ASX Announcement

Imugene Announces HER-Vaxx Phase 2 Gastric Cancer Trial Data & Flags Three New HER-Vaxx Trials

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SYDNEY, Australia, 01 September 2021: Imugene Limited (ASX:IMU), a clinical stage immuno-oncology company, today announced secondary efficacy endpoint progression free survival (PFS) data for its HER-Vaxx immunotherapy in HER-2 positive gastric cancer.

The Phase 2 HER-Vaxx clinical trial is designed to evaluate the efficacy, safety, and immune response in metastatic gastric cancer overexpressing the HER-2 protein. The study is randomised into two arms of either HER-Vaxx plus standard-of-care (SOC) chemotherapy or SOC chemotherapy alone. The primary endpoint is overall survival (OS) and secondary endpoint includes PFS by independent central review. Thirty-six (36) patients have been enrolled and twenty-four (24) have achieved a PFS event in this signal generating study. Imugene is awaiting the events needed for OS evaluation and will subsequently analyse all data including final OS, PFS, safety, and immune responses.

The centrally reviewed secondary PFS endpoint, which was designed with a specified 1-sided false positive probability of 0.10, analysis showed a hazard ratio (HR) of 0.719 with a 1-sided p-value of 0.266 between the HER-Vaxx plus SOC chemotherapy treatment arm compared to the SOC chemotherapy control arm. There was no difference in safety between the two treatment arms, showing HER-Vaxx does not add toxicity to SOC chemotherapy, with detailed safety analysis to be conducted once the trial is completed.

Imugene's PFS HR was comparable to the landmark Genentech/Roche registrational ToGA study (PFS HR of 0.71), which also examined the effect of Herceptin plus chemotherapy versus SOC chemotherapy alone in advanced HER-2 positive gastric cancer.

Based on these results, Imugene now plans two further company sponsored Phase 2 studies and one Investigator Sponsored Study with HER-Vaxx in early and late stage gastric cancer.

Imugene's MD & CEO Ms Leslie Chong said "We are encouraged by the PFS and anticipated primary OS clinical data to commence three new HER-Vaxx trials, to be called *NextHERIZON*, *NeoHERIZON and NeuHERIZON,* in early and late stage gastric cancer including combination with PD-1 and PD-L1 checkpoint inhibitors. These studies will be conducted in the US, Australia and South Korea."

Imugene's HER-Vaxx is a B-cell activating immunotherapy designed to treat tumours that over-express the HER-2/neu receptor, such as gastric, breast, ovarian, lung and pancreatic cancers. The immunotherapy is constructed from several B cell epitopes derived from the extracellular domain of HER-2/neu. It has been shown in pre-clinical studies, in Phase I and now Phase 2 studies to

stimulate a potent polyclonal antibody response to HER-2/neu, a well-known and validated cancer target.

The HERIZON Phase 2 trial, which has completed recruitment, is being conducted at multiple sites across Eastern Europe and India where clinicians have difficulty accessing approved antibody treatments such as Herceptin®.

The detailed study information can also be found on clinicaltrials.gov under study ID: NCT02795988

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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 such as CAR T's for solid tumors. 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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