

Imugene Receives Institutional Review Board approval from the University of Hong Kong for HER-Vaxx Phase 1b/2 Study in Gastric Cancer

- **University of Hong Kong Institutional Review Board Approves Imugene's HER-Vaxx Phase 1b/2 Study in Gastric Cancer.**
- **This follows submissions for all sites' Ethics Committee Review applications.**
- **Principal Investigators include Dr Thomas Yau of Hong Kong; Dr Wirote Lausontornsiri, 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.**

Melbourne, Australia, 11 July 2016: Imugene Limited (ASX: IMU), a clinical stage immuno-oncology company, is pleased to announce that it has received approval from the Institutional Review Board from the University of Hong Kong for the Phase 1b/2 study of its HER-Vaxx immuno-oncology therapy in gastric cancer.

This approval from the Ethics Committee positions Imugene to enrol patients in the Phase 1b/2 in HER2 positive gastric cancer study within the coming months. Completing this major milestone underscores HER-Vaxx re-entry into the clinic with the Phase 1b/2 in HER2 positive gastric cancer study, which represents an area of high unmet medical need, particularly in Asia.

The proposed HER-Vaxx Phase 1b/2 will be conducted in two parts. The initial Phase 1b will enrol up to 18 patients to be treated with HER-Vaxx in combination with chemotherapy to interrogate three dose levels. This first stage will provide safety data, immunogenicity data (a measure of how many of the HER2 antibodies are produced), evaluate the booster schedule and determine the optimal dose to take into the Phase 2 study or recommended Phase 2 dose (RP2D). The larger open label Phase 2 study will recruit around 68 patients randomised into two arms of either HER-Vaxx plus standard-of-care or standard-of-care alone.

Imugene's Chief Operating Officer, Leslie Chong states, "This significant milestone and achievement puts us on track to provide much needed therapy to our patients and to obtain valuable data for Imugene. I am thankful for my clinical development team on their achievement and dedication for the successful re-entry of Her-Vaxx into the clinic in 2016".

"I am also pleased to announce that our study is now listed on ClinicalTrials.gov."

Identifier: NCT02795988

Link: <https://clinicaltrials.gov/show/NCT02795988>

Hong Kong University's Dr Yau welcomes the study at his clinic and reiterates that, "In Asia HER2 positive gastric cancer represents a considerable area of unmet medical need not just because of disease incidence but also due to cost and availability issues surrounding the anti-HER2 monoclonal antibody drugs. For Hong Kong there were around 1,100 new gastric cancer cases last year, representing a high relative frequency. I welcome the opportunity to bring this new immuno-oncology therapy to HER2 positive gastric cancer patients to Hong Kong", Dr Yau stated.

About Imugene

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. This unique immunotherapy, developed by leading scientists at the Medical University of Vienna in Austria, is a peptide vaccine constructed from various B cell epitopes of HER-2/neu. It has been shown in pre-clinical work and in one Phase 1 study to stimulate a potent polyclonal antibody response to HER-2/neu, a well-known and validated cancer target. HER-Vaxx's successful Phase 1 study was in patients with breast cancer and the next stage of development will be a Phase 1b/2 study in patients with gastric cancer initiating in 2016.

In January 2016 Imugene announced a new partnership with the Medical University of Vienna 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 antibodies.

For further information, please visit www.imugene.com.

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