

13 February 2017

The Manager Companies
ASX Limited
20 Bridge Street
Sydney NSW 2000

(2 pages by email)

Dear Madam

COMMENCEMENT OF BIT225 PHASE 2 HIV-1 CLINICAL TRIAL

Sydney, Australia, 13 February 2017: The Directors of Biotron Limited (ASX: BIT) are pleased to announce that the Company has commenced a Phase 2 human clinical trial (BIT225-009) with its lead antiviral drug BIT225.

The trial is a Phase 2, multi-centre, randomised, placebo-controlled, double-blind study of BIT225 and Combination Antiretroviral Therapy (cART): Atripla® in patients with Human Immunodeficiency Virus (HIV-1) infection. HIV-1-infected patients will not have previously been on anti-HIV-1 treatment (i.e. treatment naïve) and who will be commencing a cART regimen (approved anti-HIV-1 drugs). Patients will receive cART in addition to 12 weeks with BIT225 or placebo.

The trial includes a dose escalation, with an initial group of 9 patients receiving 100 mg BIT225 once daily, or placebo, together with cART. A second group of 27 patients will receive 200 mg BIT225 once daily, or placebo, together with cART.

At the conclusion of the trial, patients will remain on cART as per standard treatment protocols.

The trial will be undertaken at HIV-NAT, Thai Red Cross AIDS Research Centre in Bangkok, Thailand. HIV-NAT is affiliated with the Kirby Institute for Infection and Immunity in Society located at the University of New South Wales (UNSW), Sydney, Australia, and with the Amsterdam Institute for Global Health and Development in Amsterdam (AIGHD), The Netherlands. HIV-NAT is an internationally recognised research organisation and its core research areas include pharmacokinetics of HIV-1 therapy, co-infections with Hepatitis B, tuberculosis and HPV, new drug development and strategic studies.

An additional trial site is expected to commence recruitment shortly once appropriate ethics and regulatory approvals are in place at that second site.

The primary objectives of the study are to:

- Determine the efficacy of 12 weeks of BIT225 treatment in HIV-1 infected subjects receiving cART: Atripla® by measuring plasma viral load decay and modelling HIV-1 decay.
- Determine the safety and tolerability of BIT225 administered once daily for 12 weeks in HIV-1 infected subjects on cART: Atripla®.

The secondary objectives of this study are to:

- Determine if 12 weeks of BIT225 treatment in addition to cART: Atripla® will impact levels of sCD163, a primary biomarker of monocyte immune activation.
- Evaluate the pharmacokinetics of 100 mg BIT225 administered once daily for 12 weeks in combination with cART:Atripla® in subjects infected with HIV-1.

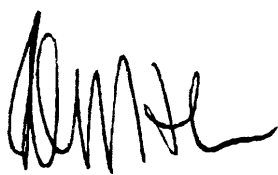
The Company is aiming to demonstrate:

- *Accelerated reduction of HIV-1 in patients treated with BIT225 in combination with cART, indicating that BIT225 can significantly improve current standard of care anti-HIV-1 treatment; and*
- *Reduction in HIV-1-induced immune activation, indicating that BIT225 is targeting viral reservoirs not impacted by cART.*

The commencement of the BIT225-009 clinical trial builds on the recent announcement by Biotron of successful results with BIT225 in a humanised mouse study of HIV-1 infection.

Biotron's Managing Director, Dr. Michelle Miller said, "Initiating this clinical trial is an important step towards demonstrating the clinical benefit that BIT225 could bring to the treatment of HIV-1. BIT225 has the potential to play a key role in the eradication of HIV-1 by targeting and clearing HIV-1 from cellular reservoirs. We expect to see early results from the trial in late Q3 this year."

Yours sincerely



Peter J. Nightingale
Company Secretary

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About Biotron

Biotron Limited is engaged in the research, development, and commercialisation of drugs targeting significant viral diseases with unmet medical need. The Company has BIT225 in clinical development for both HIV-1 and HCV and also has several earlier stage preclinical and research programs designing drugs that target a class of virus protein known as viroporins which have a key role in the virus life cycle of a very broad range of viruses, many of which have caused worldwide health issues such as Dengue, Hepatitis B, Ebola, Middle East Respiratory virus, Influenza and Zika viruses.

Enquiries

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