ASX Announcement

IMUGENE RECEIVES GUIDANCE FROM US FDA ON DEVELOPMENT PATHWAY FOR ONCOLYTIC VIROTHERAPY VAXINA

- Imugene's meeting with the FDA provides feedback on non-clinical development pathway & adaptive Phase 1 clinical development plans
- Regulatory planning initiated for conducting trial in US and Australia

SYDNEY, Australia, 6 August 2020: Imugene Limited (ASX:IMU), a clinical stage immuno-oncology company, today announced it has received guidance from the US Food and Drug Administration (FDA) in relation to the development pathway for VAXinia (CF33-hNIS), the company's lead oncolytic virotherapy for the treatment of solid tumors.

The purpose of the pre-IND (Investigational New Drug) meeting with the FDA was to obtain regulatory guidance and agreement of the pre-clinical, chemistry, manufacturing and clinical development plan to be included in an IND for Imugene's VAXinia oncolytic virotherapy.

Imugene received guidance from the FDA on the development plan for VAXinia Phase 1 study design including feedback on part 2 of the study in combination with immune checkpoint inhibitors, the proposed patient population, safety monitoring plan, and strategy for evaluating drug exposure during the study. In addition, the FDA provided further guidance on key aspects of non-clinical investigations and provided valuable feedback on studies required to support the Phase 1 development plan.

Imugene Managing Director and Chief Executive Officer Leslie Chong said, "The remote meeting was productive and provided Imugene with a clear roadmap for a successful IND submission and clinical development of VAXinia."

Given the uncertainty in the COVID-19 era, it is prudent for Imugene to be flexible in identifying regulatory pathways. In parallel with the US strategy, Imugene is also pursuing a regulatory pathway in Australia.

The first-in-human, adaptive phase 1, multi-centre, dose escalation study of VAXinia (CF33-hNIS), is investigating intratumoural and intravenous administration lines as monotherapy and in

combination with immune checkpoint inhibitors in a patient population with advanced or metastatic melanoma, non-small cell lung, TNBC, bladder, head and neck, gastric, colorectal and renal cell cancers.

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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 tumors. 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. 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