

31 July 2013

The Manager Companies
ASX Limited
20 Bridge Street
Sydney NSW 2000

(3 pages by email)

Dear Madam

PATIENT ENROLMENT IN PHASE 2 BIT225 CO-INFECTED STUDY COMPLETED

- **12 patients recruited, recruitment now closed**
- **Study evaluating BIT225 in patients infected with both HIV and HCV**
- **Trial expected to extend existing HCV efficacy data to genotype 3**
- **Results expected 2H 2013**

Biotron Limited (ASX:BIT) has completed enrolment of patients in a Phase 2 clinical trial evaluating its lead antiviral drug candidate, BIT225, in patients that are co-infected with both Hepatitis C virus (HCV) and HIV.

Enrolment is now closed, with twelve patients recruited to the trial. The trial is designed to generate the first efficacy data in this specific population and extend existing BIT225 HCV efficacy data to additional genotypes. To date, clinical trials of BIT225 in HCV patients have concentrated on the most common HCV genotype, genotype 1.

All patients recruited in the co-infected study will receive 28 days treatment with BIT225 (300 mg twice daily) in combination with current anti-HCV standard of care therapies, interferon and ribavirin (IFN/RBV). At the conclusion of BIT225 treatment, the patients will continue to receive IFN/RBV alone as per standard treatment guidelines.

All patients were on antiretroviral (i.e. anti-HIV) drugs (ART) at the time of enrolment, and will continue to receive ART throughout the trial. In addition to providing the first efficacy data in this specific population, the study will also provide detailed pharmacokinetic information on BIT225 in the presence of these other anti-HIV drugs.

The open-label trial includes patients infected with HCV genotypes 1, 2 and 3 in addition to HIV. This co-infected group presents unique medical challenges in terms of current therapeutic protocols. HCV is a more serious disease in this population, with co-infected people having three times the risk of cirrhosis, liver failure and death compared to those infected with HCV alone. At least one in four people infected with HIV in the USA are co-infected with HCV, and in some populations the rate is estimated to be 40%.

A previous Phase 2a clinical trial of BIT225 in HCV genotype 1 patients (in combination with IFN/RBV) resulted in 100% of patients having virus below the limit of detection after 48 weeks.

In addition to this trial, Biotron has completed a recent Phase 2a trial of BIT225 in patients affected by HIV alone. Data from this study demonstrated that BIT225 is able to target the virus hiding in reservoir cells, which is regarded as the 'holy grail' of current HIV research. No existing therapy works in this manner.

Biotron CEO Dr Michelle Miller said she was optimistic of further positive data from the co-infected study following these highly encouraging results from HCV and HIV trials. "We have a first-in-class drug that is capable of targeting both diseases," she said. "Both viruses present substantial challenges and there is global demand for novel therapeutics. We look forward to the outcomes from this important study."

Preliminary results from the HCV/HIV co-infected study are expected to be announced during the second half of 2013.

Enquiries

Dr Michelle Miller
Managing Director
Biotron Limited
+61-2 9805 0488
+61-(0)412313329

Rudi Michelson
Monsoon Communications
+61-3 9620 3333

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- α and combination therapy with interferon- α and the ribonucleoside analogue ribavirin are the two different regimens currently approved as therapy for chronic hepatitis C. Treatment with interferon- α 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 anaemia, 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.

About BIT225 and HIV

BIT225 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. The market for HIV is very large, with the US market alone for HIV worth over US\$3.3 billion per annum.

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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