

14 August 2013

The Manager Companies
ASX Limited
20 Bridge Street
Sydney NSW 2000

(3 pages by email)

Dear Madam

BIT225 CAPSULE FORMULATION TRIAL COMPLETED

- **Study demonstrates that the new capsule improves drug levels of lead antiviral drug BIT225 by over 160%**
- **Capsule formulation to be used in Phase 2b HCV trial 2H 2013**

Biotron Limited (ASX: BIT) has successfully developed a capsule formulation of its lead HCV and HIV drug candidate BIT225.

A Phase 1 study of the new formulation, developed in collaboration with a specialist US formulation company, has demonstrated that the capsule administered drug is associated with reproducible absorption and a relative bioavailability more than 1.6 times greater than the previous powder formulation.

Biotron Managing Director Dr Michelle Miller said the new capsule formulation has the potential to further enhance the already positive safety profile of BIT225, and will facilitate extended trials in larger patient populations.

"In essence, this trial has demonstrated we can use lower doses of BIT225 to achieve higher blood levels of the compound in patients safely and efficiently," she said.

"This is an important milestone as we progress commercialisation of this first in class drug. These results bolster BIT225's overall data package and increase its appeal to potential licensing partners."

The single-dose, two phase, cross-over study in healthy volunteers was conducted at an Australian clinical trial site. Fourteen participants were randomised to receive 400 mg of BIT225 as a single dose of either the new capsule or the existing powder formulation. They were then subject to extensive blood sampling over a 96 hour period.

Two weeks later, participants received the alternate formulation and further blood samples were taken over the same period.

Bioanalysis of these samples demonstrated that blood levels of BIT225 were more than 1.6 times higher following capsule delivery. This means that in future trials, lower doses of drug can be delivered by capsule than have been used in previous trials.

It is expected the new BIT225 capsules will be used in a three month Phase 2b trial of the drug on Hepatitis C patients later this year.

BIT225 is a novel compound which has recorded positive data in separate Phase 2 trials targeting the Hepatitis C virus and HIV.

In a Phase 2a study of BIT225 in HCV genotype 1 patients, 100% of patients who received BIT225 in combination with current standard of care therapies, interferon and ribavirin (IFN/RBV), had undetectable virus levels after 48 weeks.

The recent Phase 2a HIV study demonstrated that BIT225 is able to target the HIV virus 'hiding' in reservoir cells, which is regarded the 'holy grail' of current HIV research. No existing therapy works in this manner.

Dr Miller added, "We are consistently recording positive data in both HCV and HIV studies. The ability to conduct further trials of this compound with a new patient and trial friendly capsule formulation further improves the drug's profile and its longer term prospects as a new therapeutic to help manage these serious diseases.'

Enquiries

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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- 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', with a stylized flourish at the end.

Peter J. Nightingale
Company Secretary

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