



Announcement to ASX (135)
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IMPORTANT POSITIVE RESULT FOR VIRAX HIV DRUG

- Positive trial result to bring on next stage of HIV drug development
- Exciting boost for Virax Co-X-Gene™ technology platform

Melbourne, Australia – October 16, 2003 – Virax Holdings Ltd (ASX: VHL) announced today that the latest clinical trial of its immune-based therapy VIR201 for the treatment of HIV, has returned positive results.

Virax CEO Dr David Beames said, “We have a very promising material result in the first stage of our assessment of the effectiveness of VIR201. It builds strongly on the safety profile which was established through the Phase I trial, the results of which were announced earlier this year.”

These results arise from the measurement of the study participants’ HIV levels (viral load). Currently, this accepted clinical measurement is the only direct means of determining a drug’s effectiveness.

“VIR201 performed better than placebo in controlling HIV-infected patients’ viral load,” said Professor David Cooper AO, Director of the Australian National Centre for HIV Epidemiology and Clinical Research (NCHECR). “An aim of this pilot study was to see whether VIR201 has the potential to be a therapy that can control the virus. Control or suppression of the HIV virus is the critical factor in the treatment of HIV/AIDS.”

“This latest data provides a promising preliminary indication which merits further development,” Professor Cooper said.

“An effective immune-based therapy could enable patients to reduce their reliance on other HIV drugs (highly active anti-retroviral therapy or HAART). HAART drugs, notwithstanding their expense, impact on patients’ quality of life due to serious side-effects, and the need for strict adherence,” Professor Cooper said.

Medical scientists around the world agree that there is a demonstrable need for an alternative to HAART.

In the double-blind placebo-controlled Phase IIa Extension Study, co-ordinated by the NCHECR, participants in the earlier Phase I safety trial of VIR201 received a booster of their trial medication and then ceased taking HAART.

“The Phase I safety trial results announced early this year did not provide any guidance on VIR201’s effectiveness. This extension trial result does provide guidance, and unquestionably it is in the right direction,” Dr Beames said.

“Based on the strength of this result, Virax is moving to the next stage of clinical testing of VIR201 in larger trials,” he said.

“The result also represents a critical, clinical milestone for Virax’s Co-X-Gene™ technology. VIR201 is the first Virax product based on this platform to enter clinical trials and this result supports our earlier decision to expand our portfolio into other therapeutic areas.”

Virax and its collaborators at the Royal Adelaide Hospital are about to start pre-clinical testing of a prostate cancer treatment based on Co-X-Gene™ technology.

Similar studies are also due to start shortly on a hepatitis B treatment, which Virax is working on with the New York Blood Center.

Dr Beames believes this result should provide Virax investors with increased confidence in its drug development programs.

Professor Cooper and his colleagues at the NCHECR believe the result on VIR201 will be of special interest to the international HIV/AIDS medical and scientific community and the full details of the trial has been submitted for presentation at an international symposium early in 2004. A scientific paper will also be submitted for publication in a recognized peer-review journal.

About Virax

Headquartered in Melbourne, Virax Holdings Ltd is a development-stage biotechnology company engaged in the development of some of the world's most promising treatments for diseases such as prostate cancer, HIV/AIDS, hepatitis B and other infectious and autoimmune diseases.

Virax's strategy is to fund early stage clinical development of Australian medical research and then partner with larger biotechnology or pharmaceutical companies for later stage development, regulatory, and marketing activities.

Virax's technology focus is on biotechnology that underpins the development of immune-based therapies (immunotherapy) – therapies that use biological signals to direct the immune system to treat and defend against disease.

In addition to development, Virax operates a GMP* manufacturing facility that has the capacity to construct and manufacture immune-based therapeutic products for clinical trials to the standard that meets international regulatory requirements. It is one of only a handful of companies in the world that has this unique capability.

About NCHECR

The National Centre in HIV Epidemiology and Clinical Research (NCHECR) is a leading international medical research centre established by the Australian Government in 1986 to co-ordinate national surveillance programs and clinical trials related to HIV/AIDS.

The NCHECR carries out research on epidemiological and clinical aspects of HIV/AIDS and other blood-borne viruses and sexually transmitted diseases. It also provides input into the development and implementation of Australia's health policy and programs.

The Centre's Director Professor David Cooper AO (MD, DSc, FRACP, FRCP) is recognised internationally as a leading HIV clinician and clinical investigator. Professor Cooper is also Head of the Immunology/HIV/Infectious Diseases Clinical Services Unit at St Vincent's Hospital, Sydney, which is one of the largest inpatient and outpatient services for the treatment for AIDS in Australia. He is co-director of the medical research groups within the Centre for Immunology at St Vincent's Hospital Sydney. He is scientific co-chair of the 15th World AIDS conference in Bangkok Thailand in July 2004.

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* Good Manufacturing Practice or GMP is the standard set by regulatory authorities for the production of drugs to be used in clinical trials.