



## ASX Announcement

### **Imugene Announces Clinical Trial Collaboration with Merck & Co., Inc., Kenilworth, NJ., USA to Evaluate HER-Vaxx in Combination with Pembrolizumab for Treatment of Gastric Cancer**

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- New clinical trial supply agreement with MSD, a tradename of Merck & Co., Inc., Kenilworth, NJ., USA for Phase 2 clinical study (nextHERIZON) in HER-2 positive gastric or gastroesophageal junction adenocarcinomas
  - nextHERIZON will assess HER-Vaxx in combination with chemotherapy or pembrolizumab in patients with HER-2 positive gastric cancer that have failed trastuzumab

**Sydney, Australia, 15 March 2022:** Imugene (ASX: IMU) today announced a new clinical trial collaboration and supply agreement with MSD, a tradename of Merck & Co., Inc., Kenilworth, NJ, USA, to evaluate the safety and efficacy of Imugene's HER-Vaxx, a B-cell activating immunotherapy, in combination with MSD's anti-PD-1 therapy, pembrolizumab (KEYTRUDA®), in patients with HER-2 positive gastric cancer.

nextHERIZON is an open-label, multi-center, signal generating, Phase 2 clinical trial 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. Secondary endpoints include duration of response, progression free survival, overall survival, and biomarker evaluation.

"Imugene is excited to announce this collaboration with MSD, one of the world's leading immuno-oncology companies. HER-Vaxx has already shown a tolerable safety profile and encouraging efficacy in patients with metastatic HER-2 positive gastric cancer, and we look forward to further evaluating HER-Vaxx with pembrolizumab in a relapsed/refractory metastatic setting," said Leslie Chong, Managing Director & Chief Executive Officer of Imugene. "This collaboration with MSD is significant for our company as it provides the opportunity to optimize and enhance our formulations and utility in an additional setting in an effort to improve outcomes for more patients. We are committed to finding ways to address the unmet needs of patients living with cancer."

Effective immediately, under the terms of the agreement, Imugene will be the sponsor of the study and will fund the clinical study from existing budgets and resources. MSD will provide pembrolizumab for the duration of the study. The agreement is for an indefinite term until final reports of the study have been completed, noting that the underlying study is anticipated to run for at least 24 months. The agreement includes customary termination and intellectual property provisions for a clinical collaboration agreement.



KEYTRUDA® is a registered trademark of Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc., Kenilworth, NJ, USA.

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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 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 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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