

## Imugene Completes Submission to Hospital Ethics Committees for HER-Vaxx Phase 1b/2 Study in Gastric Cancer

- **Ethics Committee Review applications for ALL study sites have been submitted.**
- **This follows the first regulatory package submission for the study in Hong Kong in April.**
- **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, 30 May 2016:** Imugene Limited (ASX: IMU), a clinical stage immuno-oncology company, is pleased to announce that it has completed all Ethics Committee submissions for the eight study sites participating in the initial Phase 1b portion of the upcoming Phase 1b/2 study of its HER-Vaxx immuno-oncology therapy in gastric cancer. These submissions were made in conjunction with Novotech, Imugene's Contract Research Organisation for the study.

These filings represent the conclusion of the Ethics Committee submission phase of the study and position Imugene to enrol patients in the Phase 1b/2 in HER2 positive gastric cancer study within the coming months. Completing this major milestone underpins 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, hails this milestone as a significant achievement in the clinical development of HER-Vaxx. "Within my experience of developing numerous world class oncology medicines it is truly remarkable to have all our sites' Ethics Committee review applications completed and submitted within 7 weeks of finalising the study protocol. Reaching this major milestone so efficiently demonstrates the calibre of Imugene's clinical development team and strategically places us well for a successful re-entry of Her-Vaxx into the clinic in 2016".

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.

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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.

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