ASX Announcement

OGTR grants DIR licence allowing VAXINIA Phase 1 trial expansion to Australia

Sydney, Australia, 19 September 2022: Imugene Limited (ASX: IMU), a clinical stage immuno-oncology company, is pleased to announce that the Australian Government's Office of the Gene Technology Regulator (OGTR) has granted Imugene the DIR licence required to expand its VAXINIA Phase 1 clinical trial within Australia.

The licence, numbered DIR 192 and titled 'Clinical trial of a genetically modified (GM) chimeric Orthopoxvirus (CF33-hNIS) as a cancer treatment', is required as part of the Australian regulatory framework for dealings involving the intentional release of genetically modified organisms into the environment.

Imugene's multicenter Phase 1 VAXINIA trial commenced in May 2022 at US sites, 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].

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)." Overall the study aims to recruit 100 patients across approximately 10 clinical trial sites in the United States and Australia.

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: "We're pleased to see this regulatory hurdle cleared on schedule which will allow the smooth progression of our VAXINIA Phase 1 trial as planned."

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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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