Biotron Limited
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26 April 2024

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

Dear Madam

REPORT ON ACTIVITIES FOR THE QUARTER ENDED 31 MARCH 2024

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

- Reported positive outcomes from the BIT225-010 Phase 2 HIV-1 clinical trial, with all primary objectives of the trial met.
- Continued detailed post-clinical phase activities and analyses of the BIT225-011 Phase 2 clinical trial of BIT225.
- Continued detailed post-clinical phase activities and analyses of the BIT225-012 Phase 2 clinical trial of BIT225 for treatment of adults with COVID-19.
- 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.
- Received an R&D Tax Incentive cash rebate of $1,645,114 for the 2022/23 financial year.

HIV-1 and SARS-CoV-2/COVID-19 Clinical Programs

During the first quarter of 2024, the Company reported positive outcomes from the completed Phase 2 HIV-1 clinical trial (BIT225-010) with its lead antiviral drug BIT225.

The double-blind placebo-controlled Phase 2 trial was designed to characterise the effect of BIT225 (200 mg, once daily for 24 weeks) added to a standard of care antiretroviral therapy (cART: 50 mg Dolutegravir (DTG), 300 mg Tenofovir disproxil fumarate (TDF) and 200 mg Emtricitabine (FTC)) in 27 (18 BIT225: 9 Placebo) treatment naïve people infected with HIV-1. Study participants were followed for a one month period following 24 weeks of BIT225 or placebo dosing. All individuals continued on cART as per standard treatment guidelines post-study.

The primary objectives of the trial were to evaluate the safety, efficacy and impact of BIT225 administered with cART on selected inflammatory and immune markers in this patient population.

The Company reported that preliminary analyses of data from the BIT225-010 trial provided confirmation of the results of previous trials in people infected with HIV-1. BIT225 was safe and generally well tolerated at the 200mg once daily dose, with no deaths or drug-related serious adverse events. All participants achieved viral suppression and none were considered virologic failures.

The data indicated that the addition of BIT225 to cART resulted in a more rapid reduction in HIV-1 levels in the blood during the second phase of viral decay, compared to cART alone. Analyses of several immune activation and inflammatory markers in the blood showed changes that are consistent with those seen in earlier trials and suggest a possible immune modifying effect of BIT225 when used with cART.

These preliminary, positive trial data are very encouraging. The blood viral load reduction data are consistent with BIT225 having an impact on viral reservoirs. Current cART is efficient at rapidly and durably reducing virus levels in the blood, but this does not translate into clearance of long-lived reservoirs of HIV-1. The observed changes to immune markers and cells further the results from the previous BIT225-009 trial and suggest the utility of targeting viroporins as a new class of antiviral drugs.

Additional analyses are ongoing.

During the quarter, the Company has continued its focus on post-trial activities for the remaining two Phase 2 clinical trials – BIT225-011 and BIT225-012. There is a major workload associated with monitoring of all aspects of the completed trial to ensure that all information within patient master files, and subsequently in trial databases, is correct and compliant with international regulatory guidelines.

The BIT225-011 HIV-1 Phase 2 trial, together with the BIT225-010 HIV-1 Phase 2 trial (discussed above), 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 BIT225-012 SARS-CoV-2 Phase 2 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 Company understands the high level of interest of shareholders in the outcomes of the completed clinical trials. Trials such as BIT225-011 that include longitudinal analyses of a multitude of immunological markers involve complex, time-consuming modeling and consultation with relevant experts. Good progress is being made and the Company looks forward to reporting results during the second quarter of 2024.

The data from all three Phase 2 trials 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.

Hepatitis B Program

While the clinical programs for HIV-1 and COVID-19 continue to be the Company's main focus, the Company's 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.

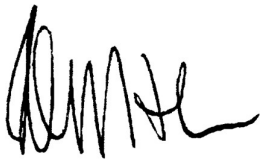
The COVID-19 pandemic highlights the importance of novel approaches, such as Biotron's viroporin compounds, which have the potential to target a broad range of existing and emerging viruses.

Expenditures

As disclosed in the Company's Quarterly Cash Flow Report, expenditure on these research and development activities during the quarter totaled $514,000 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.

During the quarter under review, the Company received an R&D Tax Incentive cash rebate of $1,645,113.64 for the 2022/23 financial year.

By order of the Board



Peter J. Nightingale
Company Secretary

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