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Inavir[®] Phase III prevention study details

Biota Holdings Limited (ASX:BTA) provides the following information in addition to that provided at the AGM (29 November 2011) in relation to the commencement of a Japanese Phase III prevention study for the influenza antiviral, laninamivir (Inavir[®]) by Daiichi Sankyo.

The study is multi-centred, placebo controlled and double blinded and designed to evaluate Inavir's ability to prevent the transmission of influenza A and B within families with a confirmed sufferer. The study will measure the relative reduction in the incidence rate of influenza among those receiving Inavir[®] or placebo. The study intends to recruit 1,500 subjects assigned to two dosage regimens and placebo.

The study is also intended to establish the optimum dosage for Inavir[®] in this indication and provide further evidence of safety.

The first subject has been enrolled and the study duration will depend on the incidence and severity of influenza in the study target population during the study period.

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 include a series of candidate drugs aimed at treatment of respiratory syncytial virus (RSV) disease and Hepatitis C (HCV) virus infections. 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 and Daiichi Sankyo Co., Ltd. co-own a range of second generation influenza antivirals, of which the lead product Inavir[®], is marketed in Japan. Biota holds a contract from the US Office of Biomedical Advanced Research and Development Authority (BARDA) for the advanced development of laninamivir in the USA.

Relenza[™] is a registered trademark of the GlaxoSmithKline group of companies. Inavir[®] is registered to Daiichi Sankyo.

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