

HER-Vaxx Re-Formulation Shows Dramatic Ten-Fold Increase in Antibodies and Early Onset Of Response; Additional Milestone Met

- **Notably faster and stronger immune response**
- **New patent filed to extend coverage to 2036**
- **Improved manufacturing - cheaper, simpler and more reliable to make**
- **Clinical program on track**

Melbourne, April 20 2015: Imugene Limited (ASX:IMU), a clinical stage immuno-oncology company developing HER-2 positive gastric and breast cancer immunotherapies, announces today that Imugene's lead candidate HER-Vaxx has demonstrated a powerful increase in the production of cancer fighting antibodies in preclinical animal model testing. This new formulation shows responses that are up to ten times those produced in previous formulations, and importantly also shows a convincing shortening in the time taken for the immune system to respond to HER-Vaxx.

This success is a result of preclinical immunologic results scheduled for reporting in 1H 2015, the initiation of which were announced in September 2014. The work has been conducted by the research team at the Medical University of Vienna under the direction of Professor Dr Ursula Wiedermann, principal investigator for the preclinical development of HER-Vaxx, and member of the Imugene Scientific Advisory Board. The enhanced formulation of HER-Vaxx incorporates an existing, clinically and commercially validated vaccine carrier protein called CRM₁₉₇ together with an adjuvant. CRM₁₉₇ replaces the virosomes used in previous formulations of HER-Vaxx.

The experiments indicate a potentially lower dose, and a fewer number of immunisations could be required for a better clinical outcome than with the previous virosome-based formulation of HER-Vaxx.

Of importance from a clinical perspective, based on the immunogenicity results against extracellular HER-2/neu, there was a clear difference in the kinetics of antibody responses in the course of immunisations, showing that the reformulated HER-Vaxx leads to earlier antibody increases (significant after 2 immunizations, with a peak response observed after 3 immunizations), compared with the earlier virosome-based formulation of HER-Vaxx. HER-Vaxx stimulates a polyclonal antibody response to HER-2/neu, the oncogene which is targeted by the currently used monoclonal antibody Herceptin®.

Further, on Friday 17th April, the Company filed new patent applications around the new formulation for major jurisdictions. When granted, these would reset Imugene's intellectual property ownership to 2036 from the current expiry of 2030 and also extend geographical coverage.

Mr. Charles Walker, Managing Director of Imugene, remarked, "The re-formulation represents not only the achievement of another milestone, but also a very significant technical improvement given the greatly improved cancer-fighting antibody production and, as important, the significantly improved response time based on animal model testing. The kinetics, or speed of response, has been a reason why some vaccines have failed in the past and it is greatly encouraging to see this element addressed. We will utilize this formulation in the Phase 1b/2 trial in HER-2 positive gastric cancer that is on track to commence in the second half of 2015."

“As a result of this significant advance, we have further de-risked the asset given the lower cost, simpler manufacturing process and potentially extended the patent life based on recently filed applications. I commend the significant efforts of our scientific team in Vienna and in Australia.”

Professor Dr Ursula Wiedermann, said “It is pleasing to see a simple formulation change optimise HER-Vaxx, which we know to have great potential. The early onset of response is important to any cancer vaccine and to see this alongside higher antibody titers is very exciting.”

Further information is available in a presentation being released alongside this press release.

About Imugene:

Imugene (ASX; IMU) is a clinical stage immuno-oncology company developing HER-2+ gastric and breast cancer immunotherapies. The Company’s lead product is HER-Vaxx, a proprietary HER-2 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 1 study in patients with breast cancer and the next stage of development will be a Phase 1b/2 study in patients with gastric cancer. Imugene’s corporate headquarters are located in Melbourne, Australia with the scientific team in Vienna, Austria.

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