

Imugene's Pre-IND FDA Meeting Provides Guidance for KEY-Vaxx Immunotherapy Clinical Development Plan

Sydney, Australia, 20 March 2019: Imugene Limited (ASX:IMU), a clinical stage immuno-oncology company, today announced it had received and accepted the minutes of its Pre-Investigational New Drug (IND) meeting with the US Food and Drug Administration (FDA) for its KEY-Vaxx cancer immunotherapy on 8 February 2019.

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

"The FDA panel members encouraged Imugene to pursue the planned IND submission and subsequent clinical studies" she said.

The purpose of the meeting was to obtain regulatory guidance and agreement of the preclinical, chemistry, manufacturing and controls and clinical development plan to be included in an IND for Imugene's PD-1 targeting KEY-Vaxx immunotherapy.

Imugene's team met with a seven member panel of the FDA Division of Regulatory Project Management Office of Tissues and Advanced Therapies in Washington DC. The meeting was aimed at seeking guidance on the studies required for Phase 1 clinical development of KEY-Vaxx. Topics addressed included the anticipated clinical indication and the treatment of cancers that overexpress PD-L1 including but not limited to non-small cell lung cancer .

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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 tumours. Our unique platform technology seeks to harness the body's immune system to generate antibodies against tumours, potentially achieving a similar or greater effect than synthetically manufactured monoclonal antibody therapies. Our product pipeline includes multiple immunotherapy B-cell vaccine candidates 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 a foundation treatment for cancer. Our goal is to ensure that Imugene and its shareholders are at the forefront of this rapidly growing global market.