

Tychan Successfully Completes Human Safety Studies for the First-in-Class Potent Monoclonal Antibody against Zika Virus

- *Tychan reports safety and pharmacokinetic data in healthy volunteers for the first-in-class anti-Zika therapeutic antibody, Tyzivumab*
- *Regulators approve testing of Tyzivumab in Zika Patients in a Phase1B trial to be conducted in Singapore*

Singapore –26 OCTOBER, 2018 – Tychan, a Singapore clinical-stage biotechnology company, announced today that it has successfully completed Phase-1 safety trials in Singapore for Tyzivumab, its first-in-class monoclonal antibody (mAb) therapeutic for Zika, Tyzivumab, in Singapore.

By invitation, the safety and pharmacokinetic data will be presented at the late breaking session of this year's annual conference of the American Society of Tropical Medicine and Hygiene (ASTMH) held October 28th – November 1st in New Orleans, USA. Tyzivumab was found to be safe and well tolerated up to the highest dose tested. This paves the way for this antibody to be tested in Zika patients in a Phase 1B study for which Tychan has received regulatory approval from the Health Sciences Authority of Singapore. Recruitment of patients is ongoing for this study.

The record time it took to complete discovery to human safety studies for this Zika therapeutic also provides early validation for Tychan's platform which is aimed at shortening the bench to bedside timelines for life-saving treatments.

The technology platform for these studies were developed by Professor Ram Sasisekharan of Massachusetts Institute of Technology (MIT) /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 (TF Ecosperity) also provided funding support for the development of this rapid response capability platform, in line with its objective to enhance liveability in Singapore and other cities.

Tychan is forging ahead to refine its platform to further enable shortening of such timelines and establishing a framework for managing response to emerging pathogens at the global level. In partnership with WuXi Biologics, Tychan is focused on making potential therapeutics for emerging infectious agents.

“Demonstration of the safety of Tyzivumab is an important milestone that puts Tychan firmly on a path towards a true rapid response capability for emerging infectious diseases that is so critically needed to overcome the threats of increasing epidemics that have often caused great misery to human lives and severe economic impact”, said Teo Ming Kian, Chairman of the Board, Tychan.

“With the resurgence in Zika disease in various parts of the world, we hope Tyzivumab will provide much needed therapeutic options to save lives at risk. This study also demonstrated the strong partnerships among the key researchers in Singapore” said Associate Professor Teoh Yee Leong, Public Health Physician and CEO of Singapore Clinical Research Institute (SCRI).

“We are happy to support Tychan to build a capability platform that can enhance epidemic preparedness. Temasek Foundation Ecosperity champions sustainability and liveability, and we support translational research to find therapeutics for deadly infectious diseases. We hope that we can continue to support many promising research in this area and improve our living environment,” said Lim Hock Chuan, Chief Executive, TF Ecosperity

“WuXi Biologics is the proud partner to enable IND filing of this exciting program in 9 months, which showcases our world-class capabilities and speed. We are committed to expediting development and manufacturing of much needed biologics for emerging infectious agents,” said Chris Chen, CEO of WuXi Biologics.

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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 Phase 1A clinical trial was conducted in Singapore in approximately 24 healthy volunteers. Volunteers in the Phase 1a trial were randomised into one of six groups each receiving a single dose of the anti-Zika monoclonal antibody. The primary endpoints of the study were safety and tolerability, and secondary endpoints include pharmacokinetics and immunogenicity. The Phase 1B trial will be conducted in approximately 28 patients with confirmed Zika infection who will be sequentially included in 4 groups each receiving a single dose of the anti-Zika monoclonal antibody. Both trials are 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. ZIKV 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 programme. In most instances, Zika is a mild, self-limiting viral infection, symptoms arise in approximately 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 is the founding investor of Tychan Pte. Ltd. For more information on Tychan Pte Ltd, please visit: 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.

About Temasek Foundation Ecosperity

Temasek Foundation Ecosperity is a Singapore-based non-profit philanthropic organisation established in 2016 that seeks to marshal ideas and innovations to address environmental, biological and other adversities that endanger people and the sustainability of our planet. It funds and supports ideas and innovations for actual applications through commercialisation and enterprise, to bring about impactful improvements to the liveability of our world, especially in cities. Temasek Foundation Ecosperity is a member of the Temasek Family of Foundations, which was established by Temasek to better serve the evolving needs of the wider community, reinforcing its approach to sustainable giving. For more information on Temasek Foundation Ecosperity, please visit <http://www.temasekfoundation-ecosperity.org.sg>.

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. For more information on SCRI, please visit <http://www.scri.edu.sg>

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