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Virax gets green light for commencement of Phase II US clinical trials of VIR201

Virax Holdings Limited (ASX: VHL) today announced the US Food and Drug Administration (FDA) have allowed an Investigational New Drug (IND) application for the Phase II testing of the Company's VIR201 vaccine for treatment of HIV/AIDS.

The IND application drew on data from the Phase I and IIa trials conducted in Australia, which showed that VIR201 suppressed the HIV viral load in patients by up to a factor of ten.

VIR201 is the only therapeutic vaccine based on stimulating the immune system known to have shown such a positive effect in suppressing virus levels in HIV infected patients in controlled clinical trials.

Many aspects of VIR201 product development including manufacture and quality control testing, pre-clinical development, including safety and efficacy tests and the design, and performance of the clinical trial have been reviewed by the FDA as part of this process.

Commenting on the announcement today, Virax Chief Executive Officer Dr. David Beames said, "This is a very significant achievement for Virax. We are one of only a few Australian companies to have a Phase II trial application allowed by the FDA".

"We firmly believe that our Co-X-Gene^{TM} technology is unique and significant, and VIR201 has the potential to significantly improve the medical outcomes for millions of HIV sufferers".

"Confirmation of our present results in a larger trial with a broader patient population would be a transforming event for the Company. This would be an important step in the development of an exciting new class of drug to treat HIV, currently a US$8.0 billion market and growing at more than 10% a year".

Commencement of the Phase II trial is subject to the availability of sufficient funds to conduct the trial. The Company is currently pursuing all available options, including admission to the Alternative Investment Market (AIM) in London, for funding the Phase II VIR201 studies.

The proposed US trial is in addition to the Phase I/IIa trial of VIR201 planned for the developing world. An application to conduct a trial in South Africa was submitted to the South African Medicines Control Council in September 2006.

Virax has received funding pledges from Melbourne-based BHP Billiton as well as several major South African and international corporations. These pledges of financial support will enable the South African trial to proceed once approval from the MCC and other regulatory bodies has been secured.

The Virax Board firmly believes that VIR201, based on Co-X-Gene^{TM} technology is a unique and potentially important new approach to treating HIV. The availability of additional, positive trial data will add significant value to the Company.

About Virax

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

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

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