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April 6, 2018  
The Manager Companies  
ASX Limited  
20 Bridge Street  
Sydney NSW 2000

(2 pages by email)

Dear Madam

## **UPDATE ON PROGRESS OF BIT225 PHASE 2 HIV-1 CLINICAL TRIAL**

Sydney, Australia, April 6, 2018: The Directors of Biotron Limited (ASX: BIT) are pleased to provide an update on the progress of the Company's 'First in Class' HIV-1 clinical trial.

The trial is a Phase 2, multi-centre, randomised, placebo-controlled, double-blind study of Biotron's lead molecule, BIT225, and Combination Antiretroviral Therapy (cART): Atripla® in patients with Human Immunodeficiency Virus (HIV-1) infection. HIV-1-infected patients had not previously been on anti-HIV-1 treatment (i.e. treatment naïve) and were commencing a cART regimen (approved anti-HIV-1 drugs). Patients received cART in addition to 12 weeks with BIT225 or placebo.

The objectives of the trial are to assess:

- Impact of BIT225 in combination with cART on plasma and intracellular HIV-1 virus levels, and
- Impact of BIT225 on HIV-1-induced immune activation.

While final data are not available, it is encouraging to note that no subjects withdrew from the highest drug dose group, and no serious adverse events were reported. In addition, preliminary data indicate that there were no major interactions between BIT225 and the other HIV-1 drugs – this is a very important consideration for a new HIV-1 drug.

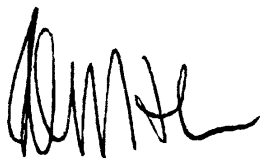
To assess the efficacy of BIT225 in this clinical trial, the Company is utilising a recently developed novel diagnostic assay. This assay has greater potential to conclusively demonstrate that BIT225 can specifically target reservoir cells that remain infected in the presence of current anti-HIV-1 drugs.

Taking this critical scientific step will extend timelines. The assay is technologically challenging and time consuming. However, the analyses form a key element in Biotron's strategy of demonstrating that the addition of BIT225 to cART has the ability to be a key component of an overall cure strategy for HIV-1.

The new assay has been tested on samples from previous trials during this period of development and validation, and the results have demonstrated that the assay has the appropriate sensitivity and ability to quantify HIV-1 within reservoir cells. Work will now proceed on samples from the 009 trial.

Once the data from this new assay is available and the results are un-blinded, Biotron will be able to assemble a complete dataset, and report on the outcomes of the trial. It is anticipated that results will be available before the end of the current financial year.

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 a promising preclinical program for 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 Dengue, Ebola, Middle East Respiratory virus, Influenza and Zika viruses.

### **Enquiries**

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