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21 November 2013

The Manager Companies
ASX Limited
20 Bridge Street
Sydney NSW 2000 (4 pages by email)

Dear Madam

ETHICS APPROVAL FOR NEW HCV THREE MONTH DOSING STUDY

- *Further international study of BIT225 in HCV patients commenced*
- *Ethics approval received to dose 60 patients*
- *Trial to focus on HCV genotypes 1 and 3*

Sydney, Australia, 21 November 2013 - Australian drug development company Biotron Limited (ASX: BIT) has received ethics approval to conduct a three month dosing study of its lead compound in patients infected with the Hepatitis C virus (HCV).

The phase 2 study (BIT225-008) of drug candidate BIT225 will be conducted on 60 patients at up to six trial sites in Thailand. Ethics approval has been received from Bangkok's Siriraj Hospital, which is the principal site, and the site initiation meeting has been held with investigators at the hospital, marking the commencement of the trial.

Initial patients are expected to commence dosing by the end of this month and the trial is expected to be fully recruited by mid 2014. The Company anticipates releasing preliminary data by November 2014.

Biotron Managing Director Dr Michelle Miller advises that this important study has been designed to generate safety and efficacy data of novel compound BIT225 when administered over a three month period in patients infected with HCV genotypes 1 or 3.

The trial will utilise the new capsule formulation of BIT225, developed over the past 12 months. Previous studies have used a powder formulation. The capsules are expected to have an improved safety profile and ease of use compared to the previous powder formulation. As previously reported, the capsule formulation results in higher drug levels in the blood than the powder formulation, hence lower doses of BIT225 can now be used.

Under the trial protocol, subjects will receive 200mg of BIT225 twice daily for three months in combination with current standard of care therapies - pegylated interferon alfa 2b (IFN) and ribavarin (RBV), before continuing to receive standard of care out to 24 weeks (genotype 3) or 48 weeks (genotype 1).

The previous BIT225 study in HCV patients focused on a four week dosing regimen. Phase 2a data demonstrated that 100% of trial subjects who received BIT225 (400mg) over four weeks had undetectable levels of virus in the blood at the 48 week follow up. This was compared to 75% of patients who received standard of care alone.

Dr Miller said she was optimistic of generating further positive efficacy data from the larger, three month trial.

She commented: "Indications to date demonstrate that BIT225 has potential to be an adjunctive agent in the future treatment of HCV alongside other new classes of direct-acting antiviral drugs.

"We look forward to generating further positive trial data validating Biotron's approach to treating HCV."

Biotron's BIT225 compound is the first in a new class of direct acting antiviral drugs for HCV. It specifically targets the p7 protein, which is involved in virus assembly.

The HCV global market is currently estimated at US$3.3 billion, but is expected to expand to over US$15 billion as safe, effective therapies enter the market.

A synopsis of the trial is attached. The trial has been registered on the Australian New Zealand Clinical Trials Registry (ANCTR) which is a primary registry in the World Health Organisation (WHO) Registry Network.

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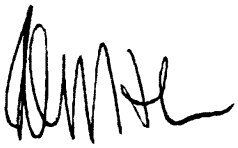
Yours sincerely



Peter J. Nightingale
Company Secretary

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TRIAL SYNOPSIS

PROTOCOL NO.: BIT225-008

STUDY TITLE: **A Phase 2, Multi-Centre, Placebo-Controlled, Randomised Study of the Safety, Pharmacokinetics and Antiviral Activity of BIT225 in Combination with Pegylated Interferon alfa-2b and Ribavirin in Patients with Hepatitis C Virus Infection.**

DRUG: BIT225 (2 x 100mg capsules BID)
Standard of care (SOC): Pegylated Interferon alfa-2b (PEG-IFN; 80 - 120 ug/week) and Ribavirin (RBV; 400 - 600 mg, weight based). Patients with genotype 1 will receive SOC for 48 weeks and genotype 3 for 24 weeks.

ROUTE: Oral: BIT225
SOC: Oral RBV and subcutaneous injection PEG-IFN.

STUDY DESIGN: A randomised, placebo-controlled, double-blind study of BIT225 in combination with PEG-IFN and RBV in patients with genotype 1 or 3 chronic HCV infection that are treatment-naïve to antiviral treatment with ribavirin and/or interferon.

One dose level of BIT225 (200mg BID) will be studied in 60 patients (30 patients with HCV genotype 1 and 30 patients with HCV genotype 3). BIT225 (200mg) and placebo will be studied with 20:10 patients per treatment group respectively, resulting in 60 patients enrolled in total. Patients will receive study treatment twice daily for 12 consecutive weeks.

OBJECTIVES: The primary objectives of this study are to:

- Evaluate the safety and tolerability of 200mg BIT225 twice daily (BID), compared with placebo, in combination with PEG-IFN and RBV for 12 consecutive weeks in patients with genotype 1 chronic HCV infection, that are treatment naïve to antiviral treatment with RBV and/or Interferon (IFN).
- Evaluate the safety and tolerability of 200mg BIT225 twice daily (BID), compared with placebo, in combination with PEG-IFN and RBV for 12 consecutive weeks in patients with genotype 3 chronic HCV infection, that are treatment naïve to antiviral treatment with RBV and/or IFN.

The secondary objectives of this study are to:

- Evaluate the antiviral activity of 200mg BIT225 BID administered for 12 consecutive weeks in combination with PEG-IFN and RBV in patients with chronic HCV infection, that are treatment naïve to antiviral treatment with RBV and/or IFN.
- Evaluate the pharmacokinetics (PK) of 200mg BIT225 BID administered for 12 consecutive weeks in combination with PEG-IFN and RBV in patients.

About Biotron and BIT225

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.

BIT225 has recorded encouraging data against HCV in clinical trials. A phase 2a trial in HCV demonstrated that 100% of HCV genotype 1-infected patients receiving BIT225 (400mg) in combination with current standard of care therapies interferon and ribavirin had undetectable virus after 48 weeks.

BIT225 is also in development for treatment of HIV, and is the first in a new class of antiviral drugs that may provide a new approach to eradication of this virus. It has shown clinical efficacy against HIV in reservoir cells, and has the potential to be combined with new or existing anti-retroviral drugs to eradicate long-lived pools of virus that are not eliminated with current treatments.

A phase 2, 4-dosing trial of BIT225 in patients co-infected with HIV and HCV genotype 1 or 3 was completed in mid-2013. Interim analysis has shown that 100% of genotype 3 patients who completed dosing are clear of virus at the 12 week time point of the trial.