemics caused by emerging infectious agents. For the first time, there is hope that painful episodes like that of SARS would not recur.

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*For media reference:*

### **About Tyzivumab**

Tyzivumab is the first-in-class monoclonal antibody designed and engineered to treat Zika infected patients to enter the clinic. Tyzivumab is directed against a specific quaternary epitope of the envelope (E) protein on the surface of the virus, limiting viral fusion to host cells and preventing viral replication.

### **About the Trial**

The first in human clinical trial is being conducted in Singapore in approximately 24 healthy volunteers. Volunteers in the Phase 1a trial will be randomised into one of six groups each receiving a single dose of the anti-Zika monoclonal antibody. The primary endpoints of the study are safety and tolerability, and secondary endpoints include pharmacokinetics and immunogenicity. The trial is administered by SingHealth Investigational Medicine Unit, led by Associate Professor Jenny Low, Senior Consultant, Department of Infectious Diseases, Singapore General Hospital and Co-Director, Viral Research and Experimental Medicine Centre@SingHealth Duke-NUS (ViREMiCS). The Singapore Clinical Research Institute as the Academic Research Organisation partner provides oversight, data management and analytical support.

### **About Zika**

ZIKV is a single-stranded RNA virus in the genus Flavivirus, thus phylogenetically related to Dengue, West Nile, Yellow Fever and Japanese encephalitis viruses. The surface-exposed envelope (E) protein is the mediator of host cell attachment and viral entry, and the predominant target for prophylactic and therapeutic antibody treatments for Flaviviruses.

Zika virus (ZIKV) has emerged to become a cause of major health concern throughout many parts of the tropical world. This flavivirus is transmitted by the same Aedes mosquitoes that spread the closely related dengue virus (DENV), and hence ZIKV has the potential to be as widely distributed as DENV globally. This possibility is emphatically underscored by the first documented outbreak of Zika in Singapore in 2016 and emergence of numerous clusters of cases in 2017, despite Singapore's extensive vector control program. In most instances, Zika is a mild, self-limiting viral infection, symptoms arise in ~20% of infected individuals and include fever, skin rash, conjunctivitis, and muscle and joint pain lasting 2-7 days. However, epidemiological observations now reveal a strong link between infection of pregnant women and severe neurological complications, including microcephaly, in the developing fetus. Rarely, infection in otherwise healthy adults would also develop neurological complications in the form of Guillain-Barré syndrome. This post-infection sequelae result in ascending paralysis that, in some cases, can be life threatening if it involves the respiratory muscles. By far the greatest concern of Zika is that infection during pregnancy could result in congenital infection resulting in malformation and stunted growth of multiple organs and especially the fetal brain. A recent study estimated that the absolute risk of microcephaly in babies from mothers who acquired antenatal ZIKV infection is as high as 17.1% in some parts of Brazil. With no approved vaccine, the need for a safe therapy to reduce viral spread and reduce the risk of congenital infection and Guillain Barré syndrome, is urgent.

### **About Tychan**

Tychan, a Singapore clinical-stage biotechnology company, is focused on bringing life-saving treatments for emerging infections to those in need through disruptive technologies. In a coordinated effort with regulatory authorities, we are accelerating the translation from non-clinical studies to clinical trials for emerging pathogens. Founded by Professor Ram Sasisekharan of Massachusetts Institute of Technology (MIT) /Singapore MIT Alliance for Research and Technology (SMART) and Professor Ooi Eng Eong of Duke-National University of Singapore (Duke-NUS), their expertise spans the fields of biologics development and biology of acute viral infections. Temasek Holdings is the founding investor of Tychan Pte. Ltd. For more information on Tychan Pte Ltd, please visit: [www.tychan.com](http://www.tychan.com)

## **About WuXi Biologics**

WuXi Biologics, a Hong Kong-listed company, is the only open-access biologics technology platform in the world offering end-to-end solutions to empower organizations to discover, develop and manufacture biologics from concept to commercial manufacturing. Our company history and achievements demonstrate our commitment to providing a truly ONE-stop service offering and value proposition to our global clients. For more information on WuXi Biologics, please visit [www.wuxibiologics.com](http://www.wuxibiologics.com).

## **About Temasek**

Incorporated in 1974, Temasek is an investment company headquartered in Singapore. Supported by 11 offices internationally, Temasek owns a S\$275 billion portfolio as at 31 March 2017, mainly in Singapore and the rest of Asia. Our portfolio covers a broad spectrum of industries: financial services; telecommunications, media & technology; transportation & industrials; consumer & real estate; life sciences & agribusiness; as well as energy & resources. As an institution, we have a stake in the well-being of our larger community. We recognise that environmental, social and governance factors can impact our stakeholders as well as the long term sustainability of companies and businesses. As an institution, we have a stake in the well-being of our larger community. We recognise that environmental, social and governance factors can impact our stakeholders as well as the long term sustainability of companies and businesses. Please visit <https://www.temasek.com.sg>

## **About Temasek Foundation Ecosperity**

Temasek Foundation Ecosperity is a Singapore-based non-profit philanthropic organisation that funds and supports strategic and impact-driven programmes focusing on championing the sustainability of our global ecosystem and the development of innovative solutions to improve liveability. Established in 2016, it aims to bring about enduring solutions, systems and capabilities against environmental, biological and other adversities in Singapore and beyond. Temasek Foundation Ecosperity is a member of the Temasek Family of Foundations.

## **About the Singapore Clinical Research Institute (SCRI)**

Singapore Clinical Research Institute (SCRI) is a National Academic Research Organisation dedicated to enhance the standards of human clinical research. Its mission is to spearhead and develop core capabilities, infrastructure and scientific leadership for clinical research in Singapore. SCRI is a national clinical trials coordination centre that works with National Medical Research Council (NMRC) to assist the Ministry of Health in implementing clinical trials policy and strategic initiatives to support and develop clinical research competencies locally. In driving towards its vision, SCRI collaborates with clinicians to enhance Singapore's clinical research and strengthen its expertise in executing multi-site, multi-national studies and the development of regional clinical research networks. SCRI is a wholly-owned subsidiary of MOH Holdings. <http://www.scri.edu.sg>

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