ASX Announcement

FDA IND APPROVAL FOR THE PHASE I CLINICAL TRIAL OF NEW ONCOLYTIC VIROTHERAPY VAXINIA

SYDNEY, Australia, 13 December 2021: Imugene Limited (ASX:IMU), a clinical stage immuno-oncology company, is pleased to announce it has received US Food and Drug Administration (FDA) Investigational New Drug (IND) approval to initiate a Phase I clinical trial of its oncolytic virotherapy candidate, VAXINIA (CF33-hNIS, HOV2).

The FDA approval of the IND, received on 10 December 2021 US EST, allows Imugene to start patient recruitment and dosing in a Phase 1 clinical trial for the MAST (Metastatic or Advanced Solid Tumors) study in multiple solid tumour type patients.

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 Tumors (MAST)".

This is an open-label, dose-escalation, multi-centre phase I study evaluating the safety of CF33-hNIS (hNIS – human sodium iodide symporter) administered via two routes of administration, intratumoural (IT) or intravenous (IV), either as a monotherapy or in combination with pembrolizumab administered intravenously in patients with metastatic or advanced solid tumours. The trial will involve a dose escalation, before the trial expands to up to 10 patients at the final monotherapy and combination dose.

CF33-hNIS is a chimeric vaccinia poxvirus from the lab of CF33 inventor Professor Yuman Fong, Chair of Sangiacomo Family Chair in Surgical Oncology at City of Hope, and a noted expert in the oncolytic virus field.

Oncolytic viruses (OVs) are designed to both selectively kill tumour cells and activate the immune system against cancer cells, with the potential to improve clinical response and survival.

Imugene MD & CEO Leslie Chong said: "Imugene receiving this IND approval for VAXINIA from the FDA is a crucial step forward. The start of our VAXINIA OV study is a significant milestone for clinicians treating patients faced with the challenge of solid tumour cancers. Accomplishing this goal speaks to the perseverance and dedication of Imugene's and City of Hope's research and development teams as we continue to build on our clinical and commercial potential."

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About the MAST Study

MAST is an open-label, dose-escalation, multi-centre phase I study evaluating the safety of CF33-hNIS (hNIS – human sodium iodide symporter) administered via 2 routes of administration, intratumoural (IT) or intravenous (IV), either as a monotherapy or in combination with pembrolizumab administered intravenously in patients with metastatic or advanced solid tumours (e.g. IT: Head & Neck, Advanced Melanoma, TNBC. IV: Head & Neck, Advanced Melanoma, TNBC, NSCLC, Bladder, Gastric, Colorectal, RCC). Patients eligible for treatment with CF33-hNIS monotherapy or in combination with pembrolizumab include those with any metastatic or advanced solid tumour who have documented radiological progression per Response Evaluation Criteria in Solid Tumors (RECIST) following Standard of Care (SOC) therapy which may have included treatment with an Immune Checkpoint Inhibitor (ICI). Approximately 10 participating sites in the United States and Australia will enrol patients.

The study will follow a traditional 3+3 dose escalation scheme independently for each route of CF33-hNIS administration (IT and IV) and regimen (monotherapy and combination therapy). Up to 4 cohorts will be investigated in the monotherapy setting (per route of administration) and up to 3 cohorts in the combination cohort (per route of administration).

Enrolment in the monotherapy regimen will begin first. The two routes of administration (IV and IT) will be investigated in parallel. The Dose Limiting Toxicity (DLT) period for the monotherapy arms is 21 days and 42 days for the combination arms. Once all patients in a given cohort (monotherapy/combination; IV/IT) have completed the DLT-period, the CRC will review patient safety data and assess any potential DLTs from that cohort and make a recommendation with respect to expansion of the Maximum Tolerated Dose (MTD) cohort and/or dose-escalation or dose-de-escalation (where and when applicable).

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

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