Biotron Limited
A.B.N. 60 086 399 144

Level 2, 66 Hunter Street
Sydney NSW 2000
Tel: (61-2) 9300 3344
Fax: (61-2) 9221 6333
E-mail: pnightingale@biotron.com.au
Website: www.biotron.com.au

28 September 2018

The Manager Companies
ASX Limited
20 Bridge Street
SYDNEY NSW 2000

(3 pages by email)

Dear Madam,

Significant Immunological Outcomes in BIT225 HIV-1 Clinical Trial

- The results indicate that BIT225 is having a unique effect in patients, over and above viral suppression seen with current antiretroviral drugs.

- Data is consistent with targeting and eradication of virus from macrophage reservoir cells by BIT225.

The Directors of Biotron Limited (Biotron) are pleased to announce a successful outcome to the BIT225-009 Phase 2 trial of its lead drug BIT225 in HIV-infected patients in combination with current antiretroviral drugs.

The data shows that there are significant immunological benefits in patients receiving antiretroviral drugs with 200 mg BIT225 compared to antiretroviral drugs plus placebo.

In HIV-infected people, the virus hides in long-lived cells known as macrophages. This cellular source of virus persists even in people taking antiretroviral drugs that result in no detectable virus in their blood. There are serious problems associated with viral persistence. These include an immune system ages more quickly, and there are other problems such as HIV-associated neurocognitive disorder (also known as AIDS-related dementia).

In previously reported laboratory-based studies, Biotron has shown that BIT225 attacks HIV-1 growing in macrophage cells, resulting in the production of replication-incompetent virus i.e. non-infectious, dead virus. The data from the current BIT225-009 clinical trial reported here shows that the body's immune system recognises this dead virus, which triggers a range of changes to the immune cells that fight disease.

The data from this BIT225-009 trial is consistent with the targeting and eradication of HIV-1 virus from these key reservoir cells in the BIT225-treated patients.

In addition to the beneficial immunological effects, there was a significant reduction in the level of the macrophage activation marker sCD163 in the BIT225-treated population by the end of the treatment period. Higher levels of sCD163 are linked with worse clinical outcomes in patients. This reduction of sCD163 by BIT225 may provide additional clinical benefit in these patients.

The headline results indicate that BIT225 has had a profound effect on a source of virus that persists in the presence of antiretroviral drugs. Eradication of this virus, produced by long-lived reservoir cells, is central to an eventual HIV cure strategy.

Dr Michelle Miller, The Company's Managing Director, explained: "This has been a complex trial. Going into it, we knew from laboratory-based studies that BIT225 targets and kills virus that hides in long-lived reservoir cells. The challenge was how to show this in humans.

"No one has done this before, and there were no guidelines to follow. We have had to use a range of techniques to show that BIT225 has done what we expected it to do i.e. clear out virus from these reservoirs. This has included the development and use of new cutting-edge assays, which has been a time-consuming process.

"When we designed this trial, we set up a range of different outcomes to look at. Some of the markers we set out to measure haven't shown any differences, while others have shown very significant changes – and these changes clearly indicate that BIT225 is having a unique and significant effect in these subjects.

"One aspect we set out to measure was whether the addition of BIT225 could improve clearance of HIV-1 from the blood. Current antiretroviral drugs are extremely efficient at rapidly clearing this virus, and the study confirms this. It was not surprising that no additional discernable reductions in blood virus levels were seen with BIT225, but it was important to measure this. But we saw other significant differences that clearly show BIT225 is doing something new and different to these current antiretroviral drugs.

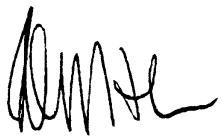
"We know that antiretroviral drugs do NOT clear cellular reservoirs. HIV-infected people have to take drugs for their lifetime to keep virus under control. This trial shows for the first time that there may be a way to clear one of the main cellular reservoirs. This is a major step to the ultimate goal of curing HIV-1 infection."

The trial was designed to assess the safety and antiviral activity of three month's dosing of BIT225 in combination with antiretroviral drugs in treatment-naïve HIV-positive subjects. This was a double-blind, placebo-controlled study undertaken at trial sites in Thailand. A total of 27 HIV-infected subjects, who had not previously taken any antiretroviral drugs, took once daily doses of 200 mg BIT225 or placebo for 12 weeks in combination with antiretroviral drugs. At the end of 12 weeks, all continued to take antiretroviral drugs as per standard protocols. A smaller cohort of 9 subjects took once daily doses of 100 mg BIT225 or placebo; this cohort was set up for detailed pharmacokinetic profiling of the BIT225 and its interactions with antiretroviral drugs.

Preliminary analysis of the safety data has shown that BIT225 was well tolerated at the 200mg once daily dose, with no severe adverse events or withdrawals.

Analysis of the trial data is ongoing. The Company aims to present detailed data at scientific conferences and to potential commercial partners in late 2018/early 2019.

Yours sincerely



Peter J. Nightingale
Company Secretary

pjn9593

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 HIV-1, and a promising preclinical program for HBV. In addition, Biotron has several earlier stage 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, Ebola, Middle East Respiratory virus, Influenza and Zika viruses.

Enquiries

Dr Michelle Miller
Managing Director
Biotron Limited
+61-(0)412313329

Rudi Michelson
Monsoon Communications
+61-3 9620 3333