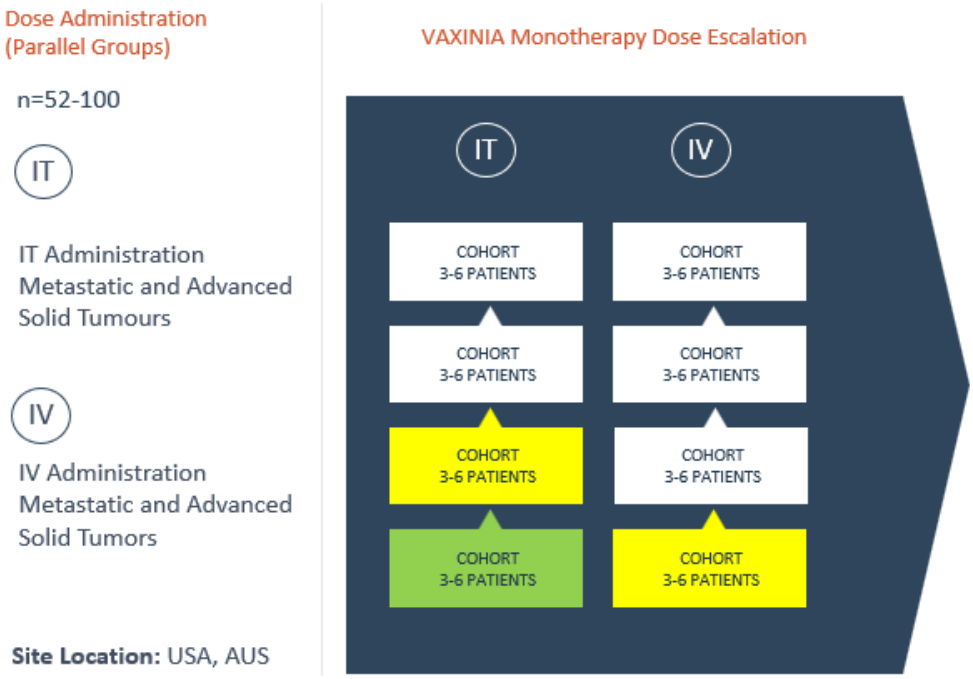
ASX Announcement

Imugene Dose Escalates in Phase I Clinical Trial of New Oncolytic Virus VAXINIA

Sydney, Australia, 1 September 2022: 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 reached key next milestones in the trial.

The intratumoral (IT) cohort 1 has now cleared, which sees the opening of cohort 2 for IT administration, while in parallel intravenous (IV) cohort 1 has also opened. Multiple sites in the United States, have dosed the patients in IT cohort 1.



The Cohort Review Committee (CRC) unanimously agreed VAXINIA to be safe, with no dose-limiting toxicities (DLTs) and no serious adverse reactions observed after CRC review of all safety and tolerability data for the first three patients dosed with the lowest dose of VAXINIA as monotherapy. At completion of the review meeting, the CRC advised Imugene to proceed with opening the second VAXINIA Phase 1 cohort at the mid-dose level.

The multicenter Phase 1 trial has 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 models[1].

Once patients in the monotherapy group have been treated with the lowest doses of VAXINIA and acceptable safety has been demonstrated, new study participants will receive it in combination with the immunotherapy pembrolizumab. This is expected to begin following cohort 2 being cleared per route of administration. 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 is anticipated to run for approximately 24 months and is funded from existing budgets and resources.

Imugene MD & CEO, Ms Leslie Chong said: "Our VAXINIA trial has made headway since commencement in May. We expect this to continue as site activation and patient recruitment builds momentum and we look forward to updating our stakeholders as this positive progress continues throughout the year."

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

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[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

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