

16 December 2021

The Manager Companies  
ASX Limited  
20 Bridge Street  
Sydney NSW 2000

(2 pages by email)

Dear Madam

### **UPDATE ON BIOTRON'S HIV-1 AND COVID-19 PROGRAMS**

The Directors of Biotron Limited (ASX: BIT) are pleased to announce that the Company's Phase 2 HIV-1 trial with its lead antiviral drug BIT225 has extended to include a second Australian site.

As previously advised, Biotron commenced a Phase 2 clinical trial (BIT225-011) of BIT225 in November 2021 to investigate key immune changes observed in a previous study. St Vincent's Hospital Human Research Ethics Committee has now approved the study, bringing on board a second key trial site at St Vincent's Hospital, Sydney.

Previous clinical trials have shown that BIT225, an oral, first-in-class anti-viral drug in capsule form, induces important immune system changes that indicate improved health outcomes in HIV-positive people commencing antiretroviral treatment for the first time. This new trial will further investigate the impact of BIT225 in 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 will be added to the BIT225-011 subjects' ART for a period of 12 weeks, after which time they will remain on ART as per standard treatment protocols.

As previously advised, a second Phase 2 HIV-1 trial (BIT225-010) is also underway at two sites in Thailand. This study includes people newly diagnosed as being HIV-1 positive but not yet commenced ART with BIT225 treatment or placebo continuing for 6 months in combination with ART.

The two HIV-1 trials are expected to conclude in mid-2022 and data to be made available during the second half of 2022.

In parallel with progressing these important Phase 2 HIV-1 clinical trials, the Company's current focus is mapping out a clinical development pathway for treatment of COVID-19 with BIT225.

As recently announced, BIT225 has demonstrated substantial and clinically meaningful efficacy against SARS-CoV-2 in a series of animal and cell-based studies performed at The SCRIPPS Research Institute, La Jolla, CA, USA. The drug protected animals infected with the virus from developing severe disease.

The Company is in discussions with its USA advisors and consultants to expedite testing of BIT225 in a human trial for treatment of COVID-19. In parallel, Biotron is seeking non-equity funding to accelerate progression into the clinic.

Biotron's Managing Director, Dr. Michelle Miller said, "We are putting significant effort into developing a robust path to expedite human trials of BIT225 for treatment of COVID-19. This process involves coordination between the Company, international medical experts in the treatment of COVID-19 and clinical trial design, regulatory authorities and funding agencies. The emergence of the new Omicron variant highlights the urgent need for oral drugs to treat the infection and prevent severe disease, especially in at-risk individuals. BIT225 has an established human safety profile and has the potential to be an important first in class drug for COVID-19 treatment."

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 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.

#### **Enquiries**

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