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Inavir prevention study achieves primary endpoint

Biota Holdings Limited (ASX:BTA) today announced that a recently completed Japanese Phase III prevention study of Inavir® (laninamivir octanoate, CS-8958) met its primary endpoint, significantly reducing the transmission of influenza within a household. The trial was conducted by Daiichi Sankyo who co-own the product and hold the marketing rights to the drug in Japan. Daiichi Sankyo intends to apply for approval to market Inavir for the prevention of influenza before the end of 2012.

"We are thrilled by the positive outcomes reported by Daiichi Sankyo of Inavir as a preventative agent," said Biota CEO, Peter Cook. "Approval in this new indication will significantly expand the market applicability for Inavir and further solidify its role in pandemic control. We continue to believe that Inavir's demonstrated efficacy, combined with its ease of use, have the opportunity to significantly improve clinical outcomes for the treatment and now prevention, of influenza."

Study Design

The study was a multi-centred, placebo controlled, double blinded study designed to evaluate Inavir's ability to prevent the transmission of influenza A and B within families with a confirmed sufferer. Over 1,500 subjects were enrolled into the study.

The prophylactic effect of the two dosage regimes against influenza infection was measured against placebo and the protective efficacy calculated. A protective efficacy equal to or greater than 70% was required to meet the primary endpoint.

The primary endpoint measure was the proportion of household members that contracted influenza, as defined by an elevated body temperature, a positive measure of influenza virus in a PCR diagnostic assay and the display of at least two (2) of the following symptoms: headache; muscle or joint pain; fatigue; chill or perspiration; nasal discharge; sore throat; or cough.

Efficacy - Primary Endpoint

Compared to placebo, Inavir® in both dose regimes significantly reduced the proportion of patients contracting influenza ($p<0.0001$) and produced protective efficacies in excess of 70%.

Safety

Inavir® was generally well tolerated and the safety profile of Inavir remained consistent with that seen previously in the clinical development program.

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Other

The above is provided as a high level summary of the study's commercially relevant findings. Further information is expected to be provided through peer reviewed scientific publications and presentations that are intended to follow in the ensuing months, including demographics of subjects and index patients, dosage, treatment of index patients, virology, and analysis of secondary endpoints.

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 a well advanced program for human rhinovirus (HRV) infection with a completed Phase IIb study in asthmatic subjects.

In addition, Biota and Daiichi Sankyo 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.

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