

17 April 2015

The Manager Companies
ASX Limited
20 Bridge Street
SYDNEY NSW 2000

(2 pages by email)

Dear Madam,

UPDATE ON PHASE 2 TRIAL AND IND PROGRESS

Sydney, Australia, 17 April 2015: Biotron Limited ('Biotron' or 'the Company') advises that its Phase 2 trial evaluating lead compound BIT225 as a potential new therapy for treatment of Hepatitis C virus (HCV) infection is progressing in accordance with the protocols of the trial.

This three-month dosing trial (BIT225-008) of BIT225 in HCV genotype 1 (G1) and genotype 3 (G3) subjects was designed to extend efficacy data against HCV G1 and G3, and to provide further information regarding BIT225's safety and tolerability profile in longer term dosing using the capsule formulation of the drug.

As previously advised, the final subject in the 60-patient trial was recruited in late 2014. Patients receive 12 weeks of treatment with 200mg BIT225, dosed twice daily, in combination with standard of care (SOC) treatment for HCV (Interferon and Ribavirin; IFN/RBV). At the conclusion of dosing with BIT225, patients infected with HCV G3 continue with SOC for a further 12 weeks (24 weeks in total), while HCV G1 patients continue with SOC for a further 36 weeks (48 weeks in total). The SOC treatment complies with standard HCV treatment guidelines. The trial is a double blind, placebo-controlled study.

Due to the complexity of the trial, being double blinded and held over six trial sites, and the strict protocols which must be followed in compilation of the data from the trial, the results, which remain blinded to the Company, are not yet available.

Since completion of 12 weeks of dosing with BIT225, the contract research organisations (CRO) contracted by Biotron to conduct the trial have been compiling all of the data records and monitoring the six trial sites to ensure that the trial complies with international guidelines of Good Clinical Practice (GCP) and generating detailed data bases for full quality assurance purposes. Once this critical process is complete, independent analyses of key data can be undertaken, and then reviewed by an independent Data and Safety Monitoring Committee (DSMC). The trial remains blinded until this review is complete.

The collation of data and subsequent DSMC review of results from BIT225-008 are on track for completion before mid-2015. This review is anticipated to cover key data including laboratory and safety data from patients, assessment whether the new capsules deliver appropriate blood levels of BIT225, and antiviral efficacy data out to the 24-week time point of the trial. This mid-2015 time point coincides with the end of treatment with all drugs (BIT225 and SOC) for the HCV G3 patients.

In parallel with the above activities, the Company has been progressing towards filing an Investigational New Drug (IND) application with the USA Food and Drug Administration (FDA).

Several IND-supporting activities are currently in progress, including:

- Modelling of pharmacokinetic data from previous trials to determine optimal BIT225 dose and frequency in future trials.
- Additional *in vitro* laboratory studies of BIT225's antiviral activity, including studies in combination with other HCV drugs.
- Determination of potential drug-drug interactions between BIT225 and other HCV drug(s), to assist with design of the proposed IND study.

Information from these studies will be important in the selection of a partner for the further development of BIT225 within the HCV treatment landscape.

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 HCV and HIV, 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. A phase 2 trial in HIV/HCV co-infected patients showed that all HCV genotype 3 patients completing 28 days of treatment with BIT225 in combination with interferon and ribavirin achieved SVR12, with undetectable HCV 12 weeks after completing all therapy.

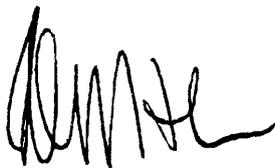
BIT225 is also in development for treatment of HIV, and is the first in a new class of antiviral drugs that may provide a new approach to eradication of this virus. It has shown clinical efficacy against HIV in reservoir cells, and has the potential to be combined with new or existing anti-retroviral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

Enquiries

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Yours sincerely



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