

For Immediate Release

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LANI Phase II completed - Phase III scheduled

Biota Holdings Limited (ASX:BTA) today announced that its second generation, influenza treatment, CS-8958, has successfully completed its initial Phase II clinical evaluation, showing favourable outcomes against all measured endpoints. The initial Phase III trial is scheduled to commence later this year. CS-8958 is a long acting neuraminidase inhibitor (LANI), and is co-owned with Daiichi-Sankyo.

The Phase II clinical trial was designed to test the safety and efficacy of CS-8958 in several hundred adult patients who had confirmed, naturally acquired influenza A or B using fever and symptom resolution endpoints after a single inhaled dose. The study was conducted in accordance with guidance from the Japanese Pharmaceuticals and Medical Devices Agency (PMDA). In the double-blinded trial, inhaled CS-8958 administered once only was statistically indistinguishable from 75mg of oseltamivir administered twice daily for 5 consecutive days. In earlier pre-clinical tests, CS-8958 has also shown efficacy against H5N1 avian influenza virus as well as influenza A and B.

Biota and Daiichi-Sankyo are satisfied that the safety, tolerability and efficacy data has fully demonstrated proof of concept for LANI and therefore intend to continue with the product's clinical development. The Phase II results are being used to finalise the design of the pivotal Phase III registration trial due to be conducted in the next northern hemisphere autumn/winter influenza season. It is intended that the Phase III study be pan-Asian and include Japan, Taiwan, Hong Kong and Korea.

A parallel Phase II study, undertaken elsewhere in Asia, has also completed dosing. The results of both trials will be used to support the international regulatory and development program planned for LANI.

Biota CEO, Peter Cook said *"This is an important milestone for LANI. We congratulate our partner, Daiichi-Sankyo, for a timely completion of Phase II."*

A range of other LANI type compounds are also co-owned by Biota and Daiichi-Sankyo and are in pre-clinical development under a grant from the US National Institutes of Health.

About Daiichi-Sankyo

Daiichi-Sankyo Co. Ltd (TSE 4568) is one of Japan's largest pharmaceutical companies.

Daiichi-Sankyo has a long history of discovering new classes of drugs, including the first-in-class statin drug for treatment of high cholesterol. In 2003, Daiichi-Sankyo and Biota combined their LANI research programs.

About Biota

Biota is a leading anti-infective drug development company based in Melbourne Australia, with key expertise in respiratory diseases, particularly influenza. Biota developed the first-in-class neuraminidase inhibitor, zanamivir, subsequently marketed by GlaxoSmithKline as Relenza.

Biota research breakthroughs have included a series of candidate drugs aimed at treatment of respiratory syncytial virus (RSV) disease, licensed to MedImmune Inc. and novel nucleoside analogues designed to treat hepatitis C virus (HCV) infections, licensed to Boehringer Ingelheim. Biota has clinical trials underway with its lead compound for human rhinovirus (HRV) infection in patients with compromised respiration or immune systems. In addition, Biota has a key partnership with Daiichi-Sankyo for the development of second generation influenza antivirals. Inverness Medical markets Biota's co-developed OIA FLU influenza diagnostics.

Relenza™ is a registered trademark of the GlaxoSmithKline group of companies.

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**Further information available at www.biota.com.au.*

About LANIs (Long-Acting Neuraminidase Inhibitors)

Current neuraminidase inhibitors for influenza require daily or more frequent dosing. The ability to dose patients on a weekly, or even less frequent, basis offers numerous benefits. Firstly, any stockpile of weekly-dosing drug will last longer and protect more people, in the case of an influenza pandemic. Additionally, a weekly dose may improve patient compliance over a more frequent regime.

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