ASX Announcement

IMUGENE RECEIVES ETHICS APPROVAL TO START PHASE I CLINICAL TRIAL OF NEW CANCER IMMUNOTHERAPY PD1-VAXX IN USA

- Hackensack University Medical Center in New Jersey USA receives WIRB approval for Phase I human trial of anti-cancer immunotherapy PD1-Vaxx
- Site activation conditional on FDA IND clearance scheduled for Q42020

SYDNEY, Australia, 3 September 2020: Imugene Limited (ASX:IMU), a clinical stage immuno-oncology company, today announced it has received Western Institutional Review Board (WIRB) approval to commence a Phase I clinical trial of its checkpoint immunotherapy candidate, PD1-Vaxx in USA.

The US component of the Phase I trial will be conducted under the Food and Drug Administration (FDA) investigational new drug (IND) process. Site activation and patient recruitment will proceed after FDA IND approval scheduled for Q42020.

The first hospital in the USA to receive WIRB ethics approval is the Hackensack University Medical Center in New Jersey. Additional USA clinical sites will be opened at the Mayo Clinic in Phoenix Arizona and the Ohio State University Medical Center in Columbus Ohio.

The first-in-human, Phase 1, multi-center, dose escalation study of PD1-Vaxx will enroll patients with non-small cell lung cancer. Medical investigators will test different doses of PD1-Vaxx as a monotherapy and in combination with immune checkpoint inhibitor drugs.

The primary aim of the Phase 1 trial is to determine safety and an optimal biological dose as a monotherapy and later in combination with immune checkpoint inhibitors. Efficacy and immune response will also be measured.

Imugene MD & CEO Leslie Chong said “The start of our USA study is a significant milestone for Imugene and clinicians treating Americans faced with the challenge of lung cancer. Accomplishing this goal speaks to the perseverance and dedication of Imugene’s clinical and research team as we continue to build on our clinical and commercial potential.”

“The concept of teaching and inducing the body to generate its own antibodies targeting PD1 expressing cells represents a paradigm shift in oncology, and is a novel treatment method for cancer”, Ms Chong added.

Full study details can also be found on clinical trials.gov under study ID: NCT04432207.

For more information please contact:

Leslie Chong
Managing Director and Chief Executive Officer
T: +61 458 040 433
Follow us on Twitter @TeamImugene
Like us on Facebook @Imugene
Connect with us on LinkedIn @Imugene Limited

About Imugene (ASX:IMU)

Imugene is a clinical stage immuno-oncology company developing a range of new and novel immunotherapies that seek to activate the immune system of cancer patients to treat and eradicate tumors. Our unique platform technologies seek to harness the body’s immune system against tumours, potentially achieving a similar or greater effect than synthetically manufactured monoclonal antibody and other immunotherapies. Our product pipeline includes multiple immunotherapy B-cell vaccine candidates and an oncolytic virotherapy (CF33) aimed at treating a variety of cancers in combination with standard of care drugs and emerging immunotherapies. We are supported by a leading team of international cancer experts with extensive experience in developing new cancer therapies with many approved for sale and marketing for global markets.

Our vision is to help transform and improve the treatment of cancer and the lives of the millions of patients who need effective treatments. This vision is backed by a growing body of clinical evidence and peer-reviewed research. Imugene is well funded and resourced, to deliver on its commercial and clinical milestones. Together with leading specialists and medical professionals, we believe Imugene’s immuno-oncology therapies will become foundation treatments for cancer. Our goal is to ensure that Imugene and its shareholders are at the forefront of this rapidly growing global market.

Release authorised by the Managing Director and Chief Executive Officer