ASX Announcement

Imugene Advances to Phase 2 in Gastric Cancer Immuno-oncology Trial

- Phase 1b study objectives met; all dose levels showed increased antibody levels in all patients
- Phase 2 study on track to start early 2019
- Dose level confirmed for Phase 2 with no safety issues reported
- Phase 2 manufacturing of HER-Vaxx completed
- Topline Phase 1b results expected December 2018

SYDNEY, Australia, 13 November 2018: Imugene Limited (ASX:IMU), a clinical stage immuno-oncology company today announced preparations were underway to begin the Phase 2 study of its HER-Vaxx cancer vaccine in gastric cancer patients in early 2019 after completing the Phase 1b study.

A Phase 1b lead-in study tested three doses of HER-Vaxx (IMU-131) in combination with current standard of care chemotherapy (Cisplatin and Fluorouracil or Capecitabine).

Medical researchers observed no safety issues and showed increase of antibody levels at all dose levels and the study Cohort Review Committee (CRC) selected the recommended Phase 2 dose (RP2D).

Imugene's Managing Director and Chief Executive Officer Leslie Chong said, "Clinicians at the trial sites observed no vaccine-related toxicities at any of the three doses. We are encouraged by the fact that all vaccinated patients developed increased antibody levels to the HER-2 target protein.

"We look forward to reporting the top-line results before the end of the year and starting the Phase 2 randomised trial early in 2019."

"Completion of the Phase 1b dose escalating trial and start of the Phase 2 study are important milestones for Imugene and the many medical professionals seeking treatments for patients with advanced gastric cancer who often have very few medical options."

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

The sequential dose escalation study in three groups of patients was 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.

Activities for Phase 2 preparation have already commenced. A new clinical batch of HER-Vaxx has been manufactured, delivered and is waiting in storage for distribution to study sites.

The Phase 2 study will test the efficacy, safety and immune response 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. The primary endpoint is overall survival and secondary endpoint will be progression-free survival.

The Phase 2 trial will be conducted at sites across Asia, Eastern Europe and India where clinicians and patients have difficulty accessing treatments such as Herceptin® and Perjeta® marketed by Swiss multinational Roche Holding AG. There is also a high prevalence of gastric cancer in many of the countries selcted. Details are summarised in the attached Appendix.

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

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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:	Phase 1B: Safety, tolerability, immunogenicity and recommended phase 2 dose (RP2D) of IMU-131. Phase 2: Primary Endpoint Overall Survival; Secondary Endpoint Progression Free Survival, safety, tolerability and immunogenicity.
Blinding status:	Open label
Treatment method:	Phase 1B: Three arms of low, mid and high dose of IMU-131 (10µg / 30µg / 50µg) plus Cisplatin and either Fluorouracil (5-FU) or Capecitabine chemotherapy. Phase 2: Randomised two arms of either HER-Vaxx plus standard-of-care (chemotherapy) or standard-of-care alone.
Standard of care chemotherapy to include:	Cisplatin IV on day 1 of each cycle with either 5-FU administered per day as continuous infusion for 96 hours on days 1 – 4 of each cycle or capecitabine for 14 days orally (twice daily) on days 1 – 14 of each cycle . Or oxaliplatin IV on day 1 of each cycle and capecitabine for 14 days orally (twice daily) on days 1 – 14 of each cycle.
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, or oxaliplatin and 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 3 months.
Trial locations:	South East Asia, Eastern Europe and India.

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.