

25 October 2013

The Manager Companies  
ASX Limited  
20 Bridge Street  
Sydney NSW 2000

(3 pages by email)

Dear Madam

**BIT 225 ENHANCES ANTI- VIRAL ACTIVITY IN HIV/HCV GENOTYPE 3 CO-  
INFECTED PATIENTS;  
PHASE 2 DATA TO BE PRESENTED AT LEADING INTERNATIONAL LIVER  
MEETING**

- **100% of Genotype 3 patients completing 28 days of treatment with BIT225 in combination with interferon and ribavirin had undetectable HCV levels**
- **BIT225 abstract accepted as late breaking poster at AASLD “The Liver Meeting”**
- **Growing data set underscores significance of Biotron’s anti-viral portfolio**

**Sydney, NSW, Australia, October 25, 2013** - Biotron Limited ('Biotron'), is a clinical-stage drug development company focused on development of new generation antiviral drugs. Biotron today announced preliminary headline data from its Phase 2 open-label pilot study of BIT225 in patients co-infected with Hepatitis C virus (HCV) and HIV. The data will be detailed in a late-breaking poster at the American Association for the Study of Liver Diseases (AASLD) 2013 annual conference (The Liver Meeting) in Washington DC, USA in early November.

This trial was an open label clinical study of BIT225 in combination with pegylated interferon alfa-2b (IFN) and weight-based ribavirin (RBV). Twelve patients (4 x HCV Genotype 1a, 8 x Genotype 3) were enrolled into the study. Patients received IFN/RBV for 7 days before commencing treatment with BIT225. They then received 300 mg BIT225 twice daily plus IFN/RBV for 28 days. After that time, patients continued to take IFN/RBV for a total of 48 weeks. All patients had undetectable levels of HIV at the time of enrolment into the study and continued to take anti-retroviral drugs throughout the study. The trial was conducted at Siriraj Hospital, Bangkok.

Interim analysis of virus levels in the treated patients indicates that all six HCV Genotype 3 subjects who completed 28 days of BIT225 therapy had undetectable levels of HCV 12 weeks into the study. Response to treatment at this time point is generally a good indication of final outcome at 48 weeks.

The Company's Managing Director, Dr Michelle Miller, commented: "The Genotype 3 data from this trial is particularly encouraging. The other new classes of direct-acting antiviral drugs (DAAs) in development are not very effective in these patients, with response rates as low as 37% after 12 weeks of treatment. In contrast, we saw 100% response at 12 weeks, with only 4 weeks of treatment with BIT225."

This was the first trial of BIT225 in the HIV/HCV co-infected patient population. These patients tend to have more serious HCV infection and have lower response rates to treatment with IFN/RBV than HCV mono-infected patients.

Dr Miller noted: "The added benefit of BIT225 in these hard-to-treat patients appears clear from the overall response rates. In addition, there was a marked improvement in the rate of virus eradication after commencing BIT225 treatment."

The current approved treatment for HIV/HCV co-infected patients IFN/RBV. However, this treatment is associated with a high rate of side effects, and up to 50% of patients do not respond to treatment with these drugs. Lack of response is linked to a particular genetic form of the IL28B gene, in particular in patients infected with HCV genotype 1. In this study, two of the HCV genotype 1-infected patients did not respond to treatment. This was likely due to their specific IL28B genes which affected their ability to respond to IFN.

"We were especially pleased to have our data selected for a Late Breaking poster as it underscores the importance of our positive clinical data with BIT225 to treat HIV/HCV co-infected patients. Only a few such submissions were chosen for Late Breaking presentation", noted Dr Miller.

This latest data of BIT225 activity against HCV genotype 3 extends the drug's data portfolio of anti-HCV activity. Previous trials have shown that the drug has good activity against the hard-to-treat genotype 1 variant of the virus.

Biotron's BIT225 targets the HCV viral protein p7, which has crucial roles in virus replication and reproduction. It is a new target, and BIT225 is a first-in-class direct acting antiviral for the treatment of HCV.

BIT225 is also in development for treatment of HIV, with demonstrated clinical efficacy against HIV in reservoir cells.

#### **Enquiries**

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## **About Biotron and BIT225**

Biotron Limited is engaged in the research, development, and commercialisation of drugs targeting significant viral diseases with unmet medical need, with a major focus on HIV and HCV. The Company has BIT225 in clinical development for both HIV and HCV, and also has several earlier stage preclinical and research programs for several other viral infections including Dengue.

BIT225 has recorded highly encouraging data against HCV in clinical trials. A phase 2a trial in HCV demonstrated that 100% of HCV genotype 1-infected patients receiving BIT225 (400 mg) in combination with current standard of care therapies interferon and ribavirin had undetectable virus after 48 weeks.

BIT225 is also in development for treatment of HIV, and is the first in a new class of antiviral drugs that may provide a new approach to eradication of this virus. It has shown clinical efficacy against HIV in reservoir cells, and has the potential to be combined with new or existing anti-retroviral drugs to eradicate long-lived pools of virus that are not eliminated with current treatments.

A further phase 2 trial, 3 month-dosing trial of BIT225 in HCV genotype 1 and 3-infected patients is anticipated to commence in late 2013.

Yours sincerely

A handwritten signature in black ink, appearing to read 'Peter J. Nightingale', written in a cursive style.

Peter J. Nightingale  
Company Secretary

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