

4 October 2022

The Manager Companies  
ASX Limited 20 Bridge Street  
SYDNEY NSW 2000

(2 pages by email)

Dear Madam

### **SECOND BIT225 PHASE 2 HIV-1 CLINICAL TRIAL FULLY RECRUITED**

The Directors of Biotron Limited ('Biotron' or 'the Company') are pleased to advise that a second Phase 2 HIV-1 clinical trial (BIT225-011; ACTRN12621001354875) of its lead antiviral drug, BIT225, has completed enrolment.

The trial, the second to complete enrolment within the last few weeks, is in progress at sites in Sydney, Australia. It is a Phase 2 study of BIT225 in HIV-1 infected people who have achieved only partial immune reconstitution despite treatment with standard antiretroviral treatment (i.e. approved anti-HIV-1 drugs; ART).

As previously advised, the study is designed to determine change of immune, immune activation, inflammation and viral markers with the addition of 200 mg BIT225 to stable, suppressive ART administered daily for 12 consecutive weeks. People enrolled in the study are monitored for four weeks prior to the addition of BIT225 to their treatment regimen to establish the baseline levels of these key markers that are then assessed during the BIT225-treatment period.

As per the clinical trial protocol, a total of 20 individuals have been enrolled in the study. At the conclusion of the trial everyone will remain on ART according to standard treatment protocols.

The trial is the first assessment of BIT225 in an ART-experienced cohort. Previous studies, including a Phase 2 trial that is current in progress in Thailand, were designed to investigate treatment in newly diagnosed HIV-infected people commencing ART.

This Australian trial includes people who have not achieved full immune reconstitution despite long term durably suppressive ART. This group, estimated to encompass more than one third of the HIV-treated population, is at an increased risk of clinical progression to AIDS and other morbidities and has higher rates of mortality than HIV-infected patients who have attained full immune reconstitution.

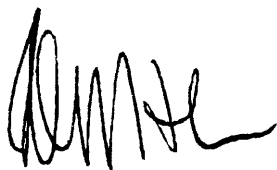
In 2021, 38.4 million people globally were living with HIV, with 1.5 million becoming newly infected with the virus and an estimated 650,000 people dying from AIDS-related illnesses. The global HIV drug market size in 2021 was estimated to be US\$30 billion. The increased prevalence of HIV-1 infections, percentage of patients on treatment due to improved disease awareness and the need for treatments to improve quality of life are expected to drive market growth to over US\$50 billion by 2030.

The two Phase 2 trials currently in progress build on favourable results from the completed BIT225-009 Phase 2 clinical trial in which BIT225 was shown to have positive effects on key immunologic markers of improved health outcomes. The two current trials are designed to investigate further the immune changes observed in the BIT225-009 study.

The clinical phase of the BIT225-011 trial (last patient, last dose) is scheduled to be completed in January 2023. Blood samples collected during the study will then be analysed and 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 very pleased to have completed patient enrolment into this important Australian trial. The COVID-19 pandemic created an extraordinarily challenging environment in which to undertake clinical trials and our sincere thanks go to the principal investigators, trial sites and coordinators for their efforts in completing this milestone. We look forward to completing the study and reporting results during the first half of 2023."*

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 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**

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