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LANI Phase III clinical trials in Asia prove successful

Biota Holdings Limited (ASX:BTA) today announced successful results from the Asian Phase III clinical trials of CS-8958, its second generation influenza treatment. CS-8958 now has been assigned the new name of 'laninamivir' by the World Health Organization under its International Non-proprietary Names (INN) drug identification system. Laninamivir is a long acting neuraminidase inhibitor (LANI) and is co-owned with Daiichi Sankyo.

In the Phase III trial in adults, a single inhaled dose of laninamivir was shown to be as effective as oseltamivir (Tamiflu) administered orally twice daily for 5 days (total of 10 doses). A parallel Phase II/III trial of CS-8958 in paediatric patients also met the primary and secondary endpoints compared to oseltamivir.

"*The success of the multifaceted Phase III trials in Asia is significant. Laninamivir offers a new therapeutic agent in the treatment of influenza with particular advantages for stockpiling applications*" said Peter Cook, Biota's Managing Director.

Trial Results

The Phase III study was conducted by Daiichi Sankyo in Japan, Taiwan, Hong Kong and Korea and enrolled approximately 1,000 adult patients who had confirmed, naturally acquired influenza A or B. Patients in the trial received either 20mg or 40mg of laninamivir as a single inhaled dose or 75mg of oseltamivir twice daily for five days. Participants in the trial were distributed equally across three treatment groups. The primary end point of the trial was time to symptom resolution, while the secondary end point was time for body temperature to return to normal. Both doses of laninamivir were as effective as oseltamivir and were well tolerated.

The parallel Phase II/III double-blind paediatric study of laninamivir was conducted in Japan in approximately 180 children aged at nine years or younger. This study also compared the safety and efficacy of 20mg or 40mg of laninamivir as a single inhaled dose with oseltamivir, administered at a dose of 2mg/kg twice daily for five days. Approximately 60 children were enrolled in each treatment arm of the study. The primary and secondary end points used in this trial were the same as those used in the adult study. Both doses of laninamivir were equivalent to oseltamivir and were well tolerated by paediatric patients. There was also a trend towards the single inhaled doses of 20mg or 40mg of laninamivir showing a faster time to the alleviation of influenza illness than oseltamivir dosed at 2mg/kg twice daily for five days.

Antiviral activity

Pre-clinical tests have shown laninamivir to be effective against influenza A & B virus as well as against the H5N1 avian influenza virus. A recent paper in the journal *Nature* published by University of Tokyo virologist Yoshihiro Kawaoka et al indicated that laninamivir is also active against the new swine originated influenza A H1N1 virus.

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Future

Daiichi Sankyo has secured the rights to manufacture and market laninamivir in Japan and funded the Japanese trials. Daiichi Sankyo is seeking approval from the Japanese regulatory authority to market laninamivir in Japan, with submission anticipated by March 2010. A clinical study for prophylaxis of influenza is expected to commence in Japan in late 2009.

Biota will receive an undisclosed royalty on sales and a number of fixed sum payments on the achievement of certain sales milestones.

Biota will continue to advance the clinical development program required to support registration in North America and Europe. The US National Institutes of Health has to date committed a total of US$5.6 million to support the western clinical development program.

A licensing partner is now being sought for all markets outside Japan, including the US. Under the Commercialisation and Licence Agreement between Biota and Daiichi Sankyo, the parties will share commercial returns from licensing outside Japan.

A separate announcement will be made by Daiichi Sankyo in Japan today.

About LANI's (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.

About Daiichi Sankyo

A global pharmaceutical innovator, Daiichi Sankyo Co., Ltd., was established in 2005 through the merger of two leading Japanese pharmaceutical companies. Daiichi Sankyo discovered laninamivir and has a key partnership with Biota for the development of the product.

**Further information, visit www.daiichisankyo.com*

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 novel nucleoside analogues designed to treat hepatitis C virus (HCV) infections, licensed to Boehringer Ingelheim, and a series of candidate drugs aimed at treatment of respiratory syncytial virus (RSV) disease. 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 anti-virals.

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

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