Prestigious BMC Cancer journal publishes encouraging HER-Vaxx research

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February 13, 2017: Imugene Limited (ASX: IMU), a clinical-stage immuno-oncology company, today announced that its preclinical research related to HER-Vaxx (clinical name IMU-131) has been accepted and published in the prestigious journal BMC Cancer [1].

The immunological characterisation of the IMU-131 formulation, which demonstrates superior activity to the previously tested HER-Vaxx, is a positive study of the current vaccine which is shortly to be administered to patients. IMU-131 is a next generation HER-2 cancer therapy using B cell peptides, which harness the body's ability to develop antibodies against the disease.

Imugene CSO Professor Ursula Wiedermann conducted the research in her laboratory at the Medical University of Vienna. She stated "The formulation P467-CRM-Montanide which makes up the IMU-131 vaccine is a meaningful step forward in the quality of the multi-B cell peptide vaccine against Her-2/neu (including the potent CRM carrier and strong adjuvant Montanide), inducing both higher antibody levels and Th1-biased cellular responses. The current formulation of HER-Vaxx therefore is superior over the previous HER-2 peptide vaccine used in Phase 1 clinical trials, which included single B cell peptides conjugated to virosomes".

The research also demonstrated strong growth inhibitory activity of HER-Vaxx antibodies alone, and in combination with Trastuzumab (Herceptin®) at a constant dose, against a human HER-2+ cancer cell line.

Importantly, the anti-HER-2 antibodies produced by HER-Vaxx possess anti-tumor growth inhibitory properties higher than by Herceptin® alone. When the HER-Vaxx antibodies were combined with Herceptin® the inhibition of growth is significantly higher than Herceptin® alone.

Imugene's Chief Executive Officer, Leslie Chong said, "With the current formulation of HER-Vaxx, and empirical-based optimism that HER-Vaxx appears superior to Herceptin®, our clinical trial for patients with gastric cancer using our novel HER-Vaxx immunotherapeutic vaccine is imminent."

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[1] Joshua Tobias, Joanna Jasinska, Karin Baier, Michael Kundi, Nicholas Ede, Christoph Zielinski, Ursula Wiedermann, *Enhanced and long term humoral and cellular immunogenicity of a Her-2/neu hybrid-CRM197 peptide vaccine, using the Th1-driving adjuvant Montanide*, BMC cancer, 2017, click here to view.

Immunological characterization of the P467-CRM-Montanide formulation, as a vaccine against a Her-2/neu

Main findings:

The right formulation and carrier in the vaccine:

a. Superiority of diphtheria toxoid CRM197 as a carrier protein over virosomes for our hybrid peptide P467 is observed.

b. Only two immunizations with the hybrid peptide P467 to the carrier protein CRM, i.e P467-CRM, induce high titer serum antibody responses compared to immunizations with P467-virosomal conjugate.

The right adjuvant:

The Th1-driving adjuvant Montanide induces a mixed Th1 and Th2 immune responses at the humoral (antibody) and cellular (cytokines) level.

Long lasting immune responses:

P467-CRM-Montanide formulation induces long lasting antibody responses (at least for half a year in mice).

Fusion of the 3 B-cell peptides has created T helper cell epitopes that help in the induction of broad immune responses (antibodies and cytokines).

Montanide additionally supports the ***expansion of cytotoxic CD8 T cells***.

Importantly, anti-P467 IgG antibodies exhibited anti-tumor properties and ***the combination of anti-P467 specific IgG with Herceptin® was found to inhibit the proliferation of Her-2/neu-overexpressing cell line SK-BR-3 in a significantly higher capacity than Herceptin® alone.***

Conclusion:

The formulation P467-CRM-Montanide is an important step forward in the quality of the multi-B cell peptide vaccine against Her-2/neu (including the potent CRM carrier and strong adjuvant Montanide), inducing both higher antibody levels and Th1-biased cellular responses. The new formulation of Her-Vaxx therefore is superior over the previous Her-2 peptide vaccine which included single B cell peptides conjugated to virosomes.

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 B Cell peptide vaccines that would replace or augment conventional monoclonal antibodies.

In December 2016, Imugene announced an exclusive agreement with the internationally respected Baker IDI Heart & Diabetes Institute in Melbourne to research, develop and commercialise a portfolio of small molecule arginine modulators for oncology.