

23 August 2022

The Manager - Companies
ASX Limited
20 Bridge Street
SYDNEY NSW 2000

(2 pages by email)

Dear Madam,

BIT225 PHASE 2 HIV-1 CLINICAL TRIAL FULLY RECRUITED

The Directors of Biotron Limited ('Biotron' or 'the Company') are pleased to advise that a Phase 2 HIV-1 clinical trial (BIT225-010; ACTRN12621000937819) of its lead antiviral drug, BIT225, is fully recruited.

The trial, which is in progress at sites in Bangkok and Chiang Mai, Thailand, is a Phase 2, multi-centre, randomised, placebo-controlled, double-blind study of BIT225 in HIV-1 infected, treatment naïve people commencing standard antiretroviral treatment (i.e. approved anti-HIV-1 drugs; ART). The study is designed to determine the safety and efficacy of 200 mg BIT225 administered daily for 24 consecutive weeks.

As per the clinical trial protocol, a total of 27 individuals, randomly assigned on a 2:1 ratio to receive BIT225 (n=18) or placebo (n=9), have been enrolled in the study. At the conclusion of the trial, everyone will remain on ART as per standard treatment protocols.

The trial was undertaken to confirm and further characterise the positive outcomes reported from previous clinical trials of BIT225 in this population and to extend the duration of treatment.

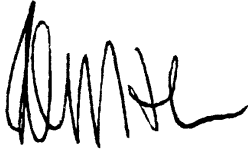
Previous clinical data indicated that treatment for 12 weeks with BIT225 in newly diagnosed HIV-infected people starting ART significantly improved key markers of immune dysfunction, which indicated a boosting of the immune system against HIV-1.

This current trial is expected to provide additional key information on the impact of BIT225 on HIV-induced immune dysfunction as well as important safety information about dosing over an extended period in this patient population (24 weeks in the current trial versus 12 weeks in a previous completed trial).

The clinical phase of the trial (last patient, last dose) is scheduled to be completed in February 2023. Blood samples collected during the study will then be analysed. Once all analyses are complete, the trial database will be locked and the results subject to statistical evaluation. The study will then be unblinded and outcomes reported. Preliminary results are anticipated in mid-2023.

Biotron's Managing Director, Dr. Michelle Miller said, *"We are pleased to have completed enrolment of all patients in a very short time frame. This is an excellent achievement, especially taking into consideration the significant challenges in undertaking clinical trials during COVID lockdowns. We also have a second HIV-1 Phase 2 trial underway here in Australia and we look forward to completing recruitment of that study shortly."*

Yours sincerely



Peter J. Nightingale
Company Secretary

pjn11342

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 HIV-1 and promising preclinical programs for SARS-CoV-2 and HBV. In addition, Biotron has several earlier stage 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 Coronavirus, Dengue, Ebola, Middle East Respiratory virus, Influenza and Zika viruses.

This announcement has been approved for release by the Company's Managing Director.

Enquiries

Dr Michelle Miller
Managing Director
Biotron Limited
+61-(0)412313329

Rudi Michelson
Monsoon Communications
+61-3 9620 3333