

ASX Announcement

VAXINIA trial advances to Combination Cohort 1 & Monotherapy Cohort 3

Sydney, Australia, 2 February 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 cleared cohort 2 of both the intravenous (IV) and intratumoral (IT) arms of the monotherapy trial, allowing it to open cohort 1 of the combination study (with Pembrolizumab) and cohort 3 for both arms of the monotherapy dose escalation.

The company announced the first patient had been dosed in IV cohort 2 on 5 December 2022, with the trial continuing its unimpeded progress since.

Dose Administration (Parallel Groups)

n=52-100



IT Administration
Metastatic and Advanced
Solid Tumors



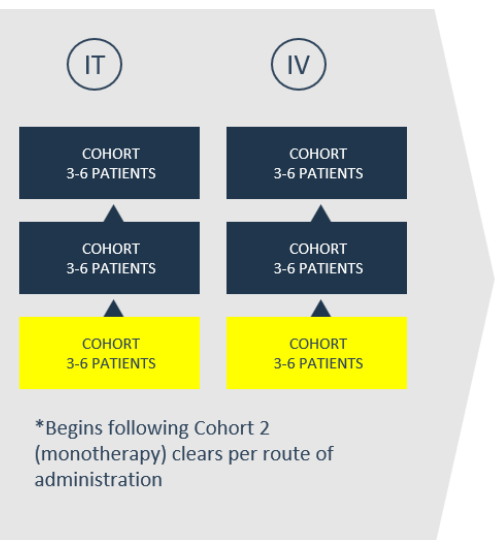
IV Administration
Metastatic and Advanced
Solid Tumors

Site Location: USA, AUS

VAXINIA Monotherapy Dose Escalation



VAXINIA + Pembrolizumab Combination Dose Escalation*



Imugene MD & CEO Leslie Chong said: “Early data arising from our patients dosed at low levels with our CF33 oncolytic virus have indicated immune activation is occurring in the tumour microenvironment, turning the tumour from ‘immunologically cold to hot’. This is a perfect time to introduce an immune checkpoint inhibitor such as pembrolizumab.”



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.

The patients treated to date in the monotherapy group have received the lowest doses of VAXINIA and have demonstrated acceptable safety, allowing new study participants to receive it in combination with the immunotherapy pembrolizumab. 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

¹ Warner 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.

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