

## **Novotech appointed Contract Research Organisation for upcoming Phase 1b/2 study of HER-Vaxx in gastric cancer**

---

- **Imugene's clinical review for HER-Vaxx is now complete**
- **HER-Vaxx Phase 1b/2 in gastric cancer to start in 2016 under an IND**
- **Trial design largely completed with focus on Asia**
- **Imugene to benefit from Novotech's oncology and regional expertise**

**Melbourne, Australia, 14 December 2015:** Imugene Limited (ASX: IMU), a clinical stage immuno-oncology company, has appointed Novotech as the lead Contract Research Organisation (CRO) for its upcoming Phase 1b/2 trial of HER-Vaxx in gastric cancer.

Novotech, based in Sydney, Australia, is a leading full-service CRO with a special focus on the Asia-Pacific region. It will bring to the HER-Vaxx study a significant network of investigator relationships in Asia. Its reputation, built over many years, is based on serving small to mid-stage biotech companies like Imugene as well as established pharmaceutical companies.

The start-up activity for the HER-Vaxx Phase 1b/2 study in gastric cancer is well underway and clinical commencement is expected in the first half of 2016. Under Novotech's auspices, Imugene's investigators will recruit patients with HER-2-positive gastric cancer at a number of leading cancer centres in Asia.

The study will be conducted in two parts. The initial Phase 1b will be an open-label dose escalation study designed to evaluate the safety as well as the pharmacokinetics of HER-Vaxx and help select the optimal dose, that is, the Recommended Phase 2 Dose (RP2D). The larger Phase 2 study will be a randomised controlled study of HER-Vaxx plus standard-of-care against standard-of-care alone.

The trial design and protocol is largely completed and an IND with the US FDA is planned for early 2016. The details of the study will be published on [clinicaltrials.gov](http://clinicaltrials.gov) in due course. Manufacturing is on track to deliver clinical doses of Her-Vaxx well ahead of trial commencement.

The Phase 1b/2 study in gastric cancer will represent HER-Vaxx's return to the clinic after a successful Phase 1 study in breast cancer indicated the potency of the HER-Vaxx approach in the induction of an anti-cancer antibody response<sup>1</sup>. The upcoming study will benefit from a new formulation where preclinical immunology studies conducted by Professor Ursula Wiedermann, Imugene's Chief Scientific Officer, continue to produce encouraging results with stronger antibody responses.

Imugene had previously indicated that it intended to take HER-Vaxx into the clinic in Australia and Eastern Europe. After full audit of the clinical plans conducted over the last three months Imugene's board and senior management have now come to the view that Asia is the ideal place to study HER-Vaxx in gastric cancer given the incidence of the disease and the availability issues around existing anti-HER2 drugs in the region. Imugene believes that its new approach, with Novotech's help, will lead to a more relevant study outcome.

---

<sup>1</sup> Breast Cancer Res Treat. 2010 Feb;119(3):673-83.

Leslie Chong, Chief Operating Officer of Imugene, commented, "I have been involved in the design and execution of multiple clinical studies in cancer throughout my career, and I have been impressed with the effort and professionalism that the Novotech team put forth in their proposal for the HER-Vaxx study. I look forward to working with Novotech's professionals in this ground-breaking study."

Alek Safarian, founder and CEO of Novotech, said 'Our company has been actively involved in hundreds of drug development programs for US and EU registration across all clinical trial phases and therapeutic areas. Earlier in 2015 Frost & Sullivan awarded Novotech its CRO Best Practice Award for the third time in recent years. We feel very confident that we can deliver for Imugene's investigators in this upcoming study'.

### **About Imugene and HER-Vaxx**

Imugene (ASX: IMU) is a clinical stage immuno-oncology company headquartered in Melbourne, Australia. Imugene's lead product is HER-Vaxx, 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 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. For further information, please visit [www.imugene.com](http://www.imugene.com). Sign up to follow @TeamImugene on Twitter at <http://www.twitter.com/TeamImugene>.

### **About Novotech**

Established in 1996 and headquartered in Sydney, Novotech is focused on the Asia-Pacific region, running clinical trials in key regional markets including Mainland China, India, the Philippines, Singapore, Malaysia, Thailand, Taiwan, Korea, Australia and New Zealand, and it also operates in South Africa. Novotech also has worldwide reach through the company's network of strategic partners. For more information, please visit [www.novotech-cro.com](http://www.novotech-cro.com).

### **For further information please contact:**

#### **Imugene:**

Leslie Chong, Chief Operating Officer  
Tel: +61 458 040 433 (Australia), [leslie.chong\[at\]imugene.com](mailto:leslie.chong[at]imugene.com)

Paul Hopper, Executive Chairman  
Tel: +61 406 671 515 (Australia), [receptogen\[at\]earthlink.net](mailto:receptogen[at]earthlink.net)

#### **Media:**

Rudi Michelson, Monsoon Communications  
Tel: +61 3 9620 3333, [rudim\[at\]monsoon.com.au](mailto:rudim[at]monsoon.com.au)