

**ASX Announcement** 

## IMUGENE DOSE ESCALATES IN PHASE I CLINICAL TRIAL OF NEW CHECKPOINT IMMUNOTHERAPY PD1-VAXX

**SYDNEY**, **Australia**, **21** January 2021: Imugene Limited (ASX:IMU), a clinical stage immuno-oncology company, is pleased to announce the Cohort Review Committee (CRC) has confirmed the Phase I clinical trial of its checkpoint immunotherapy candidate, PD1-Vaxx, will proceed to the second dose cohort.

The CRC unanimously agreed PD1-Vaxx to be safe with no dose-limiting toxicities (DLTs) and no serious adverse reactions observed after CRC review of all safety and tolerability data for the first 3 patients dosed with lowest dose of PD1-Vaxx (10mcg) as monotherapy. At completion of the review meeting, the CRC advised Imugene to proceed with opening the second PD1-Vaxx Phase 1 cohort at the 50mcg mid-dose level.

Principal Investigator Professor Gary Richardson from the Cabrini Hospital in Melbourne said, "The Cohort Review Committee for the study today reviewed the first low dose cohort of patient's data and has recommended to proceed to the next dose escalation due to safety and tolerability."

Clinicians at study sites in Australia and USA will also determine if the administration of PD1-Vaxx as a monotherapy in patients who have progressed on standard of care immune checkpoint inhibitors will prolong survival, delay tumor progression, or reduce the tumor burden in patients with lung cancer.

The first-in-human, Phase 1, multi-centre, dose escalation study of PD1-Vaxx is recruiting patients with non-small cell lung cancer. Medical investigators are testing three different doses of PD1-Vaxx. The primary goal of the Phase 1 trial is to determine safety and an optimal biological dose as a monotherapy (mOBD). Efficacy, tolerability and immune response will also be measured. Determination of mOBD will be made by the Cohort Review Committee (CRC) and requires successive dosing within cohorts of at least 3 patients each.

Imugene MD & CEO Leslie Chong said "We are pleased with the results that we have seen so far with no observed toxicity. Everyone supporting the study who are involved in developing this important new cancer therapy are very encouraged by the progress to date. We look forward to continuing this study and reporting to the market of its progress."

Imugene's PD1-Vaxx is a B-cell activating immunotherapy designed to treat tumors such as lung cancer by interfering with PD-1/PD-L1 binding and interaction, and produce an anti-cancer effect similar to Keytruda®, Opdivo® and the other immune checkpoint inhibitor monoclonal antibodies that are transforming the treatment of a range of cancers.

Full study details can also be found on clinical trials.gov under study ID: NCT04432207.

For more information please contact:

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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