ASX Announcement

Imugene Completes Phase 1a Monotherapy Dose Escalation of Immunotherapy PD1-Vaxx

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- Imugene successfully completes Phase Ia monotherapy dose escalation of PD1-Vaxx
- The ongoing Phase I data represents a clinical proof-of-concept for PD1-Vaxx monotherapy with early efficacy signals
- Imugene will now add combination therapy of PD1-Vaxx and atezolizumab in treatment naïve non-small cell lung cancer patients to the Phase Ib portion of the clinical trial

Sydney, Australia, 4 January 2022: Imugene Limited (ASX:IMU), a clinical stage immuno-oncology company, is pleased to announce the Cohort Review Committee (CRC) has confirmed its checkpoint immunotherapy candidate, PD1-Vaxx, has completed its Phase 1a monotherapy dose escalation and will proceed to combination dose escalation.

The Phase 1a monotherapy dose escalation was performed with 10, 50 and 100µg of PD1-Vaxx in non-small cell lung cancer (NSCLC) patients who progressed on one or more immune checkpoint inhibitors (ICIs).

After CRC review of monotherapy safety, tolerability and biomarker data, it advised Imugene to proceed to the combination phase of clinical development of PD1-Vaxx.

The primary objective of the phase 1 trial is to determine safety and optimal biological dose as monotherapy and in combination with immune checkpoint inhibitors (ICI). Plans are now being finalized to combine PD1-Vaxx with Roche/Genentech's PD-L1 targeting blockbuster ICI atezolizumab (Tecentriq®) as first-line in ICI treatment naïve NSCLC patients.

Dual targeting of the PD-1/PD-L1 axis is an area of considerable interest with ongoing clinical results creating strong interest inside the pharma industry[1]. Combination with PD1-Vaxx may overcome treatment resistance to ICIs[2] with dual inhibition of the PD-1/PD-L1 axis extending the treatment benefit of atezolizumab. In contrast to combination of two monoclonal antibodies, PD1-Vaxx has the advantage that it induces a unique polyclonal immune response which may increase response rates for the combination therapy.

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 and we are now progressing to the Phase 1b combination studies in treatment naïve patients.

"Our Phase 1a trial has been open_12 months and I'm pleased with both the pace of development and the early responses seen. It's particularly gratifying to have followed a patient in the trial for over 12 months where their tumour burden has been reduced to zero."

Imugene's PD1-Vaxx is a B-cell activating immunotherapy designed to treat tumours such as lung cancer by interfering with PD-1/PD-L1 binding and interaction, and produce an anti-cancer effect

similar to Tecentiq®, 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.

References:

[1] https://www.evaluate.com/vantage/articles/events/conferences/esmo-2020-some-backing-beigenes-unusual-combo-approach

[2] Burrack et al., 2019, Cell Reports 28, 2140–2155

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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 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 such as CAR T's for solid tumours. 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

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