Imugene Commences HER-Vaxx Phase 1b/2 Gastric Cancer Study

- **Imugene to begin recruiting patients in Phase 1b/2 study across 8 trial sites.**
- **Principal Investigators include: Dr Thomas Yau of Hong Kong; Dr Wirote Lausoontornsiri, Dr Arunee Dechaphunkul, Dr Jedzada Maneechavakajorn, Dr Suebpong Tansanvimon and Dr Chaiyut Charoentum of Thailand; Dr Yee Chao and Dr Chia-Jui Yen of Taiwan.**
- **HER-Vaxx utilises B cell peptides and may enable improved efficacy at a lower cost in the predicted US$36 billion immunotherapy market.**

November 7, 2016: Imugene Limited (ASX: IMU), an immuno-oncology company is pleased to announce the commencement of a Phase 1b/2 clinical study of its HER-Vaxx therapy in gastric cancer.

HER-Vaxx is a next generation HER-2 cancer therapy using B cell peptides, which harness the body's ability to develop antibodies against the disease. Gastric cancer patients will now be screened and enrolled at eight key cancer hospital sites in Asia, including Hong Kong, Thailand and Taiwan.

The Phase 1b/2 study will be conducted in two parts. Phase Ib is an open-label, multicentre dose escalation study, designed to assess the safety, tolerability and immunogenicity (which will show how well the vaccine is directing production of HER2 antibodies in patients). The trial will enrol up to 18 patients, who will be treated with HER-Vaxx in combination with chemotherapy to interrogate three dose levels. This stage will also evaluate the booster schedule to help determine optimal recommended dosing for Phase 2.

The larger open label Phase 2 study will recruit 68 patients with metastatic gastric cancer overexpressing HER2. This study will be randomised into two arms of either HER-Vaxx plus standard-of-care (chemotherapy) or standard-of-care alone.

HER-Vaxx works by targeting the same receptor (and additional receptors) as Herceptin and Perjeta, two of the leading antibody drugs on market, with annual sales of US$8.2 billion.[1] Current immunotherapies are predicted to generate sales of US$36 billion by 2025[2] but cost remain prohibitive for patients. The mechanism of action for HER-Vaxx may help generate improved efficacy over existing treatments and at a lower cost.

Since completion of Phase 1, Imugene has optimised the formulation of HER-Vaxx, enhancing the vaccine's potency ten-fold, enabling a faster immune response and lowering the cost of goods.

Imugene's Chief Operating Officer, Leslie Chong said, "This is a significant milestone for Imugene and gastric cancer patients, especially across South East Asia. Accomplishing this goal speaks to the perseverance and dedication of Imugene's team as we continue to build on our significant clinical and commercial potential."

Gastric cancer is a leading cause of cancer death worldwide, representing 10.1% of male cases[3]. Incidence of gastric cancer is substantially higher in Asia and there is difficulty in accessing current treatments.

"We are confident that HER-Vaxx could fill a significant unmet medical need in gastric cancer, particularly in Asia," commented Ms. Chong.

For further information please contact:

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Phase Ib/2 Clinical Trial details

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: 3 arms of low, mid and high dose of IMU-131 (10µg / 30µg / 50µg) plus Cisplatin and either Fluorouracil (5-FU) or Capecitabine.
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. Full criteria via link below.
Trial locations: 8 trial locations in Hong Kong, Thailand and Taiwan.
Principal Investigators:
Dr Thomas Yau (Hong Kong), Dr Wirote Lausoontornsiri, Dr Arunee Dechauphunkul, Dr Jedzada Maneechavakajorn, Dr Suebpong Tansanvimon, Dr Chaiyut Charoentum (Thailand), Dr Yee Chao, Dr Chia-Jui Yen (Taiwan)
Expected duration: Phase 1b – 12 months

Full trial details are available via the link below under the identifier number: NCT02795988
Link: https://clinicaltrials.gov/show/NCT02795988 (RECRUITING)

Sources:
1 $USD Source: Roche Finance Report 2015. http://www.roche.com/dam/jcr:74af99eb-b51a-4f13-88b2-aacaf9f53c0c/en/fb15e.pdf
2 Citigroup research note, as reported in http://www.immunotherapyforum.com/blog/deals-in-2015-infographics
3 GLOBOCAN, 2012. Estimated Cancer Incidence, Mortality and Prevalence Worldwide in 2012.

About Imugene (ASX:IMU)

Imugene (ASX:IMU) is a clinical stage immuno-oncology company headquartered in Melbourne, Australia. Its lead product is HER-Vaxx, a B Cell peptide vaccine for the treatment of gastric cancer. The company is also developing mimotope-based immunotherapies against validated and new oncology targets.

HER-Vaxx is a cancer immunotherapy designed to treat tumours that over-express the HER-2/neu receptor, such as gastric, breast, ovarian, lung and pancreatic cancers. Developed by leading scientists at the Medical University of Vienna in Austria, the peptide vaccine is constructed from several B cell epitopes of HER-2/neu. It has been shown in pre-clinical studies and in one Phase I study to stimulate a potent polyclonal antibody response to HER-2/neu, a well-known and validated cancer target.

Imugene in partnership with the Medical University of Vienna is working to discover and develop mimotope-based immunotherapies against validated and new oncology targets. This partnership has the potential to create game-changing B Cell peptide vaccines that would replace or augment conventional monoclonal antibody therapies.