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The Company Announcements Platform

ASX Limited

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## Virax to Acquire Exclusive Worldwide License to Yale University Phase 1b/2-ready Programs in Multiple Myeloma & Breast Cancer

### HIGHLIGHTS

- **Novel cancer drug from Yale known as geranylgeranyl transferase inhibitor (GGTI-2418), which has been shown to block important growth signals in cancer cells, such as Ral and Rho**
- **Phase 1 trial undertaken at Pennsylvania and Indiana Universities**
- **Phase 1b/2 trials to be conducted at leading US institutions including Moffitt Cancer Center in Florida and Montefiore Einstein Center for Cancer Care, the clinical partner of the NCI-designated Albert Einstein Cancer Center in New York**
- **Immediately transforms Virax into one of only a few ASX listed biotech companies with rapid potential for multiple clinical trials under an FDA IND**
- **Very attractive terms with acquisition of the license to the technology to be satisfied by Virax issuing up to 240 million ordinary shares payable over three tranches against value creation milestone targets**
- **Experienced life science executive Paul Hopper from Los Angeles to join the Virax Board**

**17 March 2014, Melbourne, Australia:** Virax Holdings Limited (**Virax**) (ASX:VHL) has entered into a binding agreement to acquire Pathway Oncology Pty Ltd (**Pathway**), the holder of an exclusive worldwide license of certain intellectual property from Yale University and the University of South Florida. The intellectual property includes anti-cancer technology developed at Yale University in New Haven, Connecticut and the Moffitt Cancer Center in Florida, the third largest cancer center in the United States.

The technology is the invention of Professor Said Sebti, Director of the Drug Discovery Program at Moffitt Cancer Center, and Professor Andrew Hamilton, formerly the Provost of Yale University, and now Vice-Chancellor of Oxford University.

The technology is a novel cancer drug, GGTI-2418, that blocks the important cancer growth enzyme geranyl-geranyl transferase I (GGTase I) as well as Ral & Rho circuits in cancer cells, which are key oncogenic pathways for a cancer cell to survive and grow.

GGTI-2418 is a first-in-class synthetic peptidomimetic inhibitor of GGTase I, with the potential to treat multiple myeloma, breast and pancreatic cancers, and is a potent and selective drug that induces cell death by down-regulating several pivotal oncogenic and tumor survival pathways.

The drug has been shown to cause significant breast tumor regression in transgenic mouse models, and has subsequently been demonstrated to be safe in a Phase 1 clinical trial at the University of Pennsylvania and Indiana University, where over 30% of patients with advanced stage, treatment-refractory solid tumors demonstrated stable disease.

Now the drug holds tremendous potential in a range of cancers, as a monotherapy or in combination with existing chemotherapies to improve patient outcomes.

Virax has agreed to acquire Pathway on very attractive financial terms that promise strong up-side potential for Virax shareholders. The consideration comprises: 60 million shares on settlement, plus up to another 180 million shares upon achievement of major value-creating milestones (detailed below).

Dr. Wayne Millen, Executive Chairman of Virax said: *"Securing this valuable and unique asset represents a major corporate achievement for Virax: few ASX listed biotech companies can claim two advanced clinical programs to be conducted under a US IND at two major US cancer institutions, impeccable scientific provenance with an extensive history of peer review and with GMP manufacturing established and clinical trial batch manufactured."*

*"This catapults Virax straight into an elite club of mid-clinical stage ASX listed biotech companies."*

*"Moving into these trials with key opinion leaders such as Professor Said Sebti at Moffitt and Joseph Sparano, M.D., Vice Chairman of Medical Oncology, Montefiore Einstein Center for Cancer Care and Associate Director for Clinical Research at Albert Einstein Cancer Center marks an extremely important event in the field of GGT inhibitors. We look forward to commencing the Phase 1b/2 trials and targeting patients whose tumors have disrupted signal circuitry, and therefore are most likely to respond to GGTI-2418."*

Dr. John Puziss, Director of Technology Licensing in Yale University's Office of Cooperative Research said: *"Yale is delighted to partner with the experienced team at Pathway and Virax to develop this exciting technology. This is a most important step in the development of GGTI-2418 as a novel treatment for the devastating effects of cancer."*

*"Combination therapies for cancer are a well established treatment mechanism and we hope that development of GGTI-2418 can lead to substantial benefits in patients with multiple myeloma and breast cancer."*

### **Multiple Myeloma**

A Phase 1b/2 study in multiple myeloma is planned at Moffitt Cancer Center, one of America's leading multiple myeloma clinical trial and research centers with Dr. Melissa Alsina as the Principal Investigator.

Multiple myeloma is a cancer of the plasma cells in the bone marrow, which begins when normal plasma cells grow uncontrollably. These cells induce bone resorption leading to bone pain, pathologic fractures and hypercalcemia. Other characteristics of the disease include anaemia, renal dysfunction and frequent infections. While there have been major

recent advances in the treatment of myeloma with the use of novel therapies such as immunomodulatory drugs, and proteasome inhibitors, the disease remains fatal and the majority of the patients die from relapsed and refractory disease within 5-7 years after diagnosis.

Multiple myeloma is the second most common hematologic malignancy after Non-Hodgkins lymphoma and represents approximately 1% of all cancers and 2% of all cancer deaths. The market for multiple myeloma has been forecast to grow 60% by 2021, reaching more than US\$7 billion from about US\$4.4 billion.

### **Breast Cancer**

In addition to the multiple myeloma study, a Phase 2 study (with a small 9 patient Phase 1b lead-in), in combination with paclitaxel for women with P27 positive breast cancer is planned at Montefiore Einstein Center for Cancer Care in New York, and Moffit Cancer Center in Tampa, Florida. This trial will be conducted with leading breast cancer expert Dr. Joseph Sparano as Principal Investigator. Dr. Sparano is also Professor of Medicine at Albert Einstein College of Medicine.

In normal cells, P27 plays a key role in very tightly regulating cell division. However, in some cancer types, including breast cancer, P27 is expressed at very low levels and this contributes to the uncontrolled cell division, a major hallmark of cancer. The lower the P27 levels, the worse are the patient outcomes.

GGTI-2418 increases the levels of P27 in the nucleus and, by doing so, kills tumor cells. Patients whose tumors express very low levels of P27 are more likely to respond to GGTI-2418 as a single and/or in combination with chemotherapy such as Paclitaxel.

It is estimated that the global market for breast cancer drugs will reach US\$11.2 billion by 2016.

### **About Paul Hopper – (Proposed Virax Executive Director)**

Paul Hopper has over 20 years experience in international public company markets primarily in the life sciences sectors, with a focus on start-up and rapid growth companies. He has served as either Chairman, non-executive director or CEO of 14 public companies in the US, Australia, and Asia.

Paul is an advisor at the Los Angeles-based Cappello Group where he is Head of the Life Sciences and Biotechnology Group responsible for mergers and acquisitions and capital raisings focusing on the biotechnology and life sciences sectors.

He is Executive Chairman of Imugene Ltd, and Chairman of Viralytics Ltd, both ASX listed companies.

### **Consideration for the acquisition of Pathway**

The consideration for the transaction will be apportioned amongst the Pathway shareholders in accordance with their respective shareholdings and will be as follows:

- (a) subject to the satisfaction (or waiver by Virax) of the conditions precedent, 60,000,000 fully paid ordinary shares in Virax at settlement;

- (b) subject to the re-activation or re-opening, or allowance, of an IND for any disease indication by US FDA , 90,000,000 fully paid ordinary shares in Virax within 10 Business Days of such satisfaction; and
- (c) subject to the dosing of the patient in a Phase Ib/II trial for any disease indication , 90,000,000 fully paid ordinary shares in Virax within 10 Business Days of such satisfaction.

Completion of the transaction is conditional on a shareholder's meeting to approve the transaction and the raising of a modest amount of additional capital to fund the expanded operations of Virax. This meeting is expected to be held in the coming months.

### **Summary of the terms of the Yale License Agreement**

Pathway has an exclusive, worldwide license from Yale to exploit the technology behind the novel cancer drug, GGTI-2418.

As is customary in transactions of this type, Pathway must:

- (a) pay for the future costs of maintaining the intellectual property portfolio;
- (b) make minimum yearly payments to Yale and use reasonably commercial efforts to commercialise the technology;
- (c) make lump sum payments to Yale upon achieving certain defined milestones (first dosing of patient in a Phase II and III clinical trial, upon filing and approval of an NDA for a product, approval of a product in the EU and approval of a product in Japan); and
- (d) pay to Yale commercial arm's length net sales revenue royalties in respect of any products that are commercialised.

-Ends-

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### **About Virax**

Virax is a biopharmaceutical company and is currently engaged in the discovery and development of novel immunotherapeutic products for the treatment of cancer.

Virax has granted a licence to major French biotechnology company Transgene for access to Virax's 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 – a treatment for non-small cell lung cancer (NSCLC).

In addition, the Board is actively seeking to expand its asset base with complimentary technology that will generate additional shareholder value.

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