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RESULTS FROM VIR201 HIV VACCINE PHASE I/IIa CLINICAL TRIAL

Company pursuing significant new clinical program

Australian bio-pharmaceutical company Virax Holdings Limited (ASX:VHL) advises the preliminary immunogenicity and efficacy results from the Company's Phase I/IIa Clinical Trial for its VIR201 HIV therapeutic vaccine in South Africa.

The trial was conducted on 131 patients, with 65 patients undergoing antiretroviral (ART) treatment and 66 patients being naïve to ART treatment.

The primary immunological endpoint of the trial was T-cell immune response via ELIspot assay. The secondary immunological endpoint was the measurement of Antibody isotype responses (IgG1, IgG2 and IgG3). The effects of VIR201 vaccination on HIV viral load in the ART naïve group and CD4 count were also measured as secondary efficacy endpoints.

VIR201 did not meet its primary or secondary immunological endpoints, failing to elicit a statistically significant increase in immune response relative to the control group in both T-cell assay (ELIspot) and assays of antibody isotype.

Effect of viral load was measured as time weighted mean change from baseline to the end of the trial (pVL). ART naïve patients receiving VIR201 had a 0.61 log reduction relative to placebo in pVL (p=.0934). The reduction in viral load was more pronounced soon after the first vaccination. The VIR201 group had a statistically significant 1.49 log reduction relative to placebo (p=0.0001) one week after the first vaccination with VIR201. Appendix 1 gives more details of the trial design.

The trial was funded by a global coalition of multinational and South African companies. Virax is appreciative of the support provided by these companies. A list of participating companies is attached to this announcement.

The Company is reviewing and further evaluating the trial results, and will further update shareholders in due course.

COMPANY PURSUING NEW CLINICAL PROGRAM

The Virax Board has previously communicated its desire to undertake a suitable value accretive corporate transaction to further expand its product and technology portfolios.

The Company can advise that it has been very active in this area in recent months and is in advanced discussions with a large international immunotherapeutic company regarding a significant clinical program that has the potential to add significant value for shareholders. The Company hopes to announce the results of these discussions in due course and will seek shareholder approval/support by way of a capital raising.

CO-X-GENE™ TECHNOLOGY

Virax retains a key technology asset, the Co-X-Gene™ technology. The company will continue its strategy to add value to this key technology asset through its strategic out-licensing to major French biopharmaceutical company Transgene in two cancer vaccine products, in advanced development (both products use Modified vaccine Ankara as delivery system).

These products are:

- TG4001 (cervical cancer vaccine) - Currently in Phase IIb trials and partnered with Roche; and
- TG4010 (lung cancer vaccine) - Phase IIb trials completed and now in Phase III trials. This is subject to an Option Agreement with Novartis.

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The success of both products to date provides clinical validation of the Co-X-Gene™ technology. The Co-X-Gene™ technology asset, through the Transgene license, remains of significant value to Virax.

In light of the current trial results, the Company will now review its future plans for VIR201, which also uses the Co-X-Gene™ Technology with a fowlpox delivery system.

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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

Appendix 1

Name of trial
A Phase I/IIa, double-blind, randomised, placebo-controlled, parallel group study to determine the safety, tolerability and immunogenicity of an HIV-1 immunotherapeutic vaccine expressing Clade B antigens Gag and Pol (VIR201) in HIV-1-positive participants

Protocol number
VIR201-04-06

Investigational medicinal product
VIR201

Dosing regime
During the Treatment Period, study vaccine (VIR201 or placebo) was administered four times at Weeks 0, 4, 8 and 12.

Primary endpoint:
- Safety and tolerability: Local and systemic adverse events (AEs).
- Immunogenicity: T-cell responses as determined by interferon-gamma (IFN-γ) enzyme-linked immunospot (ELISPOT) assays. The response were measured 13 weeks after the first vaccination

Secondary Immunological and efficacy endpoints analysed in preliminary report
- Antibody responses to HIV-1 (including immunoglobulin G [IgG] isotype analysis).
- HIV viral Load
- CD4 cell count

Countries:
South Africa

Number and distribution of patients:
One Hundred and thirty one patients (66 ART naïve and 65 ART experienced) were enrolled with approximately 2/3rd receiving VIR201 and 1/3rd placebo.

Safety
Safety was assessed via medical history/physical examination, vital signs (including oral temperature), injection sites for localised reactions, laboratory assessments and adverse events. This data is still being analysed and will be reported in full at a later date. An independent Data Safety Monitoring Board met throughout the trial and did not find any safety data that necessitated any change for the continuation of the trial.