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ASX Limited  
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## **Virax appoints Ground Zero Pharmaceuticals to lead IND submission for GGTI-2418**

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**23 June 2014: 2014, Melbourne, Australia:** Virax Holdings Limited (ASX:VHL) has appointed Ground Zero Pharmaceuticals Inc (GZP) to manage the US FDA investigational new drug (IND) application for its cancer drug candidate GGTI-2418.

GZP provides expert strategic and tactical guidance with a particular emphasis on IND submissions in the US.

GGTI-2418 is a novel, first in-class peptidiomimetic inhibitor with the ability to block an important cancer growth enzyme known as GGTI (geranylgeranyltransferase type 1). It also blocks the Ral and Rho circuits in cancer cells, which act as key oncogenic survival pathways.

GGTI-2418 is borne out of a collaboration between Yale University and the Moffitt Cancer Centre, the third largest cancer centre in the United States. It has shown the ability to cause breast tumour regression in ErbB2 transgenic mice models. It also established a strong safety profile during a Phase I US clinical trial where four patients with advanced stage, treatment-refractory solid tumours demonstrated stable disease.

Virax managing director Dr Robert Crombie said the appointment of GZP paves the way for the drug candidate to move toward further clinical trials.

"The IND review and allowance process is an integral part of the development of a new drug candidate and we are eager to get this process underway and understand the expectations we need to fulfil moving forward."

As part of the submission Virax will be required to provide manufacturing data, a clinical protocol, an investigator's brochure to guide the principal investigator, animal pharmacology and toxicology data, clinical safety and efficacy data to date and a clinical development plan. Based on this information GZP will produce an FDA Regulatory Pathway report, which will be considered before a new clinical study can be conducted.

GZP was established in California in 1987 and has since grown into an integrated consulting firm with offices across the US and Australia as well as associates in Canada, Germany and Sweden.

**Ends.**

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### **About Virax**

Virax is a biopharmaceutical company currently engaged in the discovery and development of novel products for the treatment of cancer. It holds an exclusive worldwide license to the novel cancer compound GGTI-2418 for the treatment of multiple myeloma, breast and pancreatic cancer. In addition, the company has granted a licence to major French biotechnology company Transgene for access to its Co-X-Gene™ technology for use in two of Transgene's immunotherapeutic products. These are: TG4001 – a treatment for pathologies relating to human papilloma virus (HPV) infection that can lead to oropharyngeal (head and neck) cancer, and TG4010 – an experimental treatment for non-small cell lung cancer (NSCLC). The board is actively seeking to expand its asset base with complementary technologies and products to maximise shareholder value.