ASX Announcement

IMUGENE RECEIVES ETHICS APPROVAL TO START PHASE I CLINICAL TRIAL OF NEW ONCOLYTIC VIROTHERAPY VAXINIA IN AUSTRALIA

- Tasman Oncology Research a comprehensive cancer hospital receives human research ethics approval for Phase I human trial of anti-cancer oncolytic virotherapy VAXINIA
- Patient screening scheduled to commence in January
- Ethics approval process represents first independent review of VAXINIA pre-clinical safety and efficacy data in Australia

SYDNEY, Australia, 9 January 2023: 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 oncolytic virotherapy candidate, VAXINIA in Australia.

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

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 Tasman Oncology Research, a comprehensive cancer hospital located in Eastwood, South Australia. Additional clinical sites will be opened in Australia, as have already been in the US following a Food and Drug Administration (FDA) investigational new drug (IND) approval 12 months ago.

The clinical trial is titled "A Phase I, Dose Escalation Safety and Tolerability Study of VAXINIA (CF33-hNIS), Administered Intratumorally or Intravenously as a Monotherapy or in Combination with Pembrolizumab in Adult Patients with Metastatic or Advanced Solid Tumours (MAST)." The trial is anticipated to run for approximately 24 months and is funded from existing budgets and resources.

The primary aim of the Phase 1 trial is to determine safety and an optimal biological dose of VAXINIA (CF33-hNIS) as a monotherapy and later in combination with immune checkpoint inhibitors. Efficacy, tolerability and immune response will also be measured.

The City of Hope-developed oncolytic virus has been shown to shrink colon, lung, breast, ovarian and pancreatic cancer tumors in preclinical laboratory and animal models[1].

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 advanced solid tumour cancers. 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. In addition to the positive preclinical results, we're incredibly eager to unlock the potential of VAXINIA and the oncolytic virotherapy platform for Australians inflicted with cancer."

Full study details can also be found on clinicaltrials.gov under study ID: NCT05346484.

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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 tumours. 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 such as CAR T's for solid tumours. 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