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The Manager Companies
ASX Limited
20 Bridge Street
Sydney NSW 2000

(2 pages by email)

COMPLETION OF PHASE 2 HIV-1 CLINICAL TRIALS

The Directors of Biotron Limited ('Biotron' or 'the Company') are pleased to advise that all participants in the two Phase 2 HIV-1 clinical trials of the Company's antiviral drug BIT225 have completed dosing, marking the end of the clinical phase of the trials.

As previously advised, the trials have been designed to generate data that extend the positive findings from previous clinical trials conducted by Biotron in which BIT225 was shown to have positive effects on key immunologic markers of improved health outcomes. The data will be central to demonstrating to potential pharmaceutical partners and regulatory authorities the safety and efficacy of BIT225 in patients with currently unmet medical needs.

The BIT225-011 Phase 2 HIV-1 trial that has been underway at sites in Sydney, Australia, including St Vincent's Hospital, Holdsworth House and East Sydney Doctors, is investigating the impact of BIT225 in HIV-infected people who have been taking approved anti-HIV-1 treatment ('ART') for an extended period with well-controlled HIV-1 infection but 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. BIT225 was added to this group's ART treatment for a period of three months. The endpoints for this trial include measurements of improved immune function and markers linked to immune reconstitution.

The BIT225-010 Phase 2 HIV-1 trial that was run at sites in Thailand included people newly diagnosed as being HIV-1 positive but not yet commenced ART with BIT225 treatment or placebo continuing for six months in combination with ART. This extended dosing period allows for a more detailed investigation of immune changes observed in previously completed HIV-1 clinical studies with BIT225. The endpoints for this trial include measurements of improved immune function and markers linked to immune reconstitution.

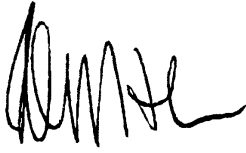
Biotron's Managing Director, Michelle Miller said, "We are very pleased to have reached this important milestone, completing not one, but two, Phase 2 trials is a remarkable achievement and adds significant value to the Company's portfolio. We look forward to completing the detailed laboratory studies on the samples collected during the trials and reporting preliminary results in mid-2023."

With the clinical phase completed, focus is now on undertaking detailed laboratory analyses of all the samples collected during the trials. The assays are complex and will take several months to complete. Once all the data is available, the study will be unblinded and the data subjected to statistical analyses.

Preliminary results from the trials are anticipated to be available in mid-2023.

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

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 expects to shortly commence a Phase 2 trial for COVID-19. Biotron has a promising preclinical program for Hepatitis B virus, as well as 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.

Enquiries

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

Rudi Michelson
Monsoon Communications
+61-3 9620 3333