ASX Announcement

Imugene Completes Phase 1b Cancer Vaccine Trial Recruitment

SYDNEY, Australia, 11 September 2018 – Imugene Limited (ASX:IMU), a clinical stage immuno-oncology company today announced the Phase 1b clinical trial of its HER-Vaxx cancer vaccine in HER-2 gastric cancer patients had completed recruitment.

The ongoing Phase 1b lead-in trial is testing three different doses of HER-Vaxx (IMU-131) in combination with current standard of care chemotherapy Cisplatin and either Fluorouracil or Capecitabine.

Imugene Managing Director and Chief Executive Officer Leslie Chong said, “Clinicians at the trial sites observed no toxicities and report all vaccinated patients developed immune responses and antibodies to the HER-2 protein which encourages cancer growth. We look forward to reporting on further milestones and completing the analysis in the coming months.”

“Completion of recruitment is an important milestone for the study and the many medical professionals seeking treatments for patients with advanced gastric cancer who often have very few medical options.”

Imugene’s HER-Vaxx is designed to produce a strong antibody response against a cancer growth signal receptor protein called HER-2 which is found on the cell surface in breast and gastric cancers.

The sequential dose escalation study in three groups of patients is designed to evaluate the safety, tolerability, immunology and clinical activity of HER-Vaxx in combination with standard of care chemotherapy and establish the optimal dose for a larger Phase 2 study.

Additional patients will be added to the third cohort until the current evaluable patients have safely passed the dose limiting toxicity window.

A cohort review committee will determine the recommended Phase 2 study dose. Activities for Phase 2 preparation has already commenced.

The Phase 2 study will test the efficacy, safety and immune response of the selected dose in 68 gastric cancer patients with metastatic gastric cancer overexpressing the HER-2 protein.

The Phase 2 study will be randomised into two arms of either HER-Vaxx plus standard-of-care (chemotherapy) or standard-of-care alone. Endpoints will be progression-free survival and overall survival.

Imugene is conducting the trials in Asia and Eastern Europe where clinicians and patients have difficulty accessing expensive antibody treatments such as Herceptin and Perjeta marketed by Swiss multinational Roche Holding AG.

Details of the study are sumarised in the attached Appendix.

Study details can also be found on clinical trials.gov under study ID: NCT02795988

For further information please contact:

Leslie Chong
Managing Director and Chief Executive Officer
T: +61 458 040 433
Follow us on Twitter @ TeamImugene

Appendix

ClinicalTrials.gov ID:	NCT02795988
Name of Trial:	A Study of IMU-131 Plus Standard of Care Chemotherapy in Patients with HER2/Neu Overexpressing Advanced Cancer of the Stomach.
Primary endpoints:	Safety, tolerability, immunogenicity and recommended phase 2 dose (RP2D) of IMU-131.
Blinding status:	Open label
Treatment method:	Three arms of low, mid and high dose of IMU-131 (10µg / 30µg / 50µg) plus Cisplatin and either Fluorouracil (5-FU) or Capecitabine chemotherapy.
Standard of care Chemotherapy to include:	Cisplatin IV on day 14, then every 21 days. Either 5-FU administered per day as continuous infusion for 96 hours on days 14, 17 and then every 21 days or Capecitabine for 14 days orally (twice daily) on days 14 to 27, then every 21 days.
Number of trial subjects:	18 (Phase 1b), followed by 68 (Phase 2).
Control group:	Standard of care drugs: Cisplatin and either Fluorouracil (5-FU) or Capecitabine.
Selection criteria:	Patients with metastatic gastric of GEJ adenocarcinoma aged over 20 years with no prior chemotherapy or radiotherapy for advanced gastric cancer within 6 months.
Trial locations:	Asia and Eastern Europe

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 technology seeks to harness the body's immune system to generate antibodies against tumours, potentially achieving a similar or greater effect than synthetically manufactured monoclonal antibody therapies. Our product pipeline includes multiple immunotherapy B-cell vaccine candidates aimed at treating a variety of cancers in combination with standard of care drugs and emerging immunotherapies. 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 a foundation treatment for cancer. Our goal is to ensure that Imugene and its shareholders are at the forefront of this rapidly growing global market.