Biotron Limited
A.B.N. 60 086 399 144

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

31 July 2024

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

Dear Madam

REPORT ON ACTIVITIES FOR THE QUARTER ENDED 30 JUNE 2024

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

- Reported positive outcomes from the BIT225-011 Phase 2 HIV-1 clinical trial, with all primary objectives of the trial met.
- Continued detailed post-clinical phase activities and analyses of the BIT225-012 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.

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

During the June 2024 quarter, the Company reported positive outcomes from the completed Phase 2 HIV-1 clinical trial (BIT225-011) with its lead antiviral drug BIT225.

This longitudinal, open-label Phase 2 trial was designed to characterise the effect of BIT225 (200 mg, once daily) added to ongoing, suppressive standard of care antiretroviral therapy (cART) for twelve weeks in twenty HIV-1 infected, treatment-experienced participants who had achieved only partial immune reconstitution.

The primary objectives of the trial were to evaluate the safety and tolerability of BIT225 in this patient population, as well as determine the impact of the addition of BIT225 to cART on immune activation, inflammation and viral markers.

As reported, preliminary analysis of the safety data showed that BIT225 was safe and generally well tolerated at the 200 mg once daily dose, with no deaths or drug-related serious adverse events. The safety and tolerability profile of BIT225 in the current trial was congruent with that seen in previous trials. Observed Adverse Events (AEs) attributed to BIT225 were of similar incidence, and mild severity, to those previously reported for the drug. One person withdrew from the study following the first dose of study drug during the treatment period.

Baseline values for a range of immune activation, inflammation and viral assays were determined for each person during an initial 4-week Observation period. Subsequent values of the same markers were assessed during the 12-week Treatment period with BIT225, as well as during a 4-week Follow-up period after completion of BIT225 treatment. Analyses of Treatment and Follow-up values were compared to those obtained during the Observation period.

All participants maintained viral suppression throughout the study. Statistically significant differences ($P<0.05$) in the change from baseline were observed during the BIT225 treatment period for several pre-specified immune markers and cell populations. These included NK cells, a key cell type involved in combating viral infection, and T-regulatory cells. Changes in these cell populations have been noted in previous trials with BIT225 and suggest a possible immune modifying effect of BIT225 when used with cART.

Individuals who do not achieve full immune reconstitution following fully suppressive antiviral therapy represent an important portion of those with HIV infection. Studies suggest that immune non-responders (INR) represent 20% - 40% of those on current antiviral therapy. These individuals are at enhanced risk for serious comorbid conditions including neurocognitive, cardiovascular, renal and hepatic disorders that impair quality of life and drive healthcare expenditures.

Viroporin targeting drugs such as BIT225 uniquely combine immune modulation with antiviral activity and have the potential to address both the immune and viral pathogenesis of numerous viral infections in a clinically relevant fashion.

The results reported are preliminary and ongoing analysis of this BIT225-011 trial and the BIT225-010 HIV-1 trial in a treatment-naïve population will be reported when complete.

During the quarter, the Company has continued its focus on post-trial activities for the BIT225-012 trial. There is a major workload associated with monitoring 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. Once completed, the results of preliminary analyses will be reported.

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 Hepatitis B virus (HBV) program continues to be an important preclinical program.

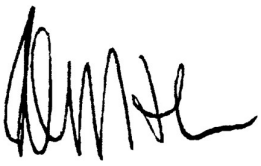
Biotron is working with other experienced groups to access key antiviral HBV assays and continues to make good progress.The aim is to identify a lead series to progress to preliminary safety studies and assessment in animal models of HBV infection.

Biotron's novel antiviral platform is focused on developing novel viroporin targeting drugs which have the potential to uniquely impact a broad range of existing and emerging viruses. The clinical data from the HIV trials have important implications for earlier stage programs as they demonstrate the feasibility of developing this novel class of antiviral drugs.

Expenditures

As disclosed in the Company's Quarterly Cash Flow Report, expenditure on these research and development activities during the quarter totaled $582,000 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 $148,000 for director fees, salaries and superannuation payments.

By order of the Board



Peter J. Nightingale
Company Secretary

pjn12261