

## ASX Announcement

### Imugene doses first patient in nextHERIZON Phase 2 clinical trial

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**Sydney, Australia, 8 September 2022:** Imugene Limited (ASX:IMU), a clinical stage immuno-oncology company, is pleased to announce the first patient has been dosed in the nextHERIZON Phase 2 clinical trial investigating Imugene's immunotherapy candidate HER-Vaxx in combination with chemotherapy or pembrolizumab in patients with HER-2+ gastric cancer.

The first patient was dosed at the Queen Elizabeth Hospital in Adelaide, Australia, under the direction of the Principal Investigator Professor Tim Price. Imugene expects to open additional study sites in Australia, as well as the USA under the Food and Drug Administration (FDA) investigational new drug (IND) approval received in December 2021.

Commencement of the trial comes following ethics approval announced on 10 May 2022. The open-label, multi-center, signal generating, Phase 2 clinical trial is designed to assess the safety and efficacy of HER-Vaxx in combination with chemotherapy or pembrolizumab in patients with metastatic HER-2/neu over-expressing gastric or gastroesophageal junction adenocarcinomas, who have previously progressed on trastuzumab. The study's primary endpoints are safety and response rate, while secondary endpoints include duration of response, progression free survival, overall survival, and biomarker evaluation.

Imugene's M.D. & CEO, Ms Leslie Chong said: "Evidence to date has shown the potential to overcome resistance to immunotherapy within GI cancers by increasing cytotoxic and effector immune cells within the tumour microenvironment. Immunotherapies such as HER-Vaxx, particularly in combination with immune checkpoint inhibitors such as pembrolizumab, may hold the solution. With the promising results we've seen from HER-Vaxx thus far, we're particularly eager to take the next step in its development with this trial and ideally improve outcomes for patients with this difficult to treat cancer."

Full details on the study can be viewed at: <https://clinicaltrials.gov/ct2/show/NCT05311176>

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### **About Gastric and Gastro-esophageal Cancer**

Treatment of gastric or gastro-esophageal cancer remains an unmet need for HER-2 positive patients after they have failed trastuzumab. Immune checkpoint inhibitors have been successfully introduced to metastatic gastric cancer. Combining HER-Vaxx with immune checkpoint inhibitors may improve treatment outcomes for patients with this difficult to treat cancer.

### **About HER-Vaxx**

Imugene's HER-Vaxx is a B-cell activating cancer immunotherapy designed to treat tumours that overexpress 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 HER2/neu. It has been shown in pre-clinical studies and in Phase 1 and 2 studies to stimulate a potent polyclonal antibody response to HER-2/neu, a well-known and validated cancer target.

### **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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