

9 November 2012

The Manager Companies
ASX Limited
20 Bridge Street
Sydney NSW 2000

(2 pages by email)

Dear Madam

KEY PHASE 2 HIV/HCV TRIAL COMMENCED

Unique approach for difficult-to-treat population First-in-class therapy

Sydney, Australia: 9 November, 2012: Australian drug development company Biotron Limited (ASX:BIT) has commenced a landmark Phase 2 human trial of its lead antiviral drug candidate, BIT225 in patients that are co-infected with both HIV and Hepatitis C virus (HCV).

Twelve HIV/HCV-positive patients will receive 28 days treatment with BIT225 (300 mg, twice daily) in combination with interferon and ribavirin (IFN/RBV), which is the standard approved treatment for HCV. At the conclusion of the treatment with BIT225 they will continue to receive IFN/RBV as per standard treatment guidelines (up to 48 weeks in total).

The patients will not have previously received IFN/RBV (i.e. treatment-naïve), but at the time of inclusion into the trial will be on antiretroviral drugs (ART), with HIV levels below the level of detection.

"While BIT225 appears to target both HIV and HCV, in this particular study we are focusing on the HCV aspect of the disease in these dual-infected patients", explained Michelle Miller, Biotron's Managing Director. "The pharmaceutical industry and international regulatory authorities are focused on new treatments in this difficult-to-treat population".

"Even though HIV will be below the level of detection, the virus will be present in the underlying reservoirs. BIT225 is being assessed for its ability to target HIV in these reservoir cells in a separate Phase 1b/2a clinical trial that is currently in progress".

The trial will be open-label, and will include patients infected with HCV genotypes 1, 2 and 3.

The proportion of patients infected with both HIV and HCV is significant. This co-infected group offers particular challenges to treatment with current therapies. HCV is a more serious disease in HIV-positive patients, and is a leading cause of death in these patients. It has been estimated that between 25% and 40% of HIV-positive patients in the USA are co-infected with HCV. These patients have a significantly worse prognosis than mono-infected patients.

Biotron's BIT225 is unique because of its dual anti-HIV and anti-HCV activity. The aim of this trial will be to generate the first efficacy data in this specific population in which there is a significant unmet medical need. The trial will provide detailed pharmacokinetic information on BIT225 in the presence of other anti-HIV drugs.

The trial is also expected to generate important safety and pharmacokinetic data with BIT225 in co-infected patients, as well as extend the efficacy data to other HCV genotypes, including genotypes 2 and 3.

As previously reported, treatment of HCV genotype 1 patients with BIT225 in combination with IFN/RBV resulted in 100% of patients having virus below the limit of detection after 48 weeks, in comparison with 75% of patients who only received IFN/RBV.

The trial, which is underway at the Siriraj Hospital in Bangkok, Thailand, is currently recruiting patients. Subject to a satisfactory enrolment rate, the study is expected to be completed in 1H 2013.

Enquiries

Dr Michelle Miller
Managing Director
Biotron Limited
+61-(0)412 313 329
mmiller@biotron.com.au

Rudi Michelson
Monsoon Communications
+61-3 9620 3333

Yours sincerely



Peter J. Nightingale
Company Secretary

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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 other viral infections including Dengue.