ASX Announcement

Imugene Presents Final HER-Vaxx Overall Survival Results in Randomized Phase 2 Trial in Advanced Gastric Cancer

- Final analysis in the randomized Phase 2 trial showed statistically significant overall survival Hazard Ratio (HR) of 0.585 (80% 2-sided CI: 0.368, 0.930); HER-Vaxx showed a reduced risk of death of 41.5% in the HER-Vaxx plus chemotherapy group compared to chemotherapy alone.
- The median overall survival (OS) for patients receiving HER-Vaxx plus chemotherapy was 13.9 months, compared to 8.3 months in patients treated with chemotherapy alone.
- The Phase 2 trial confirms a favourable survival outcome with no added toxicity for HER-Vaxx combined with standard-of-care (SOC) chemotherapy over chemotherapy alone with the Independent Data Monitoring Committee previously suggesting to shorten the study by lowering the number of patients.
- HERIZON-extension Cohort Review Committee (CRC) confirmed a dose of HER-Vaxx 100µg for future studies commencing soon.
- New clinical batch manufactured and delivered in 2022 to supply all planned HER-Vaxx clinical trials.

Sydney, Australia, 27 June 2022: Imugene Limited (ASX:IMU), a clinical stage immuno-oncology company, is pleased to present positive final overall survival data from its Phase 2 study of HER-Vaxx in Her-2/Neu overexpressing advanced/metastatic gastric/GEJ cancer following analysis of safety and efficacy data.

The final analysis results from the randomised clinical HERIZON study, which was designed with a specified 1-sided false positive probability of 0.10, showed a 41.5% survival benefit for patients treated with HER-Vaxx plus SOC chemotherapy compared to SOC chemotherapy alone. This translated into an overall survival HR of 0.585 (80% 2-sided CI: 0.368, 0.930) with a statistically significant p-value of 0.066. There was no difference in safety events between the two treatment arms, suggesting that HER-Vaxx does not add toxicity to SOC chemotherapy.

The longest HER-Vaxx treated patients remain alive 2.5 years (with one patient approaching 3 years) after starting therapy. It is noteworthy that these patients generated the strongest anti-Her-2 antibody levels from their dosing schedule on HER-Vaxx.

Principal Investigator Dr Chawla commented recently to the study team, "It has been a true pleasure to be an investigator on the HERIZON clinical trial. I have seen a positive impact on the long-term survival in my patients taking HER-Vaxx and look forward to the future development of this vaccine. "

Imugene's MD & CEO, Mrs Leslie Chong said, "I am delighted to report that we have achieved this significant milestone for patients with advanced gastric cancer. The final analysis favoured the survival outcome for HER-Vaxx and I note the Independent Data Monitoring Committee previously suggested to shorten the study by lowering the number of patients."

Historical data from the large ToGA Phase 3 study which examined the effect of Herceptin plus chemotherapy versus chemotherapy alone in advanced gastric cancer, had an overall survival HR of 0.65 for the analysis of the same patient population of HER2 overexpressing patients included in the HER-Vaxx Phase 2 study.

Imugene is also pleased to announce the HERIZON-extension Cohort Review Committee (CRC) has confirmed a new higher dose of HER-Vaxx (100μg) has been approved for use in the nextHERIZON (pretreated metastatic HER2 positive gastric cancer) and neoHERIZON (perioperative HER2 positive gastric cancer) studies commencing soon.

The CRC unanimously agreed HER-Vaxx at 100μg to be safe with no dose-limiting toxicities (DLTs) and no serious adverse reactions observed. The higher dose is expected to accelerate and strengthen antibody generation to further improve the clinical response for HER-Vaxx.

Importantly, Imugene announces completion and delivery of a large-scale batch of HER-Vaxx for use in all planned clinical trials (nextHERIZON and neoHERIZON) in patients with HER-2 positive gastric cancer. The batch which is manufactured by piCHEM (Austria) with final sterile fill and finish at Baccinex (Switzerland) has been QA/QC/QP released and delivered to Imugene's drug depot at Marken

(Singapore).

"Reliability of drug supply is a major hurdle for clinical development of many modern biological oncology drug candidates. De-risking this critical component of clinical development is a significant achievement for Imugene," said Leslie Chong, Managing Director & Chief Executive Officer of Imugene.

Imugene's HER-Vaxx is a B-cell peptide cancer 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 Phase 2 HER-Vaxx study was designed to measure the efficacy, safety and immune response in patients with metastatic gastric cancer overexpressing the HER-2 protein. The study was randomised into two arms of either HER-Vaxx plus SOC chemotherapy or SOC chemotherapy alone. The primary endpoint was overall survival and secondary endpoint was progression-free survival. Safety, tolerability and immune response was also measured.

The Phase 2 trial was conducted at multiple sites across Eastern Europe and India where clinicians have difficulty accessing approved antibody treatments such as Herceptin® and Perjeta®, marketed by Swiss multinational Roche Holding AG. There is also a high prevalence of gastric cancer in the countries selected.

Full study details 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 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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