ASX Announcement

Imugene Meets Endpoints in Phase 1b Gastric Cancer Immuno-oncology Trial

- Safety, tolerability & phase 2 dose determined
- Phase 2 trial first patient to be dosed early 2019
- 5 patients with partial responses[1]
- 4 patients with stable disease[2]

SYDNEY, Australia, 17 December 2018: Imugene Limited (ASX:IMU), a clinical stage immuno-oncology company, today announced meeting study endpoints and positive top-line results from the Phase 1b study of its HER-Vaxx gastric cancer vaccine in patients expressing the HER2 target protein.

The 14 patient study tested three dose levels of HER-Vaxx (10, 30 and 50 micrograms) in combination with current standard of care chemotherapy, cisplatin and fluorouracil or capecitabine. All dose levels showed an increased antibody response in patients.

No safety issues were reported and HER-Vaxx was found to be well tolerated.

The study Cohort Review Committee recommended a dose of 50 micrograms for the Phase 2 dose based on the safety and immunogenicity data.

Response rate is an exploratory endpoint in the Phase 1b study; of the 10 patients evaluable[3] for tumour growth assessment during the study, 5 patients showed partial response (PR) and 4 patients showed stable disease (SD) for their best overall response.

Imugene Managing Director and Chief Executive Officer Leslie Chong said, "We would like to sincerely thank the medical researchers and patients who participated in this study. Together we are cautiously encouraged by meeting all the endponts of the study and data from the top-line results in a small sample size, in particular the five patients whose best response showed more than 30% decrease in their tumour size from baseline scans."

"With these early results from the HER-Vaxx clinical study, Imugene's B-cell active immunotherapy approach is showing positive signs which provides us with further confidence in our B-cell immunotherapy pipeline. This is a promising milestone for Imugene and the many medical

[1] Partial tumour response (RECIST 1.1) is a reduction in the total tumour burden by greater than 30%.
[2] Stable disease (RECIST 1.1) is when the total tumour burden that increases less than 20% or decreases less than 30%.
[3] Evaluable patients are those on study at the Day 56 tumour assessment visit.

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 which is found on the cell surface in breast and gastric cancers.

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

The three primary endpoints for the Phase 1 study were safety and tolerability and identification of the optimal dose of the HER-Vaxx cancer vaccine for a Phase 2 study based on data collected over the first eight weeks of treatment.

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 study will be conducted at sites across Asia, Eastern Europe and India where treatments such as Herceptin® and Perjeta® are not readily available to patients. There is also a high prevalence of gastric cancer in many of the countries selected. Details of the study 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 tumours. 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.