Biotron Limited
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27 October 2023

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 2023

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

- Completed a Phase 2 trial of BIT225 (BIT225-012) for treatment of adults with COVID-19 at sites in Thailand following receipt of approvals from relevant ethics and regulatory authorities.
- Continued detailed post-clinical phase analyses of samples collected during the completed the two Phase 2 trials of BIT225 for treatment of HIV-1 infection (BIT225-010 and BIT225-011).
- Continued the design, synthesis and testing of new compounds with the aim of identifying next-generation lead anti-HIV-1 and anti-SARS-CoV-2 drugs and a lead candidate for HBV.
- Publication of BIT225 data in an animal model of COVID-19 in a peer-reviewed international scientific paper.

SARS-CoV-2/COVID-19 Program

During the quarter ended 30 September 2023, the Company completed a Phase 2 clinical trial (BIT225-012) with its lead antiviral drug BIT225 for treatment of COVID-19 at sites in Thailand.

The trial commenced in May 2023 and was very quickly fully enrolled with dosing completed in August 2023.

The double blind, placebo-controlled trial aims to determine if 7 days of treatment with BIT225 commenced within 3 days of onset of COVID-19 symptoms results in reduction in SARS-CoV-2 blood viral load, clinically favourable changes in viral, inflammatory and immune activation markers, as well as improvement in clinical symptoms of COVID-19.

The design of the trial was based on guidance received during 2022 from the USA Food and Drug Administration (FDA) and took into consideration the continually changing landscape of COVID-19. The Company consulted with international clinicians, clinical research organisations and other relevant experts to design a study aimed at being recruited quickly and generate meaningful data in a tight timeframe.

In addition to its unique clinical activity against HIV- 1, BIT225 has shown very good activity against SARS-CoV-2 and prevented development of disease in a COVID-19 mouse model. As previously announced (ASX announcements 25 November 2021, 17 March 2022 and 2 May 2022) BIT225 demonstrated both antiviral, immune modulatory and clinical benefit against SARS-CoV-2 in an accepted murine model of disease. The SARS-CoV-2-infected mice quickly die from respiratory disease very similar to human COVID-19. However, BIT225 very efficiently reduced levels of SARS-CoV-2 virus and stopped the life- threatening cytokine storm. BIT225-treated mice did not develop any signs of disease and remained healthy throughout the several studies that were conducted. 2

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 the potential to be an important first in class drug for COVID-19 treatment.

Laboratory analyses and other end of trial activities including monitoring of all information collected during the trial by an external Contract Research Organisation (CRO) is currently in progress. Once these activities are completed, the trial database will be locked, the data unblinded and statistical analyses of the data can be completed. Release of headline results is expected in coming weeks.

During the quarter, a peer-reviewed paper containing BIT225 COVID-19 mouse data was published in a prestigious scientific journal.

The paper, entitled “Post-infection treatment with the E protein inhibitor BIT225 reduces disease severity and increases survival of K18-hACE2 transgenic mice infected with a lethal dose of SARS-CoV-2” has been published as an open access online article in PLoS Pathogens. The paper, written in collaboration with international scientists in the USA and Denmark, underscores the high efficacy of BIT225 and its potential to treat COVID-19.

HIV-1 Program

During the quarter, work has continued to complete the extensive detailed laboratory analyses of the many thousands of samples collected during the two completed Phase 2 trials (BIT225-010 and BIT225-011) of BIT225 for treatment of HIV-1 infection. These assays are complex, requiring specialised facilities and expertise in a number of laboratories in Australia and overseas.

While all effort is being made to complete this work as efficiently as possible, the assays are precise and time consuming and must be done in accordance with international guidelines for undertaking such studies. Once the assays are completed the extensive data sets will be compiled and statistically evaluated.

The two HIV trials have been designed to generate data that extend the positive findings from previous clinical trials conducted by Biotron in which BIT225 was shown to have positive effects on key immunologic markers of improved health outcomes. 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.

Headline results from the two HIV-1 trials are expected in coming weeks.

Hepatitis B Program

While the clinical programs for HIV-1 and COVID-19 continue to be the Company's main focus, 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 totaled $1,016,000 and $211,000 of related staff costs. As disclosed in the Company's Quarterly Cash Flow Report, payments to related parties and their associates during the quarter totaled $149,000 for director fees, salaries and superannuation payments.

By order of the Board

Peter J. Nightingale
Company Secretary

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