ASX Announcement

Imugene PD1-Vaxx Immunotherapy Update

- GMP manufacturing including sterile fill and finish complete
- All preclinical toxicology studies complete allowing confirmation of clinical dose levels
- Toxicology studies confirm PD1-Vaxx generates high levels of antibodies

Sydney, Australia, 28 January 2020: Imugene Limited (ASX:IMU) a clinical stage immuno-oncology company today announces a clinical development update on its PD1-Vaxx cancer immunotherapy. PD1-Vaxx will be trialled in patients with non-small cell lung cancer (NSCLC), the most common type of lung cancer, accounting for around 80% of cases. The study is planned to commence in 2020 and is to be conducted at up to 6 sites in North America and Australia under a U.S. Food & Drug Administration (FDA) Investigational New Drug (IND) application.

Important pre-clinical milstones have been met with GMP manuafacturing, including final sterile fill and finish, processes completed by FDA inspected and qualified contract manufacturing organization's (CMO) in the U.S.

The final filled and finished vials of PD1-Vaxx have completed non-human primate (NHP) safety toxicology studies at a US-based contract research organization (CRO). The NHP was chosen due to its target PD1 receptor being 100% identical to human PD1 and hence the study also provided valuable data on the antibody generating potential of PD1-Vaxx in humans.

The three doses tested not only were well tolerated with no adverse findings reported, they also generated high levels of PD1-targeting polyclonal antibodies. This is an important development since it's a strong indicator that PD1-Vaxx will break tolerance in humans, generate antibodies, and may 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. These three doses will now be selected for the dose escalation phase of the Phase 1 trial commencing in 2020.

The study was completed under Good Laboratory Practice (GLP) conditions, a standard required for regulatory submissions to the Therapeutic Goods Administration in Australia and the US Food and Drug Administration in the US.

Imugene's M.D. & CEO, Ms Leslie Chong said, "We are pleased to reach both the toxicology and GMP drug product manufacturing milestones with such positive results, enabling us to progress PD1-Vaxx into Phase 1 trials in 2020 as an important next step in bringing a much-needed new therapeutic option to cancer patients".

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About PD1-Vaxx

Imugene's PD1-Vaxx is a B-cell 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.

The inhibitory immune pathway, consisting of the receptor programmed cell death 1 and its ligands, PD-L1 and PD-L2, plays a vital role in the maintenance of peripheral tolerance. Several tumors exploit this pathway by expressing PD-L1 and PD-L2 to escape T-cell–mediated tumor-specific and pathogen-specific immunity. Imugene is proposing to develop an anti-PD-1 immunotherapy to treat patients with lung tumors that over-express the ligand of PD1, PD-L1/2. The hypothesis is that a polyclonal-induced B-cell antibody response will be more effective or as effective with improved safety over current monoclonal antibody therapy. Therapies with monoclonal antibodies targeting PD-1 and its ligands are associated with remarkable response rates in various cancers and have revolutionized cancer treatment.

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