Biotron Limited ABN 60 086 399 144

BITNews

July 2015

Dear Shareholders,

Biotron recently released an update of progress on the BIT225-008 study in patients with Hepatitis C virus (HCV) infection. In this study, sixty patients infected with HCV genotypes 1 (G1) or 3 (G3) received 12 weeks of treatment with BIT225 (or placebo), in combination with the standard treatment of interferon and ribavirin (IFN/RBV).

Highlights, detailed below, include:

- A USA-based independent expert committee recommended that the Company focus on testing BIT225 with other new HCV drugs in specific patient groups.
- Significant treatment gaps remain for HCV.
- Shorter treatment times are needed.
- More patients than anticipated are failing with the new HCV drugs.
- New classes of anti-HCV drugs are needed.

BIT225 has the potential to fulfil these needs.

An independent expert review of available data by the data and safety monitoring committee (DSMC) was positive. Their recommendation that Biotron focus on groups with unmet need such as the HCV genotype 3 population in future studies with BIT225, is in line with the Company's previously stated strategy.

Significant treatment gaps remain for HCV, such as genotype 3, despite new drugs coming on the market.

There remains a need for additional drugs that will shorten treatment time and improve outcomes for particular patients who currently have limited treatment options.

In addition, it is becoming apparent that more patients than anticipated are failing treatment with the new HCV drugs. The DSMC noted this and said 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.

As previously reported, BIT225 is a first-in-class drug which targets a different stage of the virus replication cycle than other existing drugs.

None of this is a surprise, but to have an independent group of experts with direct international clinical and industry experience review Biotron's study, and then reiterate that the Company is on the right track, is endorsement of the Company's program.

The measure of successful treatment with HCV drugs is the extent to which any virus remains in the blood 12 weeks after stopping all drug treatment (SVR12 = Sustained Virological Response at Week 12). The BIT225-008 trial protocol required administration of IFN/RBV to G1 and G3 patients for different periods after the 12 weeks of treatment with BIT225. This means that SVR12 will be reached at Week 36 of the trial for HCV genotype 3, and at Week 60 of the trial for HCV genotype 1.

It is not uncommon for virus to rebound in treated patients either during treatment or soon after the course of treatment has been completed. However, if they are still clear of virus at the SVR12 time point, patients can be considered cured of HCV infection.

Subanalysis of interim data suggests that the patients who received BIT225+IFN/RBV cleared the virus from their blood faster than those on placebo+IFN/RBV. This observation is in line with what we have seen in previous trials.

Biotron anticipates receiving SVR12 data from the HCV G3 cohort in August 2015 and SVR12 data from the G1 cohort is expected in February 2016.

This was the first trial in patients using the new BIT225 capsules. The primary objective of the BIT225-008 trial was to assess the drug's safety profile and to generate information to guide future dosing regimens.

In this trial, BIT225 was administered with IFN/RBV, until recently the only available treatment for HCV. IFN/RBV have significant side effects meaning that patient dropouts from trials that include IFN/RBV are common. This makes it challenging to separate out BIT225 side effects from those of IFN/RBV. What we do know is that the side effects seen in this trial are generally in line with what we have seen in previous trials. Further, BIT225 has now been administered to over 200 people, including healthy volunteers, HCV-infected, HIV-infected and HCV/HIV co-infected patients without a trial being stopped for safety, or any other reasons.

The BIT225-008 trial has shown that the new capsules are very efficient at delivering BIT225. At this stage in the drug development pathway, a range of concentrations of drug needs to be tested to find the dose that gives the right balance between efficacy (i.e. killing the virus) and side effects. Data from this trial indicates that the capsule dosing (200 mg given twice daily) was likely to have been too high.

This information will inform the selection of the right dose and dosing regimen for future studies of BIT225.

It should be noted that this clinical trial is larger and more complex than any of the other BIT225 trials undertaken to date. The trial was conducted at many clinical sites. Compiling the data from the study while ensuring that international regulatory guidelines are observed and maintained is a complex undertaking.

The conclusion of the BIT225-008 trial, including SVR12 data, is an important milestone for the Company. The BIT225-008 trial and earlier trials have generated a lot of data. The data from these trials will now form the backbone of regulatory submissions to the USA Food and Drug Administration (FDA) in the form of Investigational New Drug (IND) applications.

Biotron has engaged with the FDA, through pre-IND meetings, and has been preparing the necessary documentation required for an IND submission. Further details will be provided as they come to hand.

Significant milestone events are before us:

- SVR12 results for BIT225-008 G3 (Q3 2015).
- HCV IND submission (Q4 2015).
- SVR12 results for BIT225-008 G1 (Q1 2016).
- HIV IND trial submission (Q1 2016).
- Commercialisation (our objective).

Biotron recently completed a $4 million capital raising to complete the above-mentioned HCV, HIV programs and IND filings.

Despite advances in HIV treatments, significant hurdles remain. There is renewed industry interest in eradicating HIV reservoirs from patients. This is likely to require several different drug strategies working in combination. Biotron's BIT225 is unique in its mode of action against HIV and has the potential to be a key part of future HIV eradication strategies. The Company has been in discussions with international HIV experts with a view to designing a pivotal clinical study that will position BIT225 within the HIV treatment landscape. We look forward to providing additional information in due course.

It is worth noting that results have been positive in all trials to date, with favourable safety, efficacy and tolerability outcomes. The focused, diligent and strategic step-by-step clinical program for BIT225 underpins the Company's commercialisation strategy. The program has been designed to ensure that Biotron is a credible and attractive partnership prospect.

Thank you for your continued support as we progress development and commercialisation plans for BIT225. You can subscribe www.biotron.com.au to receive email updates and announcements.

Sincerely,

Dr Michelle Miller
CEO & Managing Director

BIT225 was recently featured in A&U: America's AIDS Magazine – see the article on page 48 of the June 2015 edition http://issuu.com/aumagazine/docs/a_u_june_2015

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