

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

14 October 2010

The Manager Companies  
ASX Limited  
20 Bridge Street  
Sydney NSW 2000

(3 pages by email)

Dear Madam

### SHAREHOLDER UPDATE

In accordance with Listing Rule 3.17, I attach a copy of a document, being an update regarding the commencement of the Phase IIa trial of BIT225 in Hepatitis C virus infected patients, as sent to the Company's shareholders.

Yours sincerely



Peter J. Nightingale  
Company Secretary

pjn5635

October 2010

Dear Shareholder

Welcome to this edition of Biotron's newsletter, *BITNews*. We are very pleased that we can finally report the beginning of our critical phase IIa international trial with Biotron's lead drug candidate, BIT225, which is showing great promise as a new treatment for Hepatitis C and HIV.

The trial is a combination study, with patients receiving BIT225 together with the current approved treatment for Hepatitis C - Interferon and Ribavirin. We have previously shown that in the laboratory BIT225 is able to significantly improve the potency of these two common Hepatitis C drugs, resulting in greater inhibition of virus growth.

The trial is designed to assess the safety of Biotron's drug when given daily for 28 days. In addition, the trial will assess its effect on the level of virus in the blood of the patients, and determine whether Biotron's drug can improve the outcome for patients treated with Interferon and Ribavirin.

Twenty four patients will be randomly assigned to receive one of two dose levels of BIT225 (200 mg or 400 mg) or placebo for the first 28 days of their course of treatment with Interferon and Ribavirin.

Unlike other Hepatitis C drugs in clinical trials worldwide, Biotron's drug offers a first-in-class approach, targeting the p7 protein, which is essential for production and release of infectious virus from infected cells.

This trial follows on from the previous seven day human clinical trial of BIT225 on its own as a monotherapy, which showed promising results. Due to the potential to induce drug resistance, longer trials of antiviral drugs on their own are not possible, which is why we have now moved to a combination trial.

Patients involved in the trial are infected with HCV genotype 1, the most common variant of the virus in the Western world. These patients are the hardest to treat, with less than half responding to approved treatment. There is an unmet medical need for drugs that will improve treatment outcomes for this group of patients.

We would have liked to complete our trials in Australia, but this process was made difficult because of several factors.

Firstly, there are smaller patient populations in this country and many of those patients are already involved in other drug trials with big pharmaceutical companies, making them ineligible for ours.

Secondly, the whole process would have been slowed down in Australia because of the ethics approvals required at each hospital site involved in the trials – and we estimate there would have been around eight.

We decided therefore, that the fastest way forward was to utilise the services of the experienced, specialist contract research organisation ACLIRES and take our trials off-shore.

Over the past months we have been working to ensure documents such as the randomisation schedules and case report forms are complete, and to prepare and finalise site pharmacy and laboratory manuals. During the process of finalising these documents and to ensure there were no outstanding matters, Biotron undertook visits to the sites in Thailand and Argentina.

In parallel we have been preparing the drug product for shipment, and spent time ensuring smooth transit of drug into the sites, and also that blood samples can be exported from the sites and imported into Australia for analysis. The drug has now safely arrived.

As soon as regulatory and import permits were in place we held the trial initiation meeting, which is the official start of the trial. One of the PIs (specialist clinicians referring patients for the trial) has identified and prescreened 12 suitable subjects (half of what we need) and we expect they will have identified the second 12 very shortly.

As this report comes to you soon after the trial beginning, we can assure all is going well and we aim to complete dosing of patients before the end of the year.

These trials are critical steps in the Company's development. Demonstration that BIT225 can attack these viruses in patients will be a major advance.

We are focused on achieving a successful outcome, and are continually engaging with large pharmaceutical companies with the aim of partnering BIT225 for later clinical development after the successful conclusion of the trial.

We will bring you further trial updates as soon as they become available.

#### **COMING EVENTS**

While we have been working diligently behind the scenes to ensure that the Hepatitis C trial is underway, we are also keen to ensure Biotron maintains a presence in the international investment and biotechnology network.

I will be presenting at the Australian Life Science Investment Summit to be held in Melbourne during October, to an international audience of investors and fund managers.

A similar presentation will be made at the BIO-Europe meeting in Munich, Germany in November.

#### **HIV**

BIT225 also represents a first-in-class opportunity in the treatment of HIV.

It works by specifically targeting the virus in reservoir cells where it has, until now, been able to "hide" from the immune system.

No other available treatment works in the way BIT225 has demonstrated – by attacking the virus at its source in the body.

In July Dr John Wilkinson, Biotron's Senior Virologist, presented data at the International AIDS Conference in Vienna, Austria which showed that BIT225 has the potential to prevent the establishment of HIV infection in the first cells to encounter the virus at the point of infection. These cells, called dendritic cells, act as the watch dogs of the immune system, so reach the virus first when it gets into the body. Within approximately 24 hours of first infection, HIV starts replicating in these dendritic cells, and is then transmitted to the body's T cells, where the virus establishes a more explosive infection. BIT225 was able to significantly reduce levels of HIV in dendritic cells in the laboratory, with up to 89% reduction in virus transferred to uninfected T cells.

The results are significant as prevention or minimisation of the establishment of HIV infection would potentially ameliorate the devastating effects of HIV infection in the body. The finding opens up a new avenue for potential exploitation of BIT225, in addition to its potential use in controlling viral reservoirs in patients with established infection.

We have been working towards implementing next stage trials in Biotron's HIV drug development program. We are on track to begin a Phase 1b/11a study after we receive results from the HCV combination trial, subject to the Company's financial position.

We look forward to bringing you news of successful trial results and progressing the development of BIT 225.

Thank you for your continued support. We have appreciated the phone and email messages from shareholders, and we look forward to providing further updates.

Sincerely



Michelle Miller

CEO & Managing Director