

ASX Announcement

First patient dosed in intravenous cohort 1 as part of VAXINIA Phase 1 clinical trial

Sydney, Australia, 21 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 seen the first patient dosed as part of intravenous (IV) cohort 1 in the trial.

The dosing of this patient follows the recent announcement that intratumoral (IT) cohort 1 had cleared, paving the way for both cohort 2 of IT administration and cohort 1 of IV administration.

A multicenter Phase 1 trial, the VAXINIA Phase 1 MAST study has to date delivered a low dose 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 study aims to recruit 100 patients across approximately 10 trial sites in the United States and Australia. Earlier this week, Imugene announced it had received the DIR licence from the Australian Government's Office of Gene Technology Regulator, allowing for expansion of the trial within Australia.

Imugene MD & CEO, Ms Leslie Chong said: "I'm very proud of our team and partners on the VAXINIA study who continue to push through the various requirements that come with running a clinical trial. We are eager to see the results from this new route of administration for the drug, in addition to that of the IT arm of the study."

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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

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