

ASX Announcement

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

- Chris O'Brien Lifehouse, a comprehensive cancer hospital receives human research ethics approval for Phase I human trial of anti-cancer immunotherapy PD1-Vaxx
- Patient screening scheduled to commence in August
- Ethics approval process represents first independent review of PD1-Vaxx pre-clinical safety and efficacy data

SYDNEY, Australia, 14 July 2020: Imugene Limited (ASX:IMU), a clinical stage immuno-oncology company, today announced it has received Human Research Ethics Committee (HREC) approval to commence a Phase I clinical trial of its checkpoint immunotherapy candidate, PD1-Vaxx in Australia.

Ethics approval is confirmation Imugene has completed all the necessary pre-clinical safety and efficacy testing of PD1-Vaxx required to commence human clinical trials.

The Australian component of the Phase I trial will be conducted under Australia's Clinical Trials Notification (CTN) Scheme meaning Imugene will notify the Therapeutic Goods Administration (TGA) of HREC approval and complete local site initiation activities. The first hospital to receive ethics approval is the Chris O'Brien Lifehouse a comprehensive cancer hospital located in Sydney Australia. Additional clinical sites will be opened in Australia, and also in the US following a Food and Drug Administration (FDA) investigational new drug (IND).

The first-in-human, Phase 1, multi-centre, dose escalation study of PD1-Vaxx will involve 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, tolerability and immune response will also be measured.

Imugene MD & CEO Leslie Chong said “The start of our Australian study is a significant milestone for Imugene and clinicians treating Australians 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.

The Australian Lung Foundation estimates 12,800 Australians are diagnosed with lung cancer each year.

Imugene’s PD1-Vaxx is a B-cell cancer immunotherapy designed to treat tumors such as lung cancer by interfering with PD-1/PD-L1 binding and interaction, and produce an anti-cancer effect similar to Keytruda®, Opdivo® and the other immune checkpoint inhibitor monoclonal antibodies that are transforming treatment of a range of cancers. The primary objective of the phase 1 trial is to determine safety and an optimal biological dose as monotherapy and in combination with immune checkpoint inhibitors. Efficacy, tolerability and immune response will also be measured.

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

For more information please contact:

Leslie Chong

Managing Director and Chief Executive Officer

T: +61 458 040 433

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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