

## **Imugene marks new milestones in preparation for HER-Vaxx clinical trial**

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- **Clinical trial protocol finalised for 2015 Phase Ib/II clinical trial**
- **Preclinical studies confirmed for FDA IND submission; nonclinical CRO appointed**
- **CRO appointment to manage clinical trial expected 1H 2015**

Melbourne, 30 December 2014: Australian immuno-oncology company Imugene Limited (ASX:IMU) has met two more important milestones in preparing for the initiation of its 2015 HER-Vaxx clinical program.

The clinical protocol for the Phase Ib/II clinical trial of HER-Vaxx in patients with gastric cancer has been substantially finalised. The trial is set to commence in 2015 and will be titled "A Phase 1b/2, Randomized, Double-Blind, Placebo-Controlled Comparison of IMU-131 HER2/neu Peptide Vaccine Plus Cisplatin and either Capecitabine or 5-Fluorouracil Chemotherapy in Patients with HER2/neu Overexpressing Metastatic or Advanced Adenocarcinoma of the Stomach or Gastroesophageal Junction."

Imugene Chief Executive Charles Walker said "This represents another milestone passed and emphasises Imugene's focus to conduct the kind of efficient, high quality Phase II trial that pharmaceutical companies prefer to see. The next step is to appoint an internationally regarded CRO in 1H 2015 to efficiently manage the clinical trial. The trial remains on track to start in the second half of next year."

In addition to the finalisation of the clinical protocol, Imugene has appointed respected US nonclinical CRO WIL Research to conduct important FDA IND enabling preclinical studies to support the clinical trial planned by the company. WIL Research was appointed after a competitive tender process and is a global CRO that provides a range of premium discovery support services, product safety toxicological research, analytical chemistry and formulation services. It has over 1,200 employees across world-class facilities in the US, Netherlands, France and Japan.

IMU-131 (HER-Vaxx) is a proprietary therapeutic cancer immunotherapy that stimulates a polyclonal antibody response to HER-2/neu, the same biomarker targeted by the \$US6.4 billion per annum drug Herceptin®.

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About Imugene: Imugene (ASX; IMU) is an immuno-oncology biopharmaceutical company developing HER2 positive gastric and breast cancer immunotherapies. The Company's lead product is HER-Vaxx, a proprietary HER2 positive cancer immunotherapy that stimulates a polyclonal antibody response to HER-2/neu. HER-2/neu is a known and validated receptor over-expressed on various tumours including gastric, breast, ovarian, lung and pancreatic cancers. HER-Vaxx has successfully completed a Phase I study in patients with breast cancer and the next stage of development will be a Phase Ib/II study in patients with gastric cancer. Imugene's corporate headquarters are located in Melbourne, Australia with the scientific team in Vienna, Austria.