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The Company Announcements Platform

ASX Limited

By E-lodgement

FDA IND Re-Activation Request for Phase Ib/II Breast Cancer Trial Following Completion of Technical Assessment Report

9 Sept 2014, Melbourne, Australia: Virax Holdings Limited (ASX:VHL) advises that it commissioned and has now received a Technical Assessment report from Ground Zero Pharmaceuticals (GZP) on its lead compound, GGTI-2418, which will allow Virax to move quickly towards re-opening its IND for a planned Phase Ib/II breast cancer trial in 2015.

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

Virax plans to request IND reactivation, followed by a request for a meeting with FDA to discuss the GGTI-2418 development program. If granted, the meeting could be held 30 days post-request.

GGTI-2418 is a novel, first in class cancer immunotherapeutic with the ability to block an important cancer growth enzyme known as GGTI-2418. It also blocks the Ral and Rho circuits in cancer cells which act as key oncogenic survival pathways leading to apoptosis (death) of cancer cells.

GGTI-2418 has been in Phase I clinical trials at Pennsylvania State University and Indiana University which established a favorable safety profile. In addition, four of nine patients dosed experienced stable disease of their advanced stage and treatment-refractory solid tumours.

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.

Virax managing director Dr Robert Crombie commented: "Re-opening the IND application is a critical step toward next stage clinical trials. We are determined to exploit this highly encouraging clinical and commercial opportunity."

Virax is also pursuing development of GGTI-2418 as a new treatment for multiple myeloma (bone marrow cancer).

Ends.

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About Virax

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Virax is a clinical-stage oncology company currently engaged in the development of novel products for the treatment of cancers of unmet medical need. 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.