

Imugene HER-Vaxx Phase 2 Clinical Update

- **Independent Data Monitoring Committee confirms HER-Vaxx safety and recommends study continuation without modification**
- **Patients receiving HER-Vaxx cancer immunotherapy responding positively**

Sydney, Australia, 04 May 2020: Imugene Limited (ASX:IMU), a clinical stage immuno-oncology company, today announced the outcome of the HER-Vaxx Phase 2 Independent Data Monitoring Committee (IDMC) meeting.

The IDMC's role is to review the study data and conduct a formal independent review of key data such as deaths, adverse reactions and laboratory results, enabling the IDMC to clearly weigh the benefits and risks of continued study participation.

As a result of the review, the IDMC chair confirmed the IDMC members had no safety concerns, that the study continue without modification and encouraged Imugene to push ahead with this important study.

Imugene's MD & CEO, Mrs Leslie Chong said, "I am happy to report that we have achieved this significant milestone and I'm highly encouraged by the positive outcome of this first IDMC meeting. I am truly pleased with the study progress to date."

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

The IDMC ensures the interests of patients entered on the trial are being well-served (i.e., that the risk-benefit ratio is appropriate) and that the scientific integrity of the trial is maintained between trial initiation and completion. A key benefit of IDMC review of trial data is an independent



assessment to assure that study participants are not exposed to unnecessary or unreasonable risks as a consequence of their trial participation.

The IDMC is a key process by which the highest scientific and ethical standards are maintained in a clinical trial. The IDMC conducts business in “closed sessions” with meetings attended only by members of the IDMC, thereby maintaining independence from the Sponsor. IDMC’s analyse ongoing data for randomised studies, including those that involve multiple sites and when statistically required per protocol, analyse important clinical endpoints such as survival or disease progression.

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.