ASX Announcement

Imugene's HER-Vaxx shows positive Overall Survival with Hazard Ratio of 0.418 in Ongoing Randomized Phase 2 Trial in Advanced Gastric Cancer.

- Interim analysis in the randomized Phase 2 showed statistically significant overall survival Hazard Ratio (HR) of 0.418 (80% 2-sided CI: 0.186, 0.942); HER-Vaxx showed a reduced risk of death of 58.2% in the HER-Vaxx plus chemotherapy group as compared to chemotherapy alone.
- The median overall survival (OS) for patients receiving HER-Vaxx plus chemotherapy was 14.2 months, compared to 8.8 months in patients treated with chemotherapy alone.
- The Phase 2 data represent a clinical proof-of-concept signal for HER-Vaxx when added to chemotherapy and indicate that B-cell activating immunotherapy vaccines can induce clinically active antibody responses.
- The Independent Data Monitoring Committee (IDMC) confirms a favourable survival outcome with no added toxicity for HER-Vaxx combined with SOC chemotherapy over chemotherapy alone and advises to lower the number of patients required for study completion.

Sydney, Australia, 23 November 2020: Imugene Limited (ASX:IMU), a clinical stage immuno-oncology company, is pleased to share positive interim data from its ongoing Phase 2 study of HER-Vaxx in Her-2/Neu overexpressing advanced/metastatic gastric/GEJ cancer.

HER-Vaxx Phase 2 interim analysis safety and efficacy data were reviewed at the IDMC meeting. As a result of the review, the IDMC reported no safety concerns and viewed this preliminary data as strongly in favour of a HER-Vaxx survival effect.

The interim analysis results from this clinical proof-of-concept study, which was designed with a specified 1-sided false positive probability of 0.10, showed twice as many patients survived on the HER-Vaxx plus SOC chemotherapy treatment arm compared to the SOC chemotherapy control arm. This translated into an overall survival HR of 0.418 (80% 2-sided CI: 0.186, 0.942) with a statistically significant 1-sided p-value of 0.083. 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 patient remains on therapy and progression-free 16.3 months after dosing. Historical

data from the 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 0.74 for the intent-to-treat analysis of the same patient population of HER2 overexpressing patients included in the HER-Vaxx Phase 2 study.

The IDMC provided guidance that it is scientifically and ethically appropriate to reduce the overall number of patients required to complete the study given the strong signal observed in the data.

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. I am excited that the interim analysis favoured the survival outcome for HER-Vaxx and the IDMC suggested to shorten the study by lowering the number of patients. This data represents a clinical proof-of-concept for HER-Vaxx and supports our B-cell activating immunotherapy platform. I look forward to updating the market as the data matures."

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 is designed to measure the efficacy, safety and immune response in 68 patients with metastatic gastric cancer overexpressing the HER-2 protein. The study is randomised into two arms of either HER-Vaxx plus standard-of-care chemotherapy or standard-of-care chemotherapy alone. The primary endpoint is overall survival and secondary endpoint will be progression-free survival. Safety, tolerability and immune response will also be measured.

The Phase 2 trial is being 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 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.

This release has been authorised by the directors of the Company.