

7 December 2011

The Manager Companies  
ASX Limited  
20 Bridge Street  
Sydney NSW 2000

(4 pages by email)

Dear Madam

## **BIOTRON ANNOUNCES POSITIVE THREE MONTH DATA FOR BIT225 - 87% VIRUS FREE**

- *Phase 2a trial data presented at international conference*
- *87% of HCV trial patients receiving BIT225 have undetectable virus at the three month time point*

**Sydney, Australia 7 December 2011:** Sydney drug development company Biotron Limited (ASX: BIT) has presented data from its phase 2a trial of lead Hepatitis C drug candidate, BIT225, at the international HepDART conference, validating the previously released positive interim results, and providing evidence of improved benefit out to three months.

The trial's Principal Investigator, Dr Tawesak Tenwandee from Siriraj Hospital, Bangkok, Thailand, presented data from the 28 day study of Biotron's BIT225 used in combination with current approved standard of care (SOC) therapies interferon alfa-2b plus ribavirin. Patients then continued on with SOC for a further 44 weeks, with follow-up visits at two and three month time points as well as at 48 weeks.

Biotron presented data showing that 87% of trial subjects who had received BIT225 achieved a complete early viral response (EVR), defined as virus levels in the blood below the level of detection (<50 IU/ml at 12 weeks). This was compared to 63% of patients who received SOC alone.

Previously announced headline data from the four week time point (i.e. at the conclusion of treatment with BIT225) was also presented. At that time point, patients who had received BIT225 had significantly less virus than those who had received SOC alone, with an average of ~90% less virus (~1 log reduction) in the cohort receiving 400 mg of BIT225. The effect of BIT225 was dose-dependent, with patients receiving 200 mg of BIT225 showing a smaller effect on virus levels at the conclusion of dosing than those receiving the higher dose.

The three month data demonstrates that BIT225 continued to provide additional benefit to patients after the conclusion of dosing.

Biotron CEO Dr Michelle Miller said these results extended the previously released headline results and further validated plans to progress the HCV program.

"These results are impressive. To have close to 90% of patients achieving a complete EVR after three months is extremely encouraging and demonstrates the clinical benefit of BIT225," she said.

"We have now established that BIT225 significantly increases the response to the current approved anti-HCV treatment, with improved outcomes for those patients infected with HCV genotype 1, the most common form of Hepatitis C and the most difficult variant to treat."

It was also demonstrated that BIT225 was generally well tolerated. The SOC treatment is known to be associated with a range of significant side effects. The most common side effect that is possibly associated with BIT225 was nausea during the first week of the study. This may be formulation-related, and expected to be overcome with further formulation development.

Biotron's BIT225 targets the 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.

As well as being synergistic with current approved SOC HCV treatments, preclinical studies have demonstrated that BIT225 also works well *in vitro* with some polymerase inhibitors, another new drug class that is in clinical development.

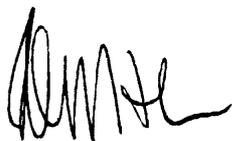
BIT225 is also in development for treatment of HIV, with a Phase 1b/2a trial currently in progress. BIT225 offers a unique opportunity for potential use in the HIV/HCV co-infected population.

## Enquiries

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Yours sincerely



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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, 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 influenza, Dengue and Hepatitis B.

## **About BIT225 and HCV**

BIT225 represents a first-in-class drug for treatment of HCV, targeting the p7 protein of HCV. It is estimated that in the USA alone, some 4 million people have been infected with Hepatitis C with 2.7 million suffering from chronic infection. Worldwide, 170 million people are infected. HCV causes inflammation of the liver, which may lead to fibrosis and cirrhosis, liver cancer and, ultimately, liver failure. Existing drugs for HCV have limited effectiveness and toxicity issues, leaving a significant need for new therapies. The worldwide market is currently almost US\$3.3 billion, but is estimated that this market will expand to over US\$10.0 billion as safe, effective therapies enter the market.

Monotherapy with interferon- $\alpha$  and combination therapy with interferon- $\alpha$  and the ribonucleoside analog ribavirin are the two different regimens currently approved as therapy for chronic hepatitis C. Treatment with interferon- $\alpha$  alone, or in combination with ribavirin, has limited effectiveness. The use of interferon based therapy for the treatment of HCV can be further limited by frequent side effects, injectable administration and poor patient tolerance and adherence. Many patients receiving interferon can experience influenza like symptoms, fatigue and depression. Ribavirin can be problematic for patients with pre-existing anemia, kidney problems or heart disease.

BIT225 has been shown to be synergistic with interferon and ribavirin, the current approved drugs for HCV treatment, as well as with NS5B inhibitors which are a new class in development. The use of BIT225 in combination with either the current standard of care treatment, or NS5B inhibitors, holds exciting potential therapeutic treatment of human HCV infections.