

Imugene submits regulatory package for HER-Vaxx Phase 1b/2 study in gastric cancer

- **Imugene initiates Phase 1b/2 gastric cancer clinical trial**
- **First regulatory package submission made in Hong Kong**
- **Regulatory filings in other jurisdictions to follow in the next two months**
- **Dr Thomas Yau of Hong Kong University will be a Principal Investigator**

Melbourne, Australia, 21 April 2016: Imugene Limited (ASX: IMU), a clinical stage immuno-oncology company, is pleased to announce that it has made a regulatory package submission for a Phase 1b/2 study of its novel HER-Vaxx immuno-oncology therapy in gastric cancer. In conjunction with Novotech, Imugene's Contract Research Organisation for the study, the company has filed to initiate the study with the Department of Health of Hong Kong.

This filing represents the first of many submissions to various regulators across Asia to initiate clinical testing of Imugene's HER-Vaxx therapy, given the high unmet need in this area for patients who have HER2 positive gastric cancer.

The proposed HER-Vaxx Phase 1b/2 study 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 is simply to obtain safety, immunogenicity (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 enrol around 68 patients randomised into two arms of either HER-Vaxx plus standard-of-care or standard-of-care alone. Imugene has identified eight study sites in Asia to participate in the Phase 1b part of the study.

For our Hong Kong site, Imugene is pleased to announce that the Principal Investigator will be Dr Thomas Yau, one of Hong Kong's leading medical oncologists, whose main research priority is gastrointestinal oncology. Dr Yau has worked at Queen Mary Hospital in Hong Kong, the Royal Marsden Hospital in London and Massachusetts General Hospital in Boston. He has an extensive publication record with more than 100 peer-reviewed publications in various leading journals including *Lancet Oncology* and *Clinical Cancer Research*.

Hong Kong University's Dr Yau welcomes the study at his clinic. '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 in Hong Kong', said Dr Yau.

Professor Christoph Zielinski, a member of Imugene's science advisory board, said the Hong Kong application is an important step for the clinical development of HER-Vaxx.

'This will be the first of many regulatory and ethics review submissions for the HER-Vaxx program, thanks largely to the dedicated and diligent work of Imugene in strong partnership with investigators of the Medical University of Vienna who were largely responsible for the development of the compound,' said Prof Zielinski, who is Director of the Clinical Division of Oncology and Chairman of the Department of Medicine at the Medical University Vienna, Austria and president of the Central European Cooperative Oncology Group (CECOG).

'Since inventing HER-Vaxx some years ago and our continued work to optimize it, we are thrilled to take this step forward to advance this important B-cell-based treatment of cancers.'

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.

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