

10 October 2014

The Manager Companies  
ASX Limited  
20 Bridge Street  
Sydney NSW 2000

(2 pages by email)

Dear Madam

### **BIT225 TRIAL RESULTS SHOW EFFECTIVE CURE OF HEPATITIS C**

- **Biotron achieves sustained virologic response (SVR12) in 100% of hepatitis C virus genotype 3 patients in an open label HIV/HCV genotype 3 trial of BIT225**

**Sydney, Australia, 10 October 2014** – Australian drug development company Biotron Limited (ASX:BIT) today announced that all Hepatitis C virus (HCV) genotype 3 (G3) patients completing a key Phase 2 trial of its lead antiviral drug, BIT225, have undetectable levels of HCV 12 weeks after ceasing all treatment.

The endpoint of HCV treatment is a sustained virologic response (SVR). Sustained virologic response at week 12 (SVR12) is defined as an undetectable HCV RNA level 12 weeks after completion of treatment. It is considered to be a prediction of permanent clearance of the virus and, effectively, a cure.

These findings extend previous data that showed that these patients had undetectable HCV at earlier stages during the treatment period.

Under the protocol of this open label pilot study (BIT225-006) undertaken at a single trial site in Bangkok, Thailand, 8 patients co-infected with HIV and HCV G3 received standard of care HCV drugs interferon and ribavirin (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 until week 48, at which time all treatment was stopped (as per standard treatment guidelines).

The primary objectives of the trial were the assessment of safety and tolerability. Secondary objectives of assessment were of pharmacokinetics and antiviral efficacy.

Of the eight HCV G3 patients enrolled in the trial, three withdrew during the first 12 weeks of the study due to intolerance of the treatment with IFN/RBV. The remaining five completed their full course of treatment and had undetectable levels of HCV from week 12 of dosing. Virus levels continued to be undetected at week 24 and at week 48, when all treatment ceased. At week 60, which is 12 weeks after stopping treatment, all remain clear of virus (SVR). The SVR rate for IFN/RBV alone in HCV G3 patients in Thailand is 68.8%. Although the number of patients in the trial is small, the fact that 100% had no HCV detected from week 12 onwards is encouraging evidence of efficacy of BIT225.

In addition, it has been shown that the rate of reduction in virus levels was accelerated once BIT225 was added to the IFN/RBV treatment at day 7.

Detailed analyses and reviews of safety and pharmacokinetic data from the trial are in progress.

Biotron Managing Director Dr Michelle Miller commented; "These SVR12 data support 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 fewer treatment options."

*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. These data further extend the Company's clinical data portfolio to include genotype 3, which is endemic in Southeast Asia.

A three-month dosing Phase 2, placebo controlled, double-blinded trial of BIT225 in combination with IFN/RBV in HCV genotype 1 (n=30) and genotype 3 (n=30) patients is currently in progress. Preliminary results are expected before the end of 2014.

Dr Miller further commented; "Both HIV and HCV viruses present substantial challenges for treatment and represent multi-billion dollar markets. We look forward to progressing commercialisation of BIT225 as a valuable new therapy that will work in combination with current and future treatment strategies."

Yours sincerely



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Company Secretary

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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.