ASX Announcement

IMUGENE RECEIVES FDA IND APPROVAL FOR THE PHASE I CLINICAL TRIAL OF NEW CHECKPOINT IMMUNOTHERAPY PD1-VAXX IN USA

SYDNEY, Australia, 2 November 2020: Imugene Limited (ASX:IMU), a clinical stage immuno-oncology company, today announced it has received US Food and Drug Administration (FDA) Investigational New Drug (IND) approval to initiate a Phase I clinical trial of its checkpoint immunotherapy candidate, PD1-Vaxx in USA.

The FDA approval of the IND allows Imugene to initiate patient recruitment and dosing in its USA Phase I clinical study in non-small cell lung cancer (NSCLC) patients.

The first hospital in the USA to commence patient dosing is the Hackensack University Medical Center in New Jersey. Additional USA clinical sites will be opened subsequently at the Mayo Clinic in Phoenix Arizona and Ohio State University Medical Center.

The primary aim of the Phase 1 trial is to determine safety and determine optimal biological dose as a monotherapy. Efficacy and immune response will also be measured.

Imugene MD & CEO Leslie Chong said "Receiving our IND approval for PD1-Vaxx from the FDA is a crucial step forward for Imugene. The start of our USA study is a significant milestone for Imugene and also 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."

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

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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