Imugene Commences FDA IND Process for Gastric Cancer vaccine

- **Experienced IND Regulatory Consultants Ground Zero Pharmaceuticals Appointed to Lead Preparation of IND Submission**
- **HER-Vaxx gastric cancer vaccine has potential to fill a major unmet medical need**

Melbourne, 17 March 2014: Australian biopharmaceutical company Imugene Limited (ASX:IMU) has appointed Ground Zero Pharmaceuticals Inc (GZP) to manage Imugene's HER-Vaxx US FDA IND (Investigational New Drug) Application. The firm specialises in supporting IND submissions globally and particularly in the US.

HER-Vaxx is a proprietary therapeutic cancer vaccine that stimulates a polyclonal antibody response to HER-2/neu, the same biomarker targeted by the $US6.9 billion per annum drug Herceptin®. HER-Vaxx has successfully completed a Phase 1 study in breast cancer and the next stage of development will be a Phase 2 study in gastric cancer. Gastric or stomach cancer is the second most common cause of cancer-related death in the world and the fourth most commonly diagnosed cancer, with over 1,000,000 new cases diagnosed each year.

HER-Vaxx has shown success in stimulating the production of lifesaving HER-2 antibodies in early-stage cancer patients enrolled in the initial clinical trial. Its further development is directed towards providing a natural, potentially more potent alternative to Roche's popular injectable antibody, Herceptin®, which has become one of the world's bestselling cancer drugs with annual sales in excess of $US6.9 billion (CHF6.08 billion, Roche Investor Update 30/1/14).

"The filing and subsequent allowance of an FDA IND will be an important milestone that sets key developmental parameters agreed with a major, "gold standard" regulatory agency," said Imugene Executive Director Nick Ede. "A successful IND can set the guidance for a key efficacy trial such as this and even reduce the time and risk involved in seeking FDA approval. It may also allow for the inclusion of additional patients with other indications who may have a chance to benefit from the new drug."

The IND involves submission of manufacturing data, a protocol, an investigator's brochure, animal testing results, clinical safety and efficacy data generated to date, and a clinical development plan, to permit the key new clinical study to be conducted. GZP will compile an FDA Regulatory Pathway report, taking into account the HER-Vaxx data.

Breast cancer and stomach cancer are among the most aggressive forms of cancer, killing more than 1.2 million people globally each year. The market for stomach cancer drugs alone is projected to rise to nearly $1.4 billion by 2020 – with an average 20% of patients suffering from HER-2 positive forms of the disease. Between 15-30% of breast cancers are HER-2 positive.

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Imugene Limited
A.C.N: 009 179 551
Suite 1, 1233 High Street, Armadale, VIC, 3142
Phone: 03 9824 5254 Fax: 03 9822 7735

Contact :

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

Dr Nick Ede
Executive Director
+61 400 642 254
nede[at]imugene.com

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

About Imugene: Imugene (ASX; IMU) is an immuno-oncology company developing clinical cancer vaccines to advance cancer care. The Company's lead product is HER-Vaxx, a proprietary therapeutic cancer vaccine 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 and pancreatic cancers. HER-Vaxx has successfully completed a Phase I study in breast cancer and the next stage of development will be a Phase II study in gastric cancer. Imugene's corporate headquarters are located in Melbourne, Australia with the scientific team in Vienna, Austria. For more information on Imugene, please visit www.imugene.com

About Ground Zero Pharmaceuticals: Based in Irvine California, Ground Zero Pharmaceuticals, Inc. is a regulatory affairs, product development and clinical consulting firm providing strategic and tactical services to the pharmaceutical, biotechnology and medical device industries. These include regulatory representation and submissions, preclinical and clinical planning, auditing of clinical, nonclinical and manufacturing sites, medical writing, chemistry, manufacturing and controls consulting, and project management. GZP has resources throughout the US, Canada, Australia and Europe and a wholly owned subsidiary in Australia.