

ASX Announcement

IMUGENE COMPLETES ENROLMENT OF FIRST COHORT IN PHASE I CLINICAL TRIAL OF NEW CHECKPOINT IMMUNOTHERAPY PD1-VAXX

SYDNEY, Australia, 17 December 2020: Imugene Limited (ASX:IMU), a clinical stage immunology company, today announced it has completed enrolment of the first three patients in the Phase I clinical trial of its checkpoint immunotherapy candidate, PD1-Vaxx. This completes enrolment in the first low dose PD1-Vaxx cohort of patients with non-small cell 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 will test 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 Cohort Review Committee (CRC) review and requires successive dosing within cohorts of at least 3 patients each. The CRC will meet to review safety and tolerability data after the last patient in a cohort has completed 30 days treatment. If the CRC confirms the dose in the cohorts as safe and tolerable, then approval will be given to enrol patients to the next higher dose level. The highest safe dose level with the best immune response becomes the mOBD.

Imugene MD & CEO Leslie Chong said “The start of our study with first patient dosed in Australia just 18 days ago was a significant milestone for Imugene and clinicians treating Australians faced with the challenge of lung cancer. I’m encouraged by the speed at which our Australian hospitals have recruited the first cohort of patients.”

Imugene’s PD1-Vaxx is a B-cell activating cancer 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 treatment of a range of cancers.

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

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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