

Positive New Data on Imugene's HER-Vaxx Cancer Vaccine Phase Ib trial presented at the American Association for Cancer Research 2019 Annual Meeting

SYDNEY, Australia, 2 April 2019: Imugene Limited (ASX:IMU), a clinical stage immuno-oncology company, today presented new data on the Phase Ib study of its HER-Vaxx cancer vaccine at the American Association for Cancer Research (AACR) 2019 Annual Meeting in Atlanta, Georgia, USA.

The poster (abstract number 8249) was presented by Professor Ursula Wiedermann from the Medical University Vienna, the lead-inventor of the HER-Vaxx cancer vaccine and member of Imugene's Scientific Advisory Board, together with a well known research team at the Medical University Vienna.

Imugene Managing Director and Chief Executive Officer Leslie Chong said, "We are encouraged by the overall positive data from the Phase Ib trial which clearly supports our B-cell platform cancer vaccine strategy for treating HER-2 positive gastric cancer."

Highlights of Professor Wiederman's presentation included:

- Eleven of 14 patients were evaluable for vaccine-specific immune responses and tumor response assessment.
- Of the three evaluable patients treated at the highest dose of 50 micrograms in cohort 3, all showed a partial response with two demonstrating greater than 40 per cent reduction in tumor size from baseline to day 56 (eight weeks).
- Patients in cohort 3 who received the highest dose of 50 micrograms recorded high antibody levels which correlated with clinical responses and reduction in tumor size.
- Higher antibody (HER-2-specific IgG) levels were observed in patients in cohort 2 who received a 30 microgram dose compared to those in cohort 1 who received a lower 10 microgram dose, showing clear dose-dependence of HER-2 specific antibody production.
- Three of five patients in cohort 2 displayed moderate or little increase in antibody tests. In contrast, all patients in cohort 3 who received a 50 microgram dose showed a marked increase of HER-2-specific antibody levels after vaccination.
- Of the patients evaluable for best response, one showed complete response, five showed a partial response and four showed a stabilisation of their disease.

- Antibodies present in the serum of one cohort 3 patient at day 56 correlated with strong tumor reduction and showed capacity to inhibit HER-2 phosphorylation, one of the key mechanisms of antibody derived anti-tumor effects.
- Moreover, in patients with a marked decrease in tumor size, the percentage of T regulatory cells declined.
- The vaccine was well tolerated and safe with antibody responses at the highest dose of 50 micrograms with no significant local or systemic reactions.
- No serious adverse events related to administration of HER-Vaxx (IMU-131) were reported. A dose of 50 micrograms was recommended for further evaluation in the Phase II trial, featuring two arms of either HER-Vaxx plus chemotherapy or chemotherapy alone.

A Phase II HER-Vaxx study was initiated in March 2019.

The abstract presentation was entitled ‘A Phase Ib open label multicenter study with a HER-2/neu peptide vaccine administered with cisplatin and 5-fluorouracil or capecitabine chemotherapy shows safety, immunogenicity and clinical response in patients with HER2/Neu overexpressing advanced cancer of the stomach”, and was authored by Prof Wiedermann and researchers at the Medical University of Vienna in Austria and Imugene Limited.

Imugene’s HER-Vaxx is a B-cell peptide cancer vaccine 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 and now in Phase I studies to stimulate a potent polyclonal antibody response to HER-2/neu, a well-known and validated cancer target.

The full presentation is available on the Imugene website [\[LINK\]](#)

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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 technology seeks to harness the body's immune system to generate antibodies against tumours, potentially achieving a similar or greater effect than synthetically manufactured monoclonal antibody therapies. Our product pipeline includes multiple immunotherapy B-cell vaccine candidates 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 a foundation treatment for cancer. Our goal is to ensure that Imugene and its shareholders are at the forefront of this rapidly growing global market.