

# Manufacturing Update: on track and below budget

- Manufacturing of new improved formulation on track and below budget
- Critical vaccine manufacturing studies pass important hurdles
- GMP clinical batch completed
- Supply on track and on time for the clinical trial

**Melbourne, Australia, 7 March 2016:** Imugene Limited (ASX: IMU), a clinical stage immuno-oncology company, is pleased to announce an update on manufacturing of its HER-Vaxx cancer immunotherapy product, currently initiating activity in gastric cancer.

Since announcing a re-formulation of HER-Vaxx on 20 April 2015, which showed a dramatic tenfold increase in cancer fighting antibody production, several batches of both the peptide antigen and the final vaccine drug substance have been manufactured by the company's new manufacturing partner, Austrian contract manufacturer piCHEM GmbH. Batch-to-batch variation and stability studies have been completed and, after a process of optimisation, manufacturing of the final GMP clinical batch is also complete. The clinical grade material will be delivered in time to begin Imugene's Phase 1b/2 clinical trial in gastric cancer.

The entire process resulting from optimising the formulation to make it more clinically and commercially viable, manufacturing process, and the CMO sourced with manufacturing the GMP batch, has resulted in a substantial saving of >\$500K to Imugene's bottom line from the original budget.

Imugene Chief Operating Officer, Ms. Leslie Chong, said, "This is a critical milestone met in our preparation for commencing our clinical trial in patients with gastric cancer. The achievement of keeping this sophisticated manufacturing process on track and even below budget is a testament to the dedication and the relationship developed between our management team and our high-quality dedicated suppliers."

## **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.

For further information, please visit www.imugene.com.

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