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14 September 2022  
The Manager Companies  
ASX Limited  
20 Bridge Street  
Sydney NSW 2000

(2 pages by email)

Dear Madam

### **BIT225 COVID-19 HUMAN STUDY COMMENCED**

The Directors of Biotron Limited ('Biotron' or 'the Company') are pleased to advise that the Company has commenced a human trial of its lead antiviral drug BIT225 against COVID-19.

The COVID-19 trial of BIT225 has been approved as a sub-study in the ongoing Phase 2 BIT225-010 HIV-1 clinical trial (ACTRN12621000937819) currently in progress at sites in Thailand.

The COVID-19 sub-study was approved by the Institutional Review Board of the Faculty of Medicine, Chulalongkorn University, Bangkok which is responsible for ethics approval at the HIV-NAT site where the trial is underway.

Twenty-seven people have been enrolled into the BIT225-010 HIV-1 clinical trial. Any of these people who are diagnosed with symptomatic COVID-19 infection during the six-month treatment period will be enrolled in the COVID-19 sub-study. SARS-CoV-2 viral load and clinical symptoms will be intensively assessed over a 28-day period.

Participants included in the COVID-19 sub-study will continue on the HIV-1 trial throughout the sub-study and after the sub-study's conclusion. The BIT225-010 study's randomisation and blind will be maintained throughout the COVID-19 sub-study. Primary and secondary objectives of the trial remain unchanged from those previously announced on 1 Nov 2021. The changes in SARS-CoV-2 viral loads and COVID-related symptoms have been incorporated as exploratory objectives.

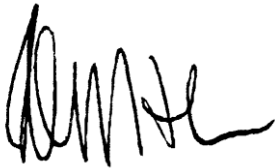
BIT225 has demonstrated both antiviral and favourable immunomodulatory effect in its current development for HIV-1 (ASX announcements 28 September 2018, 28 November 2018, 3 December 2019, 12 March 2020) and has recently demonstrated both antiviral, immune modulatory and clinical benefit against SARS-CoV-2 in an accepted murine model of disease (ASX announcements 25 November 2021, 17 March 2022, 2 May 2022).

The sub-study will follow the same timetable as the parent HIV-1 trial. As previously advised (ASX announcement 23 August 2022) the BIT225-010 trial is expected to conclude in February 2023, with preliminary results anticipated in mid-2023.

Biotron's Managing Director, Dr. Michelle Miller said, *"We are very pleased to be able to incorporate an assessment of BIT225 against SARS-CoV-2 infection and COVID-19 into our on-going Phase 2 HIV-1 clinical trial. There are minimal additional costs associated with the sub-study and no expected impact on timing of the results of the BIT225-010 trial as it is fully recruited."*

*The sub-study provides a speedy and cost effective pathway to explore the potential benefit of BIT225 against SARS-CoV-2 in a high-risk patient population. We look forward to completing the study and reporting results in mid-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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