HER-Vaxx Demonstrates Significant Inhibition of Tumour Cell Growth vs Herceptin®

- **Research shows promising inhibition of tumour cells by HER-Vaxx when compared with Herceptin® in tumour model**
- **HER-Vaxx re-formulation shows a more rapid and greater anti-cancer antibody production**
- **Clinical program on track**

Melbourne, Australia, 22 May 2015: Imugene Limited (ASX:IMU), a clinical stage immuno-oncology company developing HER-2 positive gastric and breast cancer immunotherapies, provides a progress update as per attached.

Charles Walker, Managing Director of Imugene, said, "With improvements to the formulation of HER-Vaxx, and empirical-based optimism that HER-Vaxx appears superior to Herceptin, we are rapidly finalising plans to trial our novel HER-Vaxx immunotherapeutic vaccine in patients with gastric cancer later this year. We are developing HER-Vaxx to generate a fast and strong stimulation of patients' immune systems to produce natural antibodies superior to Herceptin. We are pleased to report that this Phase 1b/2 clinical program remains on track."

This update includes key preclinical data in a tumour model where HER-Vaxx shows an advantage over Herceptin as well as other company progress.

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.

Charles Walker
Managing Director
Tel: +61 (0) 4 5044 6990
cwalker[at]imugene.com
www.imugene.com

Paul Hopper (Los Angeles)
Executive Chairman
Tel: +1 858 334 5820 (US)
Tel: +61 406 671 515 (Australia)
receptogen[at]earthlink.net

Media contact:
Rudi Michelson
Monsoon Communications
+61 3 9620 3333
rudim[at]monsoon.com.au

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Imugene Limited
ACN 009 179 551

Suite 1, 1233 High Street
Armadale VIC 3142

Imugene Shareholder Update

Letter From Managing Director

Dear Shareholders

I have pleasure in providing this update on developments at Imugene. This update covers many topics, but for the first time we have included data concerning an anti tumour in vitro experiment that studied the effects on a particular tumour cell line of antibodies developed by HER-Vaxx versus Herceptin. While this is just one study, we have reproduced this data to remind investors of our optimism not only in HER-Vaxx, but especially in the new formulation of HER-Vaxx as recently announced.

HER-Vaxx Data – Improved Growth Inhibition of Breast Cancer Cells Compared with Herceptin®

- Improved inhibition at comparable dose of Herceptin®
- Identical inhibition at one third dose compared with Herceptin®
- Highly statistically significant result (P<0.001)
- Data supports optimism that HER-Vaxx produces antibodies potentially superior to Herceptin®

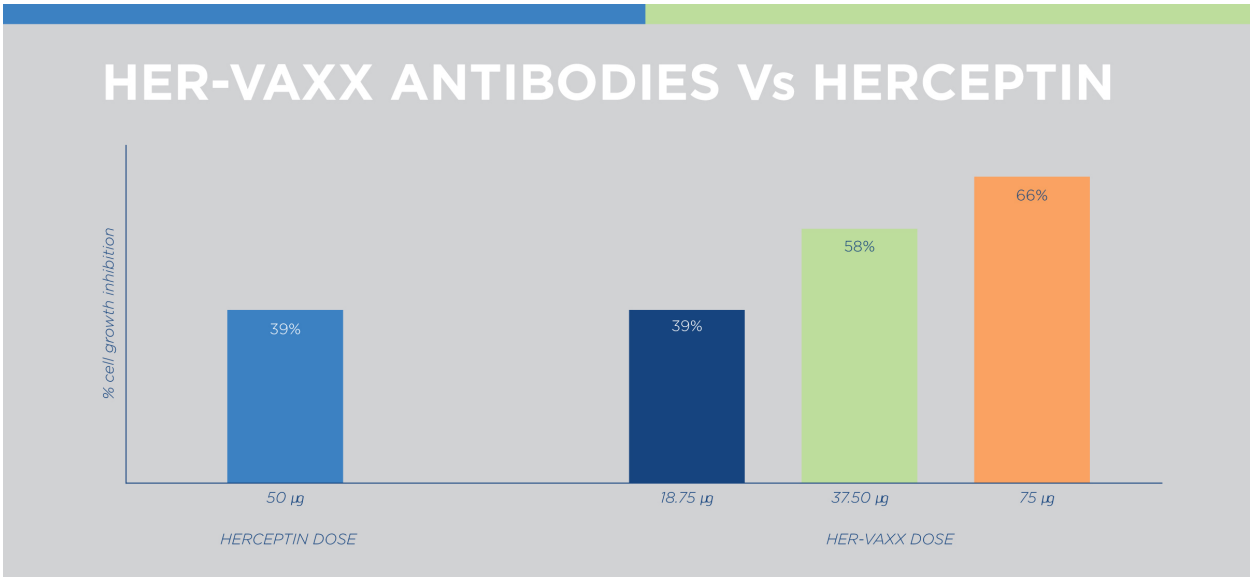
HER-Vaxx demonstrated an improved growth inhibition on the human breast cancer cell line SK-BR-3 compared with the currently prescribed gold standard antibody Herceptin® (Trastuzamab).

Herceptin® recorded sales for pharma giant Roche of US$6.4 billion in 2014. HER-Vaxx stimulates a polyclonal antibody response to HER-2/neu, the same oncogene that is targeted by Herceptin®.

The work was conducted by the research team at the Medical University of Vienna under the direction of Professor Dr Ursula Wiedermann and is reproduced from the patent entitled "*A multi-peptide - multiepitope - vaccine against cancerous diseases associated with HER-2/neu onco-gene*", patent number EP 1 844 788 A1, and the publication entitled "*Delayed tumor onset and reduced tumor growth progression after immunization with a HER-2/neu multi-peptide vaccine and IL-12 in c-neu transgenic mice*" from Breast Cancer Res. Treat (2007) **106**:29-38.

Combined with the HER-Vaxx reformulation results announced on 20 April, the experiments embolden our belief that HER-Vaxx may outperform Herceptin® in HER-2 positive cancers. We are developing HER-Vaxx to generate a fast and strong stimulation of patients' immune systems to produce natural antibodies superior to Herceptin®. Our clinical trial starting later this year will hopefully be a clinical demonstration of this efficacy.

The human breast cancer cell line SK-BR-3 overexpressing HER-2/neu was incubated with increasing concentrations of purified HER-Vaxx antibody or with Trastuzamab (Herceptin®). Proliferation of SK-BR-3 cells expressing high levels of HER-2/neu was significantly inhibited in a dose dependent manner by the peptide-specific antibodies (P<0.001) ranging from 39% to 66% at 18□g/mL and 75 □g/mL of antibodies respectively. Trastuzamab at a concentration of 50□g/mL inhibited the proliferation of SK-BR-3 cells by only 39%. Results represent mean values of three independent experiments and are statistically significant (P<0.001).



Reproduced from patent EP 1 844 788 A1, fig. 7&8

It can be seen from the graph above that HER-Vaxx is able inhibit the cancer cell growth with a dose of less than half that required for Herceptin® (18.75ug of HER-Vaxx compared with 50ug Herceptin). In total, the higher dose of HER-Vaxx is able to generate a response 70% greater than that of Herceptin®.

HER-Vaxx Superior Re-formulation

The HER-Vaxx formulation in this year's trial has been substantially upgraded with preclinical studies showing we can expect a more rapid immune response and a far greater number of cancer fighting antibodies to be produced with the optimised HER-Vaxx.

In short, this means:

- Our HER-Vaxx re-formulation shows a faster and more potent production of antibodies
- We have been able to file a new patent that could extend coverage to 2036, generally allowing us another six years on the market at peak sales
- Manufacturing is more simple, more reliable and cheaper
- HER-Vaxx generated antibodies inhibit tumour cell growth better than Herceptin® (with a significance of $p<0.001$)
- Our clinical program remains on track

These developments mean we have a better immunotherapeutic drug with a greater chance of clinical success that will not change clinical program timing.

Upcoming Clinical Trial

We have designed our trial to yield as much data and information as possible to guide us and potential partners to develop HER-Vaxx into a commercial pharmaceutical as quickly and as efficiently as possible.

Our trial has two elements; Phase 1b and Phase 2:

- The Phase 1b element is designed to confirm low toxicity and select the optimal dose from three different doses of HER-Vaxx. This part of the trial examines three groups of six patients, and will be "open label", meaning we can report data as the trial is conducted.
- The Phase 2 element will use the dose identified in Phase 1b and assess clinical efficacy (prolonged patient survival) of HER-Vaxx in two groups of 34 patients in a placebo-controlled trial design.

This trial will help us better understand HER-Vaxx's functioning from an early stage including showing the increased modulation of the immune system and demonstrating again the

production of HER-2 antibodies by patients' immune systems. Such data may help potential partners in early assessments of the drug and its effect on the immune system, which is a key indicator of improvement in patient survival.

Launching this study later this year will be a key Imugene inflection point underpinned by many years of research. Once the study begins, we will increase business development work and meet with prospective partners to inform them of our progress, our innovative technology and trial design.

With the depreciation in the Australian dollar and incentives in Australia, we plan to conduct the trial in as many Australian hospitals as we can without compromising speed or efficiency. This will be better value for money, trial management will be more efficient and will likely benefit Australian trial participants with gastric cancer.

Why Gastric Cancer?

These important trials are on gastric cancer patients, which includes all those patients with stomach or oesophageal cancers. This is our optimal commercial indication.

Globally, gastric cancer is the second most common cancer in men and the third most common in women. For all, prognosis is poor with median survival of about 11 months.

The global standard of care for gastric cancers in Western society is the blockbuster drug Herceptin®. Like HER-Vaxx, Herceptin® works by targeting HER-2 positive tumours found in many cancers including breast, gastric, ovarian, lung and pancreatic cancers. The HER-2 receptor is associated with aggressively growing tumours that are a hallmark of all these cancers with poor prognoses.

But while Herceptin® is a highly successful drug approved for use and reimbursed for breast cancer patients in Australia, it is not reimbursed for gastric cancer patients in Australia. Gastric oncologists around the country are frustrated by this lack of access to Herceptin® and are actively seeking promising alternatives. They are enthusiastic about taking part in HER-Vaxx trials and look forward with interest to data reports. This augurs well for Imugene as our drug is exhibiting strong potential to not only match, but *improve* on Herceptin® outcomes, as evidenced by our tumour cell inhibition studies.

Herceptin® is a $US6-7 billion per annum global market. If we can provide a superior alternative we have an extremely valuable asset. Unlike Herceptin® (a monoclonal antibody) our drug is a polyclonal antibody – expected to produce a more powerful anti-tumour effect. Moreover, we have lower production costs and potentially an opportunity for a single vaccination. Herceptin® requires a more expansive treatment cycle.

R&D Tax Refund

Imugene received a research and development tax refund of $230,690 as part of the Australian government's R&D incentive program. These funds and the Company's $3.5 million capital raising all help with HER-Vaxx advancement.

Edison Investment Research
Your Company was recently the subject of a comprehensive research report prepared by Edison, valuing Imugene at 4.1 cents per share.

Analysts indicated that HER-Vaxx success at Phase II could attract a big pharma partner. This has long been our intention and we will prepare a comprehensive data package that makes us more valuable to big pharma companies. Much of this relies on these next stage trials.

The full report can be viewed at our website, www.imugene.com and clicking on the link under investor centre.

Finally
We thank you for your ongoing support and look forward to delivering shareholder value by achieving key milestones in the next 6-12 months. You will see several news updates on the initiation of our trial, such as the appointment of a CRO and further preclinical results. These will precede our next inflection points that are expected to be the launch of key trial and reporting interim data from the open label, phase 1b part of our Phase 1b/2 clinical trial.

Yours faithfully
Charles Walker

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Contact
Charles Walker
Managing Director
cwalker@imugene.com
+61 (0) 4 5044 6990

Rudi Michelson
Monsoon Communications
+61 (0) 3 9620 3333

Stephanie Carrington (New York)
(ICR) Integrated Corporate Relations
stephanie.carrington@icrinc.com
+1 858 334 5820

Paul Hopper (Los Angeles)
Executive Chairman
+1 646-277-1282