Biotron Limited
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24 October 2022

The Manager Companies
ASX Limited
20 Bridge Street
Sydney NSW 2000 (3 pages by email)

Dear Madam

REPORT ON ACTIVITIES FOR THE QUARTER ENDED 30 SEPTEMBER 2022

Biotron Limited ('Biotron' or 'the Company') has achieved key outcomes including:

- Completed recruitment for the BIT225-010 Phase 2 clinical trial of BIT225 for treatment of HIV-1 infection that is underway at sites in Thailand.
- Completed recruitment for the BIT225-011 Phase 2 clinical trial of BIT225 for treatment of HIV-1 infection that is underway at sites in Australia.
- Commenced a human study of BIT225 for treatment of COVID-19 as a sub-study in the BIT225-010 HIV-1 Phase 2 trial underway at sites in Thailand.
- Continued the design, synthesis and testing of new compounds under its HIV-1 and Hepatitis B virus (HBV) programs, with the aim of identifying a next-generation lead anti-HIV-1 drug and a lead candidate for HBV.

HIV-1 Program

During the quarter ended 30 September 2022, Biotron completed recruitment of the BIT225-010 clinical trial underway in Thailand and, subsequent to the end of the quarter, completed recruitment of the BIT225-011 clinical trial underway in Australia. Both trials are Phase 2 clinical trials of BIT225 for treatment of HIV-1 infection.

The fully recruited BIT225-011 trial will investigate the impact of BIT225 in HIV-infected people who have been taking approved anti-HIV-1 treatment (ART) for an extended period with well-controlled HIV-1 infection but who have not achieved full immune reconstitution despite long term durably suppressive ART. The trial includes BIT225 treatment or placebo continuing for 12 weeks in combination with ART.

This group, estimated to encompass more than one-third of the HIV-treated population, is at an increased risk of clinical progression to AIDS and other morbidities and has higher rates of mortality than HIV-infected patients who have attained full immune reconstitution. The trial is in progress at sites in Sydney, Australia including St Vincent's Hospital, Holdsworth House and East Sydney Doctors.

The second fully recruited trial, BIT225-010, is underway at sites in Thailand. This study includes people who are newly diagnosed as being HIV-1 positive but have not yet commenced ART. The trial includes BIT225 treatment or placebo continuing for 24 weeks in combination with ART.

Both trials are designed to generate data that extend the positive findings from previous clinical trials conducted by Biotron. The data will be central to demonstrating to potential pharmaceutical partners and regulatory authorities the safety and efficacy of BIT225 in patients with currently unmet medical needs.

Preliminary results from the trials are anticipated to be available in mid-2023.

SARS-CoV-2

During the quarter ended 30 September 2022, the Company received approval for, and commenced, a human study of BIT225 for treatment of COVID-19.

The trial is being run as a sub-study in the ongoing BIT225-010 HIV-1 Phase 2 trial underway in Thailand. As announced on 14 September 2022, any eligible person enrolled in the HIV-1 trial who becomes infected with SARS-CoV-2 will be intensively monitored for SARS-CoV-2 viral load and clinical symptoms over a 28-day period.

Previous data showed that BIT225 demonstrated antiviral, immune modulatory and clinical benefit against SARS-CoV-2 in an accepted murine model of COVID-19 disease (announced 25 November 2021, 17 March 2022 and 2 May 2022).

The sub-study provides an efficient, cost-effective and timely opportunity to generate preliminary human data with BIT225 for this indication.

BIT225 belongs to a new class of antiviral drugs known as viroporin inhibitors. Viroporins are virus-encoded proteins that are central to establishing and maintaining infections through modulation of the body's immune system. BIT225 is Biotron's lead antiviral clinical-stage, investigational, orally administered small molecule antiviral drug that has been evaluated in nine completed clinical trials involving healthy volunteers, patients with HIV-1 infection, patients co-infected with Hepatitis C virus (HCV) and HIV-1 and patients with HCV (as monotherapy and in combination with pegylated interferon-alfa and ribavirin).

Despite the availability of SARS-CoV-2 vaccines, there remains a need for oral drugs to treat the infection and prevent severe disease, especially in at-risk individuals.

BIT225 has an established human safety profile and has the potential to be an important first in class drug for COVID-19 treatment.

The Company is currently finalising a trial protocol and other necessary documentation for a Phase 2 trial of BIT225 as a potential treatment of COVID-19 based on guidance received in May 2022 from the USA Food and Drug Administration (FDA).

In parallel, the Company is consulting with clinical research organisations to identify potential trial sites and work through the logistics and costs of undertaking a COVID-19 treatment trial.

Hepatitis B Program

While the Company's main focus during the quarter has been its clinical programs for HIV-1 and COVID-19, the Hepatitis B virus (HBV) program continues to be an important preclinical program.

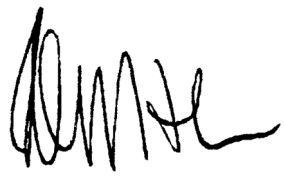
Biotron is working with other experienced groups to access key antiviral HBV assays and continues to make good progress.The aim is to identify a lead series to progress to preliminary safety studies and assessment in animal models of HBV infection.

The current pandemic highlights the importance of novel approaches such as Biotron's viroporin compounds which have the potential to target a broad range of existing and emerging viruses.

Expenditures

As disclosed in the Company's Quarterly Cash Flow Report, expenditure on these research and development activities during the quarter totalled $686,000 and $210,000 of related staff costs. As disclosed in the Company's Quarterly Cash Flow Report, payments to related parties and their associates during the quarter totalled $148,000 for director fees, salaries and superannuation payments.

By order of the Board



Peter J. Nightingale
Company Secretary

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