First Patients Dosed in Combination Study of VAXINIA MAST Trial

Sydney, Australia, 3 March 2023: Imugene Limited (ASX: IMU), a clinical stage immuno-oncology company, is pleased to announce that its Phase 1 MAST (metastatic advanced solid tumours) study evaluating the safety of novel cancer-killing virus CF33-hNIS (VAXINIA) has seen the first patients dosed in the intravenous (IV) and intratumoral (IT) cohorts of CF33-hNIS in combination with Pembrolizumab.

Following the recent announcement that the trial cleared cohort 2 of the monotherapy dose escalation, it has been able to progress to cohort 1 of the combination study and cohort 3 for both arms of the monotherapy dose escalation.

Imugene MD & CEO Leslie Chong said: “Having continued through the monotherapy dose escalation with safety and early positive signals, we’re eager to see VAXINIA used in combination with the well-known drug Pembrolizumab and see the potential benefit this could bring to patients. We’re setting an excellent pace with the trial and look forward to data and results in due course.”
The multicenter Phase 1 MAST trial commenced by delivering a low dose of VAXINIA to patients with metastatic or advanced solid tumours who have had at least two prior lines of standard of care treatment. The City of Hope–developed oncolytic virus has been shown to shrink colon, lung, breast, ovarian and pancreatic cancer tumours in preclinical laboratory and animal models¹. Overall the study aims to recruit up to 100 patients across approximately 10 trial sites in the United States and Australia.

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 commenced in May 2022 and is anticipated to run for approximately 24 months while being funded from existing budgets and resources.

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

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References
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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