ASX Announcement

Imugene Announces Clinical Trial Supply Agreement with Merck KGaA, Darmstadt, Germany and Pfizer to Evaluate HER-Vaxx in Combination with Avelumab for Treatment of Gastric Cancer

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- New clinical trial supply agreement with Merck KGaA, Darmstadt, Germany and Pfizer Inc.
- Avelumab (BAVENCIO®) to be provided to Imugene for Phase 2 clinical study in HER-2 positive gastric or gastroesophageal junction adenocarcinomas (neoHERIZON)
- neoHERIZON will assess HER-Vaxx in combination with chemotherapy with or without avelumab in HER-2 positive gastric cancer

Sydney, Australia, 16 November 2021 AEST – Imugene (ASX: IMU) today announced a new clinical trial supply agreement with Merck KGaA, Darmstadt, Germany (ETR: MRK) and Pfizer Inc. (NYSE: PFE) to evaluate the safety and efficacy of Imugene's HER-Vaxx, a B-cell activating immunotherapy, in combination with avelumab, an immune checkpoint inhibitor targeting PD-L1, in patients with HER-2 positive gastric cancer. Avelumab, which is marketed as BAVENCIO®, is co-developed and co-commercialized by Merck KGaA, Darmstadt, Germany and Pfizer Inc.

neoHERIZON is an open-label, multi-center, randomized, Phase 2 clinical trial designed to assess the safety and efficacy of perioperative HER-Vaxx combined with chemotherapy with or without avelumab compared to chemotherapy alone in patients with HER-2 positive gastric or gastroesophageal junction adenocarcinomas. The study's primary endpoint is pathologic complete response. Secondary endpoints include safety and biomarker evaluation.

"We are very excited for the opportunity to treat patients with this new generation of HER-2 targeted B-cell immunotherapy, which has the potential to address significant unmet need in early HER-2 overexpressing gastric cancer that remains a challenging indication with poor prognosis. The combination of chemotherapy and HER-Vaxx alone or in combination with avelumab in this type of gastric cancer may support a better treatment outcome for patients " said Dirk Arnold M.D., Ph.D., Director of the Asklepios Tumorzentrum in Hamburg.

"Imugene is excited to announce this collaboration with Merck KGaA, Darmstadt, Germany and Pfizer. HER-Vaxx has shown a tolerable safety profile and encouraging efficacy in patients with metastatic HER-2 positive gastric cancer, and we are looking forward to evaluating HER-Vaxx with avelumab in the perioperative clinical setting," said Leslie Chong, Managing Director & Chief Executive Officer of Imugene. "Working together, we're 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. Merck KGaA, Darmstadt, Germany and Pfizer will provide avelumab for the duration of the study.

About Gastric and Gastro-esophageal Cancer

Perioperative (pre- and post-surgery) treatment in gastric or gastro-esophageal cancer remains an unmet need for patients with HER-2 positive tumours. The current standard of care is limited to chemotherapy, radiotherapy, and surgery when gastric cancer is diagnosed in its early stages. Immune checkpoint inhibitors have been successfully introduced to metastatic gastric cancer. Moving HER-Vaxx into earlier gastric cancer in combination with chemotherapy or an immune checkpoint inhibitor may improve treatment outcomes for patients with this difficult to treat cancer.

About HER-Vaxx

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

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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 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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