IMUGENE
Developing Cancer Immunotherapies

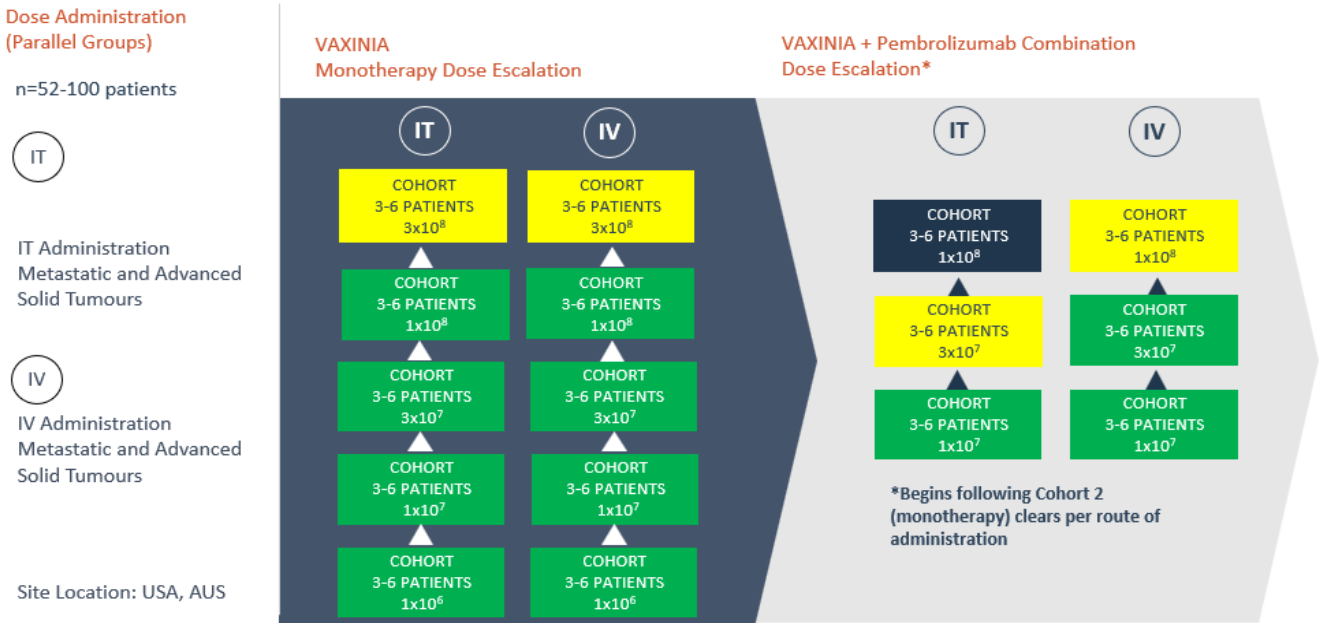
ASX Announcement

VAXINIA MAST oncolytic virus Phase 1 trial doses first patients in higher dose cohorts

- First patients dosed in cohort 5 of each monotherapy arm (intratumoral and intravenous)
- Thymus cancer patient treated at St Vincent's Hospital in Fitzroy, Victoria
- Melanoma cancer patient treated at UCSD in San Diego, California
- 24 patients to date dosed in monotherapy arms with no safety issues observed
- 38 patients enrolled in trial to date across monotherapy and combination arms

Sydney, Australia, 19 January 2024: 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 continued to progress with the first patients dosed in each arm of the higher dose cohort as part of the Phase 1 study.

In the monotherapy dose escalation, cohort 5 of the trial's intratumoural (IT) and intravenous (IV) arm are now open with the first patients dosed on 16 January and 18 January 2024, respectively. The combination study, where VAXINIA is administered with pembrolizumab, also continues to actively enrol new patients with 13 patients enrolled to date.



Imugene Managing Director & CEO Leslie Chong said: "Following the positive news on VAXINIA's early signals and FDA Fast Track Designation to end 2023, we are pleased to start the new year by announcing the ongoing progress of the MAST trial as we continue to see no safety issues with the drug. We also look forward to expanding the trial to take a closer look at bile duct cancer where we've seen early encouraging results."

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. With no safety signals identified to date, the trial has since progressed through the monotherapy dose escalation cohorts as well as the combination study, whereby VAXINIA is administered with well-known checkpoint inhibitor pembrolizumab. The City of Hope-developed CF33 oncolytic virus has been shown to shrink colon, lung, breast, ovarian and pancreatic cancer tumours in preclinical laboratory and animal models[1]. 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 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.