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UPDATE ON VIR201 HIV THERAPEUTIC VACCINE PHASE IIa CLINICAL TRIAL

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

The Company is making rapid progress towards presenting the overall preliminary results of the trial in the period late July/August, and advises that the following achievements and milestones have now been completed.

Final Data Safety Monitoring Board meeting completed

The final meeting of the Data Safety Monitoring Board (DSMB) for the VIR201 HIV vaccine was recently completed. The DSMB is a key component in the trial process as it monitors patient safety data through the clinical trial period. The trial's DSMB is composed of a group of clinical trial and HIV experts, and it has advised Virax that there has been no adverse vaccine related safety data in the trial that caused concern.

Immunological analysis and database lock being finalised

The trial is currently focused on completing all immunological analyses. This is being conducted in leading South African laboratories, with trial data being entered into a central database prior to database lock and statistical analysis. The mode of statistical analysis is described in a documented Statistical Analysis plan.

The trial's major immunological read-outs are being performed in four leading South African laboratories; National Institute of Communicable Diseases (NICD) in Johannesburg, TOGA Laboratories in Johannesburg, Contract Laboratory Services in Johannesburg, and Qlabs in Pretoria.

The major immunological readouts being measured are HIV specific T-cell responses as measured by ELIspot assay being performed at NICD, and antibody isotyping which is being performed at Contract Laboratory Services in conjunction with the National Serology Reference Laboratory in Melbourne, Australia.

Increased dose of more highly purified vaccine utilised in trial

Virax advises that an increased dose of a more highly purified VIR201 vaccine is being utilised in the current trial to boost the immune response in comparison to prior Australian clinical trials. A comprehensive immune monitoring program is being undertaken to measure and compare antibody and T-cell immune responses generated in both participant groups.

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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.

The ability to demonstrate that VIR201 modulates the level of antibody isotype (eg IgG2 levels) against HIV antigens and/or induces significant changes in the level of HIV specific T-cell responses via ELIspot analysis in the current trial will significantly enhance the prospects for the further development and commercialisation of VIR201.

Peer reviewed paper to be published in AIDS Journal

A peer reviewed paper describing Professor French's work has been accepted for publication in esteemed international journal AIDS and is expected to be published in the coming few weeks.

Virax CEO Dr Larry Ward said: "We are very pleased at the progress of this major clinical trial for the VIR201 HIV immunotherapy vaccine. The trial is nearing completion and we look forward to the prospect of being able to deliver the trial results in the near future. A successful trial result would be a major milestone in the development and commercialisation plans for VIR201. We are also extremely grateful to the donor syndicate for supporting the clinical research."

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.

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

VIR201 is a therapeutic vaccine, not a preventative vaccine, which allows it to be used to treat HIV infected individuals by lowering viral load.

Current HIV treatments typically use a combination of antiretroviral therapies (ART). The market for HIV medications is huge and projected to increase 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 who have discontinued antiretroviral treatment after vaccination. 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-XGene™ technology, which 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).