

ASX Announcement

IMUGENE RECEIVES ETHICS APPROVAL TO START PHASE 2 nextHERIZON CLINICAL TRIAL OF CANCER IMMUNOTHERAPY HER-VAXX

SYDNEY, Australia, 10 May 2022: Imugene Limited (ASX:IMU), a clinical stage immuno-oncology company, today announced it has received Human Research Ethics Committee (HREC) approval to commence a Phase 2 clinical trial of its immunotherapy candidate, HER-Vaxx in Australia.

Ethics approval is confirmation Imugene has completed all the necessary pre-clinical safety and efficacy testing of HER-Vaxx required to commence its nextHERIZON clinical trial in Australia.

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.

The Australian component of the Phase 2 trial will be conducted under Australia's Clinical Trials Notification (CTN) Scheme meaning Imugene will notify the Therapeutic Goods Administration (TGA) of HREC approval and complete local site initiation activities. The first hospital to receive ethics approval is the Queen Elizabeth Hospital, Adelaide Australia under the direction of Principal Investigator Dr Tim Price. Additional clinical sites will be opened in Australia, and also in the US under Food and Drug Administration (FDA) investigational new drug (IND) approval in December 2021.

Imugene MD & CEO Leslie Chong said "The start of our Australian study is a significant milestone for Imugene and clinicians treating Australians faced with the challenge of HER-2+ gastric cancer and we look forward to further evaluating HER-Vaxx in combination with pembrolizumab in a relapsed/refractory metastatic setting."

Full study details can also be found on clinicaltrials.gov under study ID: 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 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 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 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