

ASX Announcement

Next cohort reached in intravenous arms of monotherapy and combination study for cancer-killing virus CF33-hNIS (VAXINIA)

Sydney, Australia, 2 November 2023: Imugene Limited (ASX: IMU), a clinical stage immuno-oncology company, is pleased to announce that its Phase 1 MAST (metastatic advanced solid tumours) trial evaluating the safety of novel cancer-killing virus CF33-hNIS (VAXINIA) has now cleared cohort 4 of the intravenous (IV) arm of the monotherapy dose escalation study, as well as IV cohort 2 of the combination study where VAXINIA is administered with blockbuster checkpoint inhibitor drug pembrolizumab (KEYTRUDA®).

Cohort 5 of the IV arm for the monotherapy dose escalation is now open as is IV cohort 3 of the combination study.

Dose Administration (Parallel Groups)

n=52-100 patients

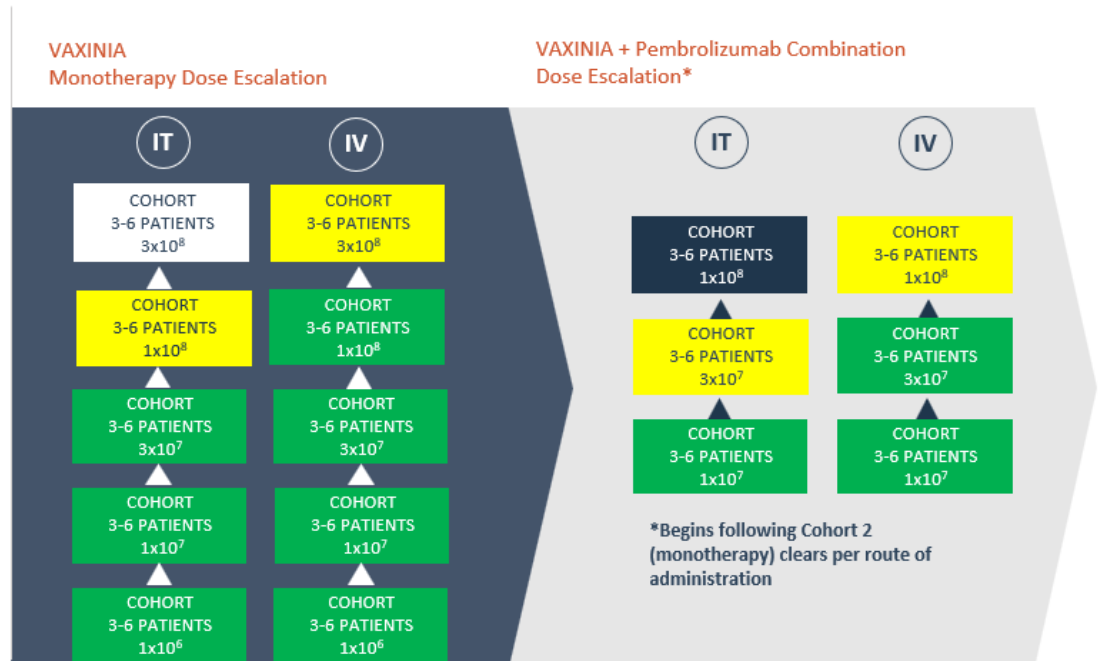


IT Administration
Metastatic and Advanced
Solid Tumours



IV Administration
Metastatic and Advanced
Solid Tumours

Site Location: USA, AUS



Imugene MD & CEO Leslie Chong said: “As we near closer to opening and completing the final cohorts that were planned at the beginning of the trial, we have an opportunity to expand the trial by enrolling patients in additional cohorts for the monotherapy dose escalation component. This will provide us with a far more robust data set to analyse and



“speak to at the conclusion of the MAST study, and provide us with a stronger platform as we further the clinical development of CF33 and VAXINIA.”

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.

References

¹Warner SG, Kim SI, Chaurasiya S, O’Leary MP, Lu J, Sivanandam V, Woo Y, Chen NG, Fong Y. A Novel Chimeric Poxvirus Encoding hNIS Is Tumor-Tropic, Imageable, and Synergistic with Radioiodine to Sustain Colon Cancer Regression. *Mol Ther Oncolytics*. 2019 Apr 11;13:82–92. doi: 10.1016/j.omto.2019.04.001. PMID: 31061881; PMCID: PMC6495072.

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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 pipeline includes an off-the-shelf (allogeneic) cell therapy CAR T drug azer-cel (azercabtagene zapreleucel) which targets CD19 to treat blood cancers. Our pipeline also 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 Imugene Limited.