

10 March 2011

The Manager Companies  
ASX Limited  
20 Bridge Street  
Sydney NSW 2000

(2 pages by email)

Dear Madam

## **STAGE ONE OF LANDMARK HEPATITIS C DRUG TRIAL COMPLETED**

*Second half of trial now underway*

*Results expected June 2011*

Sydney, Australia, 10 March 2011: Australian drug development company Biotron Limited (ASX: BIT) has completed stage one of a landmark human trial of its lead Hepatitis C drug candidate, BIT225.

Twelve patients have been dosed in the first half of the trial being undertaken by ACLIRES, an international contract research organisation (CRO) that specialises in running antiviral drug clinical trials. All are infected with the most common strain of the Hepatitis C virus, genotype 1.

The second half of the trial - which also involves 12 patients - is now underway and expected to be completed in May, with results anticipated to be analysed and released in June. The trial is blinded, so no results are available until samples are analysed at the conclusion of the trial and the data is unblinded.

Biotron CEO, Dr Michelle Miller, said the trial was proceeding as expected and the results would be "of international interest".

She said BIT225 was a first-in-class drug candidate which specifically targeted the p7 protein, a viral protein essential to virus production and replication.

"We are happy with how the trial is progressing. We achieved the necessary ethics and drug import approvals to move to the second stage of the trial, which is now underway."

Twelve further patients are now being recruited and dosed over four weeks with BIT225.

As in stage one of the study, one-third of patients are being given a placebo, one-third a dose of 400mg BIT225 and another one-third are being dosed at 200mg BIT225.

This Phase II trial is examining how BIT225 works in combination with current approved treatments for HCV, Interferon and Ribavarin.

Existing drugs have limited effectiveness and can be toxic. Doctors say fifty per cent of sufferers do not respond to current therapies, signalling a need for new treatments that directly target and halt replication and reproduction of the virus.

### **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, which causes inflammation of the liver and 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\$3.0 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 and combination therapy with Interferon and the ribonucleoside analog Ribavirin are the two different regimens currently approved as therapy for chronic hepatitis C. Treatment with Interferon 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.

Preclinical studies have shown that BIT225 is highly 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.

For further information please contact Dr Michelle Miller, CEO and Managing Director on (61-2) 9805 0488.

Yours sincerely



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