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30 May 2022

The Manager Companies
ASX Limited
20 Bridge Street
SYDNEY NSW 2000 (2 pages by email)

Dear Madam

POSITIVE FDA GUIDANCE FOR COVID-19 CLINICAL PROGRAM

The Directors are pleased to advise that Biotron Limited ('Biotron' or 'the Company') has received guidance from the U.S. Food and Drug Administrations ('FDA') for development of its lead antiviral drug BIT225 as a potential treatment of Coronavirus Disease 2019 (COVID-19) infection in adults.

The FDA's guidance was received in written response to Biotron's pre-IND briefing package and request in March 2022, which included an overview of preclinical and (HIV) clinical development, and specific questions relating to regulatory requirements for progression to filing an investigational new drug ('IND') application for the COVID-19 indication.

Biotron sought guidance on the design of a proposed Phase 2 clinical trial in recently diagnosed COVID-19 infected individuals and assurance that the preclinical data package and manufacturing processes were sufficient to support this next stage of clinical development.

Biotron's Managing Director, Dr Michelle Miller, said:

"The FDA responses were constructive, highly informative, and provide direction in the design of the proposed Phase 2 clinical trial. The recommendations for a small, placebo-controlled, proof-of-concept, dose-finding study, with agreed end points, in line with studies for other respiratory diseases, including influenza, are very welcome. This design is de-risking and will provide the Company with important time and resource savings.

The feedback on the existing supporting non-clinical studies and the manufacturing processes, specification and composition of the drug product was positive.

The design of regulatory-quality clinical studies for SARS-CoV-2 therapeutic advancement during this currently evolving disease and treatment landscape, requires careful consideration. We now have a clear directive for the design of a Phase 2 study. This guidance will inform the on-going development of BIT225 and subsequent next-generation follow-on drugs in Biotron's portfolio.

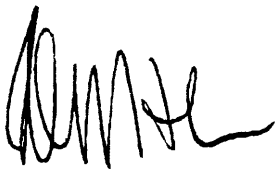
The FDA responses indicate that we are on the right path to the clinic. Our confidence levels for this new class of anti-SARS-Cov-2 drug remain high."

The FDA response gives clear indication of the Agency's interest in this novel drug target that combines direct antiviral effect and beneficial immunomodulatory activities.

Recent animal studies conducted at the Scripps Institute in San Diego have demonstrated that the drug is protective of disease progression and the cytokine storm that is linked to development of severe respiratory disease. BIT225 rapidly reduced viral loads in the lungs of infected animals treated before or following SARS-CoV-2 infection (see announcements of 25 November 2021, 17 March 2022 and 2 May 2022).

With this guidance and acceptable trial design in hand, the Company will now determine its capital requirements for the COVID-19 clinical program and seek funding from potential partners and non-equity funding sources.

Yours sincerely



Peter J. Nightingale
Company Secretary

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About Biotron
Biotron Limited is engaged in the research, development, and commercialisation of drugs targeting significant viral diseases with unmet medical need. The Company has BIT225 in clinical development for HIV-1 and promising preclinical programs for SARS-CoV-2 and HBV. In addition, Biotron has several earlier stage programs designing drugs that target a class of virus protein known as viroporins which have a key role in the virus life cycle of a very broad range of viruses, many of which have caused worldwide health issues such as Coronavirus, Dengue, Ebola, Middle East Respiratory virus, Influenza and Zika viruses.

This announcement has been approved for release by the Company's Managing Director.

Enquiries

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