

## **Imugene commences first patient dosing of HER-Vaxx Phase 1b/2 Gastric Cancer Study**

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- **Imugene has successfully commenced first patient dosing**
- **All 8 clinical sites actively recruiting**
- **Trial provides early validation of HER-Vaxx potential for treatment of gastric cancer**

**MELBOURNE Australia 31 August 2017:** Imugene Limited (ASX: IMU), an immuno-oncology company is pleased to announce it has commenced first patient dosing of the Phase 1b/2 clinical study of its HER-Vaxx immunotherapy in gastric cancer. Patients are currently being enrolled at eight key cancer hospital sites in Asia, including Hong Kong, Thailand and Taiwan.

Imugene is testing a therapeutic anti-cancer vaccine called HER-Vaxx, in HER2+ gastric cancer patients.

Principal investigator, Univ. Professor Dr. Dr.h.c. Christoph Zielinski and Chairman, Clinical Division of Oncology and Department of Medicine at the Medical University Vienna stated, "Our team is excited to be part of this important study and the search for effective new treatments for gastric cancer as there are limited options for patients."

Imugene Chief Executive Officer, Leslie Chong said, "The successful start of this study represents an important development milestone for our business and medical professionals seeking new ways to treat patients with gastric cancer."

HER-Vaxx is designed to produce a strong antibody response against a growth signal receptor protein called HER2 which is found on the cell surface in gastric cancers.

The study is being conducted in Asian countries where there are high rates of gastric cancer and where patients have difficulty accessing expensive antibody treatments such as Herceptin and Perjeta.

Based on preclinical data recently published<sup>1</sup>, Imugene believes HER-Vaxx will stimulate a rapid and strong immune response against cancerous cells.

The Phase 1b lead-in trial is testing three different doses of the HER-Vaxx vaccine with up to 18 patients (three groups up to six patients) in combination with chemotherapy across eight trial sites.

The key endpoints are to identify the optimal dose of HER-Vaxx for the Phase II part of the study, and confirm safety. Researchers will monitor the patient's immune responses to the vaccine.

The current study will be followed by a randomised open label Phase II study with around 68 patients with metastatic gastric cancer overexpressing HER2. The study will be randomised into two arms of either HER-Vaxx plus standard-of-care (chemotherapy) or standard-of-care alone.

The endpoints of this randomised trial will be safety, immune response, progression-free survival and overall survival.

For further information please contact:

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[1] Joshua Tobias, Joanna Jasinska, Karin Baier, Michael Kundi, Nicholas Ede, Christoph Zielinski, Ursula Wiedermann, *Enhanced and long term humoral and cellular immunogenicity of a Her-2/neu hybrid-CRM197 peptide vaccine, using the Th1-driving adjuvant Montanide*, BMC cancer, 2017, **17**, 118 [click here](#) to view.

#### 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.

Imugene is also building a pipeline of small molecule immuno-oncology drugs which modulate the bioavailability of arginine in the tumour microenvironment. Arginine is a critical amino acid for the health of cancer fighting T-cells and depletion of it limits the effectiveness of T-cells to fight tumours.

## Appendix

<b>ClinicalTrials.gov ID:</b>	NCT02795988
<b>Name of Trial:</b>	A Study of IMU-131 Plus Standard of Care Chemotherapy in Patients with HER2/Neu Overexpressing Advanced Cancer of the Stomach.
<b>Primary endpoints:</b>	Safety, tolerability, immunogenicity and recommended phase 2 dose (RP2D) of IMU-131.
<b>Blinding status:</b>	Open label
<b>Treatment method:</b>	Three arms of low, mid and high dose of IMU-131 (10µg / 30µg / 50µg) plus Cisplatin and either Fluorouracil (5-FU) or Capecitabine.
<b>Standard of care Chemotherapy to include:</b>	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.
<b>Number of trial subjects:</b>	18 (Phase 1b), followed by 68 (Phase 2).
<b>Control group:</b>	Standard of care drugs: Cisplatin and either Fluorouracil (5-FU) or Capecitabine.
<b>Selection criteria:</b>	Patients with metastatic gastric of GEJ adenocarcinoma aged over 20 years with no prior chemotherapy or radiotherapy for advanced gastric cancer within 6 months.
<b>Trial locations:</b>	Eight locations in Hong Kong, Thailand and Taiwan.
<b>Principal Investigators:</b>	Dr Thomas Yau (Hong Kong), Dr Wirote Lausoontornsiri, Dr Arunee Dechauphunkul, Dr Jedzada Maneechavakajorn, Dr Suebpong Tansanvimon, Dr Chaiyut Charoentum (Thailand), Dr Yee Chao and Dr Chia-Jui Yen (Taiwan)