

7 August 2008

The Manager Companies  
Australian Stock Exchange Limited  
20 Bridge Street  
Sydney NSW 2000

(3 pages by email)

Dear Madam

### **PHASE Ib/IIa HCV CLINICAL TRIAL COMMENCED**

The Directors are pleased to advise that Biotron Limited ('Biotron') has commenced a Phase Ib/IIa clinical trial of BIT225 in Hepatitis C virus ('HCV') infected patients.

A Phase I clinical trial for BIT225 was successfully completed in uninfected volunteers in 2007. This Phase Ib/IIa clinical trial is the first time that the drug will be assessed in HCV-infected patients.

"The initiation of clinical testing of Biotron's HCV inhibitor in infected patients is a major milestone for the Company" said Michelle Miller, Ph.D., Biotron's Managing Director. "Hepatitis C is a significant health problem, with a large percentage of patients failing current treatments. BIT225 may offer an alternative for those patients."

BIT225 is an orally administered, novel antiviral compound in development by Biotron for treatment of HCV infections. BIT225, which represents a first-in-class drug for treatment of HCV, targeting the p7 protein of HCV, has demonstrated good antiviral activity in surrogate models of HCV infection, and has been shown to be highly synergistic with current leading therapies for this disease.

The clinical trial is a placebo-controlled, randomised study of the safety, pharmacokinetics and antiviral activity of BIT225 in patients with HCV infection. The primary objective is to assess the safety and tolerability of BIT225, given twice daily, for 14 consecutive days. The secondary objectives are to assess the pharmacokinetics of BIT225 as well as to assess the antiviral efficacy of BIT225 in these patients. Eighteen patients will receive one of two dose levels of BIT225 or placebo on a random selection basis. Additional information relating to the study design is set out in the attached Appendix.

It is anticipated that the trial will be completed by the end of 2008.

## **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 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\$3.0 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- $\alpha$  and combination therapy with interferon- $\alpha$  and the ribonucleoside analogue 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.

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

Yours sincerely



Peter J. Nightingale  
Company Secretary

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## APPENDIX

A summary of the key aspects of this HCV clinical trial is set out below:

|                             |  |
|-----------------------------|--|
| Study title:                | A Phase I, placebo-controlled, randomised study of the safety, pharmacokinetics and antiviral activity of BIT225 in patients (male and female) with HCV infection.   |
| Primary objective:          | To evaluate the safety and tolerability of 35 mg and 200 mg BIT225 administered twice daily compared with placebo in patients with chronic HCV infection.  |
| Secondary objectives:       | <ol style="list-style-type: none"><li>1. To evaluate the pharmacokinetics of 35 mg and 200 mg BIT225 administered for 14 consecutive days in patients with chronic HCV infection.</li><li>2. To evaluate the antiviral activity of BIT225 administered for 14 consecutive days in patients with chronic HCV infection.</li></ol> |
| Route:                      | Oral.  |
| Test formulation:           | BIT225 powder mixed with 25 mL OraSweetSF™   |
| Placebo formulation:        | Lactose mixed with 25 mL OraSweetSF™   |
| Dose levels:                | Two dose levels of BIT225 (35 mg and 200 mg) and placebo will be studied. Patients will receive study treatment once daily on Day 1 and Day 14 and twice daily on Days 2 to 13.  |
| Blinding status:            | Blinded.   |
| No. of trial subjects:      | 6 patients per treatment group, resulting in 18 patients enrolled in total.  |
| Study population:           | Target population are males and females (of non-childbearing potential), aged 18 to 55 years inclusive, with chronic HCV infection.  |
| Product development status: | Drug product was manufactured to GMP standards.  |
| Trial location:             | Sydney, Australia.   |
| Trial standard:             | ICH-GCP.   |