



ASX ANNOUNCEMENT (147)
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**NCHECR Presentation of VIR201 Clinical Results
at the 11th International Conference
on Retroviruses and Opportunistic Infections**

Virax Holdings Limited (ASX: VHL) today advises that its research partner, the Australian National Centre for HIV Epidemiology and Clinical Research (NCHECR) presented data and released results of the recent clinical trial of Virax's immune based therapy VIR201 at the prestigious 11th International Conference on Retroviruses and Opportunistic Infections in San Francisco.

"VIR201 is the first treatment of its kind in the world to show an ability to block the progression of this potentially deadly virus in HIV positive patients," said NCHECR Director Professor David Cooper AO.

"On the clinical evidence now available, VIR201 is one of the most promising treatment vaccines currently under development and further trials are warranted," he said.

The study found that patients on VIR201 had a viral load approximately six times lower than those on placebo.

"This is a significant milestone in the validation of Virax's HIV therapy and the more widely applicable technology underpinning it," said Virax CEO Dr David Beames.

"We look forward to the response of the scientific community to this independently derived data and are currently working with the NCHECR to urgently progress VIR201's development," said Dr Beames.

Note: NCHECR Media Release follows.

About Virax

Headquartered in Melbourne, Virax Holdings Limited (ASX:VHL) is a 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 medical research and then partner with larger biotechnology or pharmaceutical companies for later stage development, regulatory, and marketing activities.

Virax's Co-X-Gene™ technology platform underpins its development of immune-based therapies (immunotherapy) – therapies that use biological signals to direct the immune system to treat and defend against disease.

To accelerate its product development programs, Virax operates a GMP manufacturing facility that has the capacity to construct and manufacture immune-based therapeutic products for its own 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.

For further information, contact:
Hinton & Associates
Phone: 03 9600 1979

Olivia Withers: 0421 999 098
Tim Duncan: 0408 441 122



MEDIA RELEASE

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PROMISING NEW AUSTRALIAN HIV TREATMENT VACCINE GAINS INTERNATIONAL ATTENTION

- Australian-developed HIV treatment vaccine achieves world-first clinical trial results
- Results accepted at prestigious international medical conference in San Francisco

Positive results of a landmark clinical trial conducted in Australia have identified an Australian-developed HIV treatment vaccine as one of the most promising of its kind warranting further development, a pre-eminent international conference of HIV/AIDS researchers was told today.

Professor David Cooper AO, Director of the Australian National Centre in HIV Epidemiology and Clinical Research (NCHECR), School of Medicine at The University of New South Wales, which conducted the trial, today presented the results of clinical testing of the potential HIV treatment vaccine VIR201 to medical and scientific research peers at the prestigious 11th Conference on Retroviruses and Opportunistic Infections in San Francisco.

In his presentation Professor Cooper explained the extent to which VIR201 controlled patients' HIV level or viral load, when compared to placebo. "On the clinical evidence now available, VIR201 is one of the most promising treatment vaccines currently under development and further trials are warranted," said Professor Cooper. "Twenty weeks after a booster injection, patients on VIR201 had a lower HIV level, compared to the participants who received placebo."

"Controlling the level of virus is fundamental for the management of HIV. If we are able to keep the viral load low, patients will not develop AIDS and can live long and relatively healthy, normal lives," he said.

Although current treatments, known as Highly Active Anti-Retroviral Therapy (HAART), have been successful in maintaining low viral load and prolonging the lives of many HIV positive people around the world, an alternative like VIR201 is needed, as there are inherent and growing problems with HAART.

The trial results indicate that VIR 201 has the potential to change the future management of HIV.

VIR201 is a treatment vaccine developed and manufactured by the Melbourne based biotechnology company Virax Holdings Limited.

"Together with Virax, we are looking to progress VIR201's development with a larger Phase II trial," said Professor Cooper.

Need for next generation of HIV treatment

“Anti-retroviral therapy is tough,” said Dr Cassy Workman, Darlinghurst General Practitioner and a key co-investigator in the trial. “These existing drugs impact significantly on the patients’ quality of life”.

“Several tablets must be taken without fail once or twice a day, every day. A lapse in this routine can lead to the development of resistance to the therapy,” said Dr Workman.

“Toxicity problems associated with these drugs also mean that current therapies do not offer a long term solution or cure – VIR201 is looking very promising and offers hope for people living with HIV/AIDS around the world,” she said.

“Many scientific and medical groups around the world believe treatment vaccines like VIR201 offer the greatest chance for a solution to this problem and therefore will find the results presented in San Francisco to be of interest.”

Treatment Vaccines and VIR201

VIR201 is a treatment vaccine that harnesses the power of the body’s own immune system. Rather than fight the virus itself, like current anti-retroviral drugs, VIR201 in animal studies stimulates the immune system to produce a specific response to the HIV virus.

VIR201 is a recombinant pox virus with co-expression properties, which set it apart from most other treatment vaccines under development. By expression of two genes together it is designed to stimulate an immune response to fight disease and target this immune response towards the HIV virus.

Given that no obvious side-effects have emerged in the NCHECR’s trials to date and the therapy consists of a straightforward injection, a treatment vaccine like VIR201 is an attractive candidate for further development.

The Trial

In a Phase I/IIa multi-centre, randomised, double-blind, placebo-controlled trial, researchers at the NCHECR examined VIR201’s safety and its ability to control the level of virus in the blood (viral load) of 35 HIV positive patients.

Three doses of the treatment, given at weeks 0, 4 and 12, were shown to be safe for patients whose viral load was controlled by highly active anti-retroviral therapy (HAART). No adverse side-effects were found.

Twelve months after their commencement in the safety study, participants were given the opportunity to participate in an extension study. After receiving a booster (4th dose), 25 participants ceased their anti-retroviral therapy. Viral load was measured almost every week for 20 weeks.

VIR201 appeared to control replication of HIV better than placebo.

The primary endpoint for the extension study was time weighted mean change (\pm sd) from participants’ baseline plasma viral load (pVL). Analysis showed the change from baseline pVL was 0.96 (0.91) \log_{10} copies/ml for patients receiving VIR201 compared to 1.80 (0.72) \log_{10} for those on placebo. This is a 0.8 log reduction in pVL for VIR201 compared with placebo. Thus patients on VIR201 had a viral load that was approximately 6.3 times lower than those on placebo.

Although lacking statistical significance, the impact of VIR201 is striking and warrants further development.

HIV / AIDS Statistics¹

- HIV/AIDS remains a serious epidemic – it is the world's fourth largest killer
- HIV/AIDS killed more than 3 million people in 2003
- An estimated 5 million people acquired HIV in the same year bringing to 40 million the number of people living with the virus around the world
- Over 13,000 people have HIV/AIDS in Australia
- Approximately 850,000 to 950,000 U.S. residents are living with HIV infection.²

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 (DSc, MD, FRACP, FRCPA, FRCP) is recognised internationally as a leading HIV clinician and clinical investigator. Professor Cooper is also Head of the HIV/Immunology/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 HIV/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 XV International AIDS Conference in Bangkok, Thailand in July 2004.

The Head of the Therapeutic and Vaccine Research Program at NCHECR, Associate Professor Sean Emery PhD, coordinated these studies.

About Virax

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For further information, contact:
Associate Professor Sean Emery
Head, NCHECR, Therapeutic & Vaccine Research Program
MOB: 61 (0)414949363

Tracy Hocking
Virax Holdings Ltd
MOB: 61 (0)421061166

¹ *AIDS Epidemic Update 2003* (UNAIDS / WHO, 2003); *2003 Annual Surveillance Report - HIV/AIDS, viral hepatitis and sexually transmissible infections in Australia* (Edited by National Centre in HIV Epidemiology and Clinical Research); and AIDS Trust of Australia.

² Fleming, P.L. et al. [HIV Prevalence in the United States, 2000](#). 9th Conference on Retroviruses and Opportunistic Infections, Seattle, Wash., Feb. 24-28, 2002. Abstract 11.