

**Biota Holdings Limited**

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**LANI Phase II clinical trials commence**

Biota Holdings Limited (ASX:BTA) today announced that its long acting neuraminidase inhibitor (LANI), CS8958, an anti-influenza treatment, has commenced Phase II clinical evaluation. The first patient has commenced treatment. The study is being carried out by Daiichi-Sankyo in the northern hemisphere influenza season.

Key aspects of the Phase II clinical trials are as follows:

- Two trials are planned, one in Japan and the other elsewhere in Asia;
- The studies aim to test the effectiveness of CS8958 in adult patients who have naturally acquired influenza A or B;
- Fever resolution after a single inhaled dose of CS8958 will be the primary end point, although influenza carries a range of symptoms in addition to fever. The reduction in these other symptoms will also be measured;
- The double blind trials will examine the safety and efficacy of CS8958 and assist in selecting the best doses for treating influenza; and
- The duration of the trial will depend on the severity of the influenza season and hence the availability of patients for the trial.

CS8958 is an inhaled long acting neuraminidase inhibitor and offers higher potency and a lower dose than zanamivir and oseltamivir, the currently available products. CS8958 offers the potential for once only treatment and once weekly prophylactic protection from influenza, known consumer advantages over existing inhaled and oral therapies.

CS8958 and a range of other LANI type compounds are co-owned by Biota and Daiichi-Sankyo.

Biota CEO, Peter Cook said *"The commencement of the Phase II clinical trials is another critical step in the evolution of these valuable second generation anti-influenza products"*.

## **About Daiichi-Sankyo**

Daiichi-Sankyo Co. Ltd (TSE 4568) is one of Japan's largest pharmaceutical companies, with annualised worldwide sales of US\$8.2 billion (A\$10 billion).

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 key partnerships with Daiichi-Sankyo for the development of second generation influenza antivirals and with Inverness Medical to market Biota 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](http://www.biota.com.au).*

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