

6 March 2014

The Manager Companies  
ASX Limited  
20 Bridge Street  
Sydney NSW 2000

(2 pages by email)

Dear Madam

### **BIT225 HIV/HCV TRIAL PATIENTS VIRUS FREE AT SIX MONTHS**

- *Study evaluated BIT225 in patients co-infected with HIV and HCV*
- *All HCV genotype 3 patients completing treatment are virus-free at 24 weeks*
- *Preliminary data from subset of patients shows benefit extends out to 48 weeks*

**Sydney, Australia, 6 March 2014** – Australian drug development company Biotron Limited (ASX:BIT) today announced additional interim positive data from a key phase 2 trial of its lead antiviral drug, BIT225, in patients co-infected with HIV and Hepatitis C virus (HCV).

Analysis of blood samples from patients indicated that all of the HCV genotype 3 patients completing treatment are virus free at the 24 week (6 month) time point. This extends previous data that showed patients had undetectable virus levels at 12 weeks.

Response to treatment at this time point is generally a good indication of final outcome at 48 weeks. Preliminary data from patients who have completed 48 weeks of treatment indicate that they remain virus free at this key time point.

Under the protocol of this open label pilot study, 12 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 48 weeks.

Biotron Managing Director Dr Michelle Miller commented; "This 24 week data further validates the efficacy of BIT225 as a potential new therapy for HCV and, in particular, for this difficult to treat group of HIV/HCV co-infected patients who typically have more serious HCV infection and lower response rates to treatment with existing standard therapies."

In vitro assays have shown that BIT225 has pan-genotypic activity. Previous clinical trials of BIT225 have focused on patients infected with the genotype 1 variant of the virus, which is the most common genotype in Western populations. This data further extends the Company's clinical data portfolio to include genotype 3, which is endemic in south-east Asia.

In HCV, BIT225 targets the p7 protein which is responsible for virus assembly. BIT225 also impacts on the assembly of the HIV virus and specifically targets the virus in reservoir cells. No existing therapy works in this way.

Dr Miller further commented; "Both the HIV and HCV viruses present substantial challenges and there is global demand for novel therapeutics. We look forward to progressing commercialisation of this important compound as a valuable new therapy that is synergistic with current and future treatment strategies."

#### **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 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, 3 month-dosing trial of BIT225 in HCV genotype 1 and 3-infected patients is currently in progress.

Yours sincerely



Peter J. Nightingale  
Company Secretary

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