ASX Announcement

FDA IND APPROVAL FOR THE nextHERIZON PHASE 2 CLINICAL TRIAL OF HER-VAXX

SYDNEY, Australia, 13 December 2021: Imugene Limited (ASX:IMU), a clinical stage immuno-oncology company, is pleased to announce it has received US Food and Drug Administration (FDA) Investigational New Drug (IND) approval to initiate a new phase 2 clinical trial of its immunotherapy candidate, HER-Vaxx.

The FDA approval of the IND, received on 10 December 2021 US EST, allows Imugene to start patient recruitment and dosing for the nextHERIZON study in HER2/neu overexpressing metastatic or advanced adenocarcinoma of the stomach or gastroesophageal junction, also known as Advanced Gastric Cancer (AGC).

The clinical trial is titled "nextHERIZON: An open-label, signal generating, phase 2 study of HER-Vaxx in combination with chemotherapy or pembrolizumab in patients with metastatic HER2/neu over-expressing gastric or gastroesophageal junction (GEJ) adenocarcinomas who have previously received trastuzumab and progressed on this treatment".

To overcome resistance to immunotherapy within GI cancer, one promising strategy is to increase the number of cytotoxic immune cells within the tumour microenvironment (TME) via the use of immunotherapies such as HER-Vaxx. Active immunization with HER-Vaxx has induced high and long-lasting antibody levels and expanded lymphocytes' subpopulations, such as interferon gamma (IFNγ) producing CD4 and CD8 T cells[1].

Therefore, the introduction of HER-Vaxx after first line treatment in patients that have progressed under trastuzumab may overcome potential resistance. Based on pre-clinical data, HER-Vaxx may also synergize with PD-1 targeting immune checkpoint inhibitor pembrolizumab (sold and marketed as KEYTRUDA® by Merck), and therefore serve as a potentially better tolerated and chemotherapy-free treatment opportunity in metastatic patients.

Imugene MD & CEO Leslie Chong said: "Imugene receiving this IND approval for HER-Vaxx from the FDA is another important step forward. To achieve two IND's for our programs (OV and B Cell) concurrently is an outstanding result for the team."

1. *Tobias J, et al. Enhanced and long-term immunogenicity of a Her-2/neu multi-epitope vaccine conjugated to the carrier CRM197 in conjunction with the adjuvant Montanide. BMC Cancer 2017: 118 (2017)*

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About the nextHERIZON study

The study is designed to generate safety data and efficacy signals to support further development of HER-Vaxx in ≥ 2L mGC/GEJ cancer after progression with trastuzumab. All patients must have received trastuzumab and progressed after 1L to be eligible for enrolment. Patients who have received an immune checkpoint inhibitor (ICI) previously will preferentially be enrolled in Arm 1 (HER-Vaxx + chemotherapy). Patients who are naïve to ICI treatment will preferentially be enrolled into Arm 2 (HER-Vaxx + pembrolizumab). Patients who have had chemotherapy-only treatment after progression on trastuzumab (+/- ICI) are considered eligible for this study.

Patients who have received trastuzumab-deruxtecan (Enhertu®) or any other anti-HER2 targeted therapy other than trastuzumab are ineligible.

The study includes two treatment arms that will be analyzed independently using a 2-Stage design:

- Arm 1: 50µg HER-Vaxx in combination with chemotherapy (irinotecan or paclitaxel)
- Arm 2: 50µg HER-Vaxx in combination with pembrolizumab.

Primary Objectives:

- To evaluate the safety and tolerability of HER-Vaxx in combination with chemotherapy (irinotecan or paclitaxel) or pembrolizumab.
- To evaluate the ORR of HER-Vaxx in combination with chemotherapy or pembrolizumab according to RECIST 1.1.

Secondary Objective:

- To evaluate additional efficacy and survival measures (OS, PFS, DoR) of HER-Vaxx in each arm.

Exploratory Objectives:

- To evaluate humoral and cellular immunogenicity data of HER-Vaxx plus chemotherapy (irinotecan or paclitaxel) or pembrolizumab.
- To evaluate arm-specific associations of immunogenicity and biochemical markers of tumour progression to clinical outcomes of ORR, OS, PFS, and DoR.

- To evaluate arm-specific associations between clinical outcome and HER2/neu, PD-L1 and PD-1 expression.

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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