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

Dear Madam

UPDATE ON PROGRESS OF BIT225 PHASE 2 HIV-1 CLINICAL TRIAL

- **Initial cohort recruited and undergoing treatment.**
- **Independent Data and Safety Monitoring Committee unanimously voted to proceed with second, and larger, cohort at a higher dose.**
- **Second cohort recruitment and enrolment proceeding on schedule as planned.**
- **Previous results support the trial design.**
- **Trial headline results anticipated Q3 this year.**

As previously advised, the BIT225 Phase 2 HIV-1 clinical trial (BIT225-009) includes a dose escalation in patients with HIV-1 infection, with an initial group of 9 patients receiving 100 mg BIT225 once daily, or placebo, together with Combination Antiretroviral Therapy (approved anti-HIV-1 drugs; cART),which HIV-1 patients currently have to take for the rest of their lives.

The first cohort of 9 patients has been fully recruited and treatment commenced, following a detailed screening process.

An independent Data and Safety Monitoring Committee (DSMC) has reviewed preliminary safety data from this first cohort. The DSMC unanimously voted to proceed with the enrolment of the second cohort of patients. The DSMC's role is to ensure safety for patients in clinical trials and advises on the continuation or stopping of trials based upon safety and efficacy considerations. The positive outcome from this review of preliminary safety data indicates an absence of any major safety concerns regarding BIT225 in the trial to date.

The second group of 27 patients will receive 200 mg BIT225 once daily, or placebo, together with cART. At the conclusion of the trial, patients will remain on cART as per standard treatment protocols.

Screening, recruitment and enrolment of patients for this second cohort is progressing well, with 18 subjects commencing treatment this week.

The trial is a Phase 2, multi-centre, randomised, placebo-controlled, double-blind study of BIT225 and cART in patients with HIV-1 infection. Patients will not have previously been on anti-HIV-1 treatment (i.e. treatment naïve) and will be on a cART regimen. Patients will receive cART in addition to 12 weeks with BIT225 or placebo.

This trial is designed to show that BIT225 can further improve cART either by:

- Faster decline in viral loads compared to cART drugs alone, and/or
- A lowering of 'immune activation', this is a lessening of the deleterious effect of having HIV-1 continually 'smouldering' in the reservoirs or background of a patient.

The results from a humanised mouse study conducted by the Company clearly demonstrate that the addition of BIT225 to cART resulted in significantly faster clearance of HIV-1 as well as delayed viral rebound, confirming the hypothesis that BIT225 attacks a different source of virus than current anti-HIV-1 drugs.

If these improvements are confirmed by the current BIT225 Phase 2 HIV-1 clinical trial, the data will imply that BIT225 is targeting a different source of virus than that currently treated with cART standard drugs and that the drug may have a key role in eradication or 'cure' of HIV-1.

Successful results from this Phase 2 clinical trial would support the Company's path towards a partnership and commercial outcome. Preliminary headline data is anticipated in late 3Q17.

Yours sincerely

Peter J. Nightingale
Company Secretary

pjn8917

About Biotron
Biotron Limited is engaged in the research, development, and commercialisation of drugs targeting significant viral diseases with unmet medical need. The Company has BIT225 in clinical development for both HIV-1 and HCV and also has several earlier stage preclinical and research programs designing drugs that target a class of virus protein known as viroporins which have a key role in the virus life cycle of a very broad range of viruses, many of which have caused worldwide health issues such as Dengue, Hepatitis B, Ebola, Middle East Respiratory virus, Influenza and Zika viruses.

Enquiries

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