

23 May 2014

The Manager Companies  
ASX Limited  
20 Bridge Street  
Sydney NSW 2000

(2 pages by email)

Dear Madam

### **BIT225 HCV TRIAL UPDATE – THAILAND**

**Sydney, Australia, 23 May, 2014** – Australian drug development company Biotron Limited (ASX:BIT) today provided an update on its mid-clinical stage program for treatment of Hepatitis C virus (HCV) with the Company's lead antiviral drug, BIT225.

A Phase 2 study (BIT225-008) of BIT225 is currently in progress at key teaching hospitals in Thailand. The trial commenced at Siriraj Hospital, Bangkok in late 2013. Three additional sites in Chiang Mai, Khon Kaen and Bangkok are also screening and enrolling patients.

The Company has been closely monitoring the current situation in Thailand. Information received from the hospital trial sites indicates that no disruptions in operations are expected, and that recruitment and dosing will continue. The Company will continue to monitor the situation in real time.

The study is a placebo controlled, double blind study of BIT225 in 60 patients infected with HCV genotypes 1 or 3. Trial participants will receive 12 weeks of 200 mg BIT225 or placebo, dosed twice daily, in combination with current standard of care therapies - pegylated interferon alfa 2b (IFN) and ribavirin (RBV). On completion of dosing with BIT225, they will remain on IFN/RBV for an additional 12 weeks (genotype 3) or 36 weeks (genotype 1).

The trial has been designed to generate safety and efficacy data on BIT225 over an extended treatment period. Previous studies have shown BIT225 to be safe and well tolerated over a 28 day dosing period, with positive efficacy data in patients infected with HCV genotypes 1 and 3, as well as in HIV/HCV co-infected patients.

Biotron Managing Director Dr Michelle Miller commented; "Good progress is being made with this key phase 2 trial. Information from the trial sites continues to indicate that the trial will be fully recruited in mid-2014, with preliminary data available during the second half of the year."

## Enquiries

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Yours sincerely



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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.

A phase 2 trial in HIV/HCV co-infected patients showed that all HCV genotype 3 patients completing 28 days of treatment with BIT225 in combination with interferon and ribavirin were clear of virus at the 3 and 6 month time points of the trial.

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.