

ASX Announcement

IMUGENE DOSE ESCALATES TO FINAL HIGHEST DOSE IN PHASE I CLINICAL TRIAL OF NEW CHECKPOINT IMMUNOTHERAPY PD1-VAXX

- Imugene dose escalates to the final highest dose (100µg) cohort in Phase I clinical trial of PD1-Vaxx.
- PD1-Vaxx deemed safe with no dose-limiting toxicities (DLTs) and no serious adverse reactions observed at mid-dose (50µg) level.
- The ongoing Phase 1 data represent a clinical proof-of-concept signal for PD1-Vaxx monotherapy with early efficacy signals, and indicate that B-cell activating immunotherapies can induce clinically active antibody responses against an important immune regulation receptor target.
- Mayo Clinic in Arizona USA receives IRB approval for Phase I human trial of anti-cancer immunotherapy PD1-Vaxx.

SYDNEY, Australia, 7 April 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 third and final highest 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 second mid-dose patients dosed with PD1-Vaxx (50µg) as monotherapy. At completion of the review meeting, the CRC advised Imugene to proceed with opening the third PD1-Vaxx Phase 1 cohort at the 100µg highest-dose level.

Principal Investigator Professor Gary Richardson from the Cabrini Hospital in Melbourne said, " I am excited to hear the Cohort Review Committee recommended opening the third and final dose cohort based on the outstanding safety and tolerability of PD1-Vaxx reviewed to date."

After 6 weeks (day 43) treatment with PD1-Vaxx, one patient's tumor was non-measurable indicating a complete response (CR), with three patients showing stabilization of disease (SD) and a single patient progressing (PD). The status of two patients from cohort 1 (1 x SD, 1 x CR) were unchanged

at day 85. These are encouraging results in patients who have progressed after previous treatment with checkpoint inhibitors including Keytruda[®], Opdivo[®] or Tecentriq[®]. Further results and scans are scheduled over the coming weeks.

The clinical results indicate that PD1-Vaxx is showing early signs of an immune responses in patients, with antibodies to the target biomarker PD1 evident in validated assays.

Imugene MD & CEO Leslie Chong said “Phase 1 trials are generally designed to look for safety, tolerability and early response signals to determine the optimal dose for further development. I am encouraged that we are seeing positive signals at such an early stage of our PD1-Vaxx Phase I trial”.

In other news, Imugene is pleased to announce that the prestigious Mayo Clinic in Phoenix Arizona has received Institutional Review Board (IRB) approval to commence and join the Phase I clinical trial of PD1-Vaxx in USA.

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’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](https://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