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The Manager Companies ASX Limited 20 Bridge Street SYDNEY NSW 2000

(3 pages by email)

Dear Madam,

# Biotron Limited to report new clinical data from BIT225 Hepatitis C Phase 2a trial in a late-breaking presentation at the AASLD 2012 annual conference

# - 100% of HCV trial patients receiving 400mg of BIT225 daily for 1 month, had undetectable virus the at 48 week time point

**Sydney, NSW, Australia, October 16, 2012 -** Biotron Limited ('Biotron'), a clinical-stage drug development company focused on development of new generation antiviral drugs, today announced that the Company will report new clinical data from its Phase 2a trial of BIT225 in patients infected with Hepatitis C virus (HCV). The data will be detailed in a late-breaking presentation at the American Association for the Study of Liver Diseases (AASLD) 2012 annual conference in Boston, USA.

Previously released data from the 28 day Phase 2a trial of BIT225 demonstrated that BIT225 significantly increased the response to the current approved anti-HCV treatment, with improved outcomes for those patients infected with HCV. At the three-month time point 87% of patients who received BIT225 in addition to standard of care (SOC), interferon alfa-2b plus ribavirin (IFN/RBV), were clear of virus, compared to 63% of those receiving IFN/RBV alone.

The abstract titled "High sustained viral response with a HCV p7 inhibitor, BIT225: Antiviral activity and tolerability of BIT225 plus pegylated interferon alfa 2b and weight-based ribavirin for 28 days in HCV treatment-naïve patients" will be presented in a late-breaking presentation on November 12 at The Liver Meeting® 2012, the 63rd annual meeting of the AASLD, which will take place from November 9-13 in Boston, Massachusetts.

Key new data that will be presented include results from the week 48 follow-up of trial participants. These latest results demonstrate that 100% of patients who received 400mg dose of BIT225 in addition to IFN/RBV maintained a sustained virological response (SVR), with virus levels below the limit of detection. Patients who received 200mg of BIT225 in addition to IFN/RBV had 87.5% SVR, while patients who only received treatment with IFN/RBV had 75% SVR.

The 48-week data extends the previous three-month data, and demonstrates that BIT225 appeared to continue to provide additional benefit to patients after the conclusion of dosing.

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.

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 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. A trial in this patient population is anticipated to commence before the end of 2012.

## **Enquiries**

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Yours sincerely

Peter J. Nightingale Company Secretary

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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 Dengue.

### **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.