

6 October 2009

The Manager Companies
ASX Limited
20 Bridge Street
Sydney NSW 2000

(2 pages by email)

Dear Madam

SUCCESSFUL HCV TRIAL RESULTS

The Directors of Biotron Limited are pleased to announce the successful completion of its proof-of-concept study of BIT225 in Hepatitis C virus (HCV) infected subjects.

- **Study meets primary endpoint of safety and tolerability.**
- **Several subjects receiving highest dose of BIT225 had significant reduction in viral loads.**

The data from this Phase Ib/IIa clinical trial (Protocol BIT225-003) indicate that BIT225 has met its primary end point of safety and tolerability in subjects dosed twice daily for 7 days. BIT225 was well tolerated with no serious adverse events reported and no discontinuations from the study.

The secondary objectives were to assess the pharmacokinetics of BIT225 and to assess the antiviral efficacy of BIT225 in these patients. Preliminary analysis of the pharmacokinetic profile of BIT225 demonstrated sustained plasma levels of BIT225 that are within the potential therapeutic range and are consistent with the potential for once or twice daily oral dosing.

BIT225 has also met the objective of antiviral efficacy, which was assessed by measurement of viral load in the plasma of the subjects. Preliminary statistical analysis of viral load reductions, as measured by the mean change in virus levels from baseline at Day 0 through to the end of the study at Day 21, indicate that the effect of BIT225 treatment on the 200 milligram cohort as a group was modest but highly significant compared to placebo controls. On an individual level, 3 of the 6 subjects receiving 200 mg of BIT225 had significant reductions in viral loads.

While the reductions in viral loads were modest (with a maximum of 0.5log₁₀) they were statistically significant, and importantly, demonstrated that BIT225's previously reported *in vitro* activity translates to *in vivo* efficacy in a clinical setting.

"We are encouraged by the results of this trial, with 50% of subjects receiving 200 mg of BIT225 showing significant reduction in viral loads. We know from previous preclinical studies that BIT225's potency is significantly enhanced in combination with interferon-alpha and ribavirin, so we would expect greater efficacy levels in future combination studies" said Dr Michelle Miller, CEO and Managing Director. "This current result demonstrates proof-of-concept, i.e. that BIT225 is able to target and reduce HCV replication in a clinical setting."

This study is the first demonstration of efficacy with a new class of anti-HCV drug, targeting the p7 protein of HCV.

There is a demand for new classes of antiviral drugs in HCV treatment; the current standard of care (interferon-alpha and ribavirin) is ineffective in around 50% of cases and is often associated with severe side effects, and the use of new classes of HCV drugs in development known as protease and polymerase inhibitors lead to rapid resistance when used on their own. To increase the barrier to generating drug resistant virus, future HCV treatment is likely to involve cocktails of several specific antiviral drugs, and BIT225 has the potential to be included in such a combination as it has demonstrated high degrees of synergism with other HCV treatments in cell culture models.

With the successful completion of this proof-of-concept study in HCV-infected patients, Biotron plans to advance BIT225 into a 14 day dose ranging study in combination with the current standard of care, interferon-alpha and ribavirin.

Biotron anticipates presentation of data from this trial at a forthcoming international conference.

About BIT225

BIT225 is an investigational, orally-administered, novel antiviral compounds in development by Biotron for treatment of HIV and HCV infections.

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\$3.0 billion, but is estimated that this market will expand to over US\$10.0 billion as safe, effective therapies enter the market.

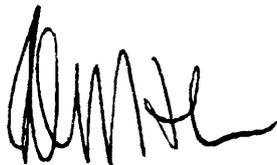
As previously announced, BIT225 is highly synergistic in an in vitro surrogate model system as a triple combination with two of the most common HCV therapies in use today - ribavirin and interferon- alpha. BIT225 also represents a novel, first in class approach to the treatment of HIV. BIT225 specifically targets HIV in reservoir cells and represents an opportunity to attack HIV at its source in the body. Current HIV therapies have little or no effect on HIV in the underlying reservoir of infected cells where the virus hides from the immune system.

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.

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

Yours sincerely

A handwritten signature in black ink, appearing to read 'Peter J. Nightingale', written in a cursive style.

Peter J. Nightingale
Company Secretary

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