



09 August 2010  
Announcement # 386

ASX Code: VHL

## UPDATE ON VIR201 HIV VACCINE PHASE IIa CLINICAL TRIAL

### Database Lock Successfully Achieved and Trial results due imminently

Australian bio-pharmaceutical company Virax Holdings Limited (ASX:VHL) is pleased to provide the following update on its Phase IIa Clinical Trial in South Africa of its HIV therapeutic vaccine, VIR201.

Further to its most recent update on the progress of the trial (ASX announcement of 7 July), the Company confirms that it continues to make strong progress towards presentation of preliminary trial results this month.

The Company can now advise that all immunological laboratory analyses have been completed and data input into the clinical trial database. Database lock was successfully achieved on 6 August 2010 in South Africa. Statistical analysis and release of the Preliminary results for the major primary and secondary endpoints of the trial are expected to be released 1-2 weeks post database lock.

The Company is pleased with the progress and successful completion of these trial milestones and now looks forward to the pending release of trial results.

The Preliminary report will detail results of a comprehensive immune monitoring program designed to measure and compare antibody and T-cell immune responses generated in both the trial's VIR201 participant group and the control group.

The major immunological readouts being measured are:

- **HIV specific T-cell responses** as measured by ELIspot assay. Such T-cells are critical in the detection and removal of HIV infected cells, and
- **Antibody isotyping** as measured by western blot analysis. A recent analysis of samples from previous Australian VIR201 trials by Royal Perth and Fremantle Hospital clinical immunologist Professor Martyn French's team identified an immune readout that correlated with the ability of VIR201 to control viral load. Professor French's work has showed that the level of a particular type of antibody (IgG2 antibody) directed against a HIV protein (p24) was elevated in the group that received VIR201 and that this correlated with the patient's ability to suppress HIV viral load.

VIR201 is an immunotherapy vaccine which treats HIV infected individuals by lowering viral load. Current HIV treatments typically use a combination of antiretroviral therapies (ART), which often have unwanted side effects, including acute and chronic toxicities plus the potential emergence of drug resistant viruses. It is proposed that VIR201 be used with ART to delay antiretroviral therapies and thereby postpone the unwanted side effects, and to also provide patients with a drug holiday within the ART regime.

### About the Phase IIa VIR201 Clinical Trial

The Phase IIa Clinical Trial for the VIR201 HIV Therapeutic Vaccine is designed to build on previous trial results in Australia where VIR201 demonstrated a ten-fold suppression in the HIV viral load in the context of patients discontinuing antiretroviral treatment (ART) after vaccination. This suppression has subsequently been correlated with a novel antibody based mechanism of action. The trial is utilising an increased dose of a more highly purified VIR201 vaccine and includes both ART naïve and ART experienced participants. The more purified, higher dosed vaccine is designed to promote a stronger immune response which would be predicted to have a greater effect on HIV viral load.

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The trial aims to compare the immune responses to VIR201 in both ART naïve and experienced patient populations. The trial data will help identify optimum times and conditions to vaccinate patients. It will also assist subsequent clinical trial design.

The US\$6 million trial has been funded by a global coalition of multinational and South African companies in a non-dilutive manner for Virax shareholders (a list of the participating companies is attached to this announcement).

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**About VIR201 HIV therapeutic vaccine**

Current HIV treatments typically use a combination of antiretroviral therapies (ART). The market for HIV medications is huge and projected to increase from \$US9.3 billion in 2007 to \$US15.1 billion in 2017 (source: Datamonitor). The use of ART has reduced mortality and morbidity for HIV patients but often has unwanted side effects, including acute and chronic toxicities plus the potential emergence of drug resistant viruses.

It is proposed that VIR201 would be used with ART, not as a replacement for ART, to delay antiretroviral therapies thereby postponing the unwanted side effects. A secondary application would be to provide the patient with a drug holiday within the ART regime.

VIR201 has been tested in two Australian Phase I/IIa trials and has shown to be safe and well tolerated with the ability to suppress viral load in patients undergoing antiretroviral treatment. This positions VIR201 as one of the most advanced therapeutic vaccines for HIV.

**Participating companies in Virax's Southern Africa HIV Therapeutic Vaccine Project**

- African Rainbow Minerals Limited
- Anvil Mining Limited
- Assmang Limited
- BHP Billiton Limited
- Gold Fields Limited
- Harmony Gold Mining Company Ltd
- Lonmin Plc
- Mitsubishi Materials Corporation
- Nippon Mining and Metals Co. Ltd
- Paladin Energy Limited
- Rio Tinto Limited
- Sumitomo Metal Mining Co. Ltd

**About Virax Holdings**

Virax is an Australian biopharmaceutical company engaged in the discovery and development of novel immunotherapeutic products for the treatment of chronic infectious diseases and cancer.

The Company's lead product is VIR201, a HIV/AIDS immunotherapeutic (therapeutic vaccine) utilising Co-X-Gene™ technology, has been successfully tested in two clinical trials in Australia. A Phase IIa Clinical Trial for VIR201 is nearing completion in South Africa.

Virax also has a Licence Agreement with major French biotechnology company Transgene (Eurolist Paris: FR0005175080) 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 cervical cancer, and TG4010 – a treatment for non-small cell lung cancer (NSCLC).