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The Manager Companies
ASX Limited
20 Bridge Street
SYDNEY NSW 2000 (2 pages by email)

Dear Madam,

INDEPENDENT REVIEW OF BIT225 TRIAL DATA SUPPORTS DEVELOPMENT IN COMBINATION WITH NEW HCV DRUGS

Sydney, Australia, 6 July 2015: - Australian drug development company Biotron Limited ('Biotron' or the 'Company') has provided an update on its three-month dosing trial with its lead antiviral drug, BIT225.

A USA-based, independent Data and Safety Monitoring Committee ('DSMC') has reviewed key interim, preliminary data from the three-month dosing study of Biotron's lead antiviral drug, BIT225. It recommended that future trials focus on patients infected with Hepatitis C virus ('HCV') genotype 3 ('G3'). The recommendation was to further study BIT225 in combination with other direct acting antiviral drugs ('DAAs'). Current DAA therapies for this group involve treatment for up to 24 weeks duration and response rates with G3 infections are lower than for other HCV genotypes.

This DSMC recommendation is in line with Biotron's proposed strategy to focus on specific HCV patient groups, which include G3 patients. The Company has been progressing towards filing an investigational new drug ('IND') application with the USA Food and Drug Administration ('FDA') for a trial of BIT225 in combination with one or more DAAs in HCV G3 patients.

The phase 2, randomised, double-blind, placebo controlled study of BIT225 on 60 patients infected with HCV G1 or G3 is ongoing at several trial sites in Thailand. Patients received 400 mg of BIT225 twice daily for three months in combination with current standard of care therapies - pegylated interferon alfa 2b and ribavirin ('IFN/RBV'), before continuing to receive standard of care out to 24 weeks (G3) or 48 weeks (G1).

The DSMC reviewed preliminary safety data for all subjects out to week 12 of the trial, marking the completion of dosing with either BIT225 or placebo in combination with IFN/RBV. The adverse events seen in this study appear to be in line with those seen in previous trials. The Committee noted that more subjects in the BIT225 arms were withdrawn from the study than in the placebo arms. Investigations are ongoing, but these withdrawals are likely to be related to the higher than expected drug exposure with the new, capsule formulation used in this study, compared to the formulation used in previous studies.

Safety and pharmacokinetic ('PK') data from this trial are key to determining the dosage of BIT225 for use in future studies. Modelling of this data is currently in progress, but future dosages are expected to be less than used in this trial. A safety review of data from all trials is currently underway. This data will be used to generate a complete package to enable submission of an IND application to the USA regulatory authorities.

The DSMC also reviewed the preliminary data on the antiviral effect of BIT225. At the time of completion of dosing with either BIT225 or placebo with IFN/RBV, i.e. week 12 of the trial, both arms had very good response rates, with 96% of subjects in the BIT225 arm having more than 2 log reduction in virus levels, compared to 90% of the placebo arm. However, it is expected that virus levels may rebound in a proportion of patients receiving IFN/RBV once they stop receiving treatment. For this reason, the key time point for analysis of an antiviral effect for BIT225 is twelve weeks after completing all drug treatment, known as SVR12 (sustained virological response at Week 12).

Patients with undetectable virus at this time are considered cured of HCV infection. The SVR12 time point for the G3 cohort is mid-August 2015, and the SVR12 time point for the G1 cohort is February 2016.

The DSMC noted that sub-analyses of the trial data at this point in time may reveal further differences. Preliminary analyses have indicated that subjects in the BIT225 arms cleared virus from plasma faster than those in the placebo arm. These results support findings from previous trials of BIT225 and suggest the potential use of BIT225 in combination with other DAAs to reduce treatment time.

The DSMC also noted that more patients than expected are failing treatment with the new DAAs and that this population, which has very limited choices, may be an area of interest for BIT225 given its novel and different anti-viral mechanism of action.

Biotron expects to file an IND application with the USA FDA in 2H2015. This will enable further pivotal trials of the drug to be conducted in the United States and will be a key milestone towards commercialisation.

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, IFN/RBV, 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 IFN/RBV 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.

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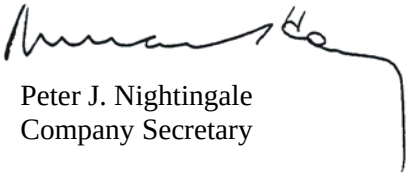
Yours sincerely



Peter J. Nightingale
Company Secretary

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