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Phase III prophylaxis trial for CS-8958

Dr Seizaburo Kashiwagi presented the preliminary data from an influenza Phase III prophylaxis study conducted during the 2009/2010 pandemic flu season in Japan. The SHIELD study (Study of Household Influenza prophylaxis Effect of Long-acting anti-influenza Drug) presentation was made at the 59th Annual Meeting of the Japanese Society of Chemotherapy.

SHIELD was a multicenter, placebo-controlled, double-blind trial that evaluated prevention and safety of laninamivir octanoate (CS-8958 or Inavir®) in families of influenza A and B sufferers. The study measured influenza transmission to other members of the household with a confirmed influenza infected patient. Subjects received one of two dose levels of CS-8958 or placebo. There were no restrictions on other preventative measures undertaken within the household such as the use of masks, hand washing or isolation of the infected patient to a particular room.

The trial demonstrated the protective efficacies of a single, inhaled dose of CS-8958 of 20mg and 40mg as measured by the Risk Reduction Rate (RRR) were 43.7% and 43.2% respectively but were lower than the preset RRR endpoint of 70%.

The possible reasons offered for the lower protective efficacies were the low infection rate within families in the placebo group (8.6%) and the growth in public awareness, resulting in the use of other preventative infection measures during the 09H1N1 pandemic.

Biota will continue to update shareholders when additional trials commence.

Daiichi Sankyo has achieved significant sales with Inavir® in Japan since its approval in September 2010, for the treatment of influenza.

About Inavir®

Inavir® (laninamivir octanoate) is the first of a new class of long acting neuraminidase inhibitors (LANIs) designed to address the limitation of the current influenza anti-virals, which require daily or more frequent dosing. The new class provides the opportunity to treat patients on a "one and done" basis and provides a number of additional potential benefits, these include improved patient compliance that is the patient is more likely to use the product properly and as intended and also offers a reduced cost of storage and transport per course, where the product is intended to be stockpiled.

Inavir® is Daiichi Sankyo's registered brand and was referred to as CS-8958 during development. Inavir® is delivered via a novel disposable proprietary dry power inhaler.

About Long-Acting Neuraminidase Inhibitors (LANIs)

Current influenza anti-virals or neuraminidase inhibitors for influenza require a minimum of twice daily dosing for the treatment of an influenza infection. LANI compounds persist in the lungs allowing them to be administered once only for treatment and are intended to be used once weekly for prevention of influenza. The ability to dose patients on a less frequent basis offers numerous potential benefits, including greater efficiencies of storage and distribution for a given treatment period and/or number of patients and improved patient compliance. This represents a significant advance over existing influenza anti-virals.

Laninamivir octanoate is a pro-drug and is converted to the active species, laninamivir, in the respiratory tract following administration and is effective on a once only dosing for treatment and intended as a once weekly dosing for prophylaxis.

Features of laninamivir octanoate:

- A Phase III clinical trial in Asia in adults with influenza A or B demonstrated that a single inhaled dose of CS-8958 has equivalent safety and efficacy to Tamiflu® (oseltamivir) dosed twice daily for five days;
- A Phase II/III trial of inhaled CS-8958 in children in Japan also demonstrated equivalent safety and efficacy to Tamiflu dosed orally twice daily for five days;
- CS-8958 is effective against all strains of influenza A and B, including seasonal flu, pandemic influenza A (H1N1) 2009 and avian flu (H5N1);
- CS-8958 is effective against oseltamivir resistant influenza viruses; and
- CS-8958 has an excellent safety profile.

In addition to laninamivir octanoate Biota is currently in preclinical development with FLUNET. Development programs for both laninamivir and FLUNET have been or are supported by US NIH funding. In addition, the advanced development of laninamivir octanoate, for introduction into the US market, is being funded under a contract with the Office of Biomedical Advanced Research and Development Authority of the US Department of Health and Human Services (BARDA).

About Daiichi Sankyo

The Daiichi Sankyo Group is dedicated to the creation and supply of innovative pharmaceutical products to address the diversified, unmet medical needs of patients in both mature and emerging markets. While maintaining its portfolio of marketed pharmaceuticals for hypertension, hyperlipidemia, and bacterial infections, the Group is engaged in the development of treatments for thrombotic disorders and focused on the discovery of novel oncology and cardiovascular-metabolic therapies. Furthermore, the Daiichi Sankyo Group has created a "Hybrid Business Model," which will respond to market and customer diversity and optimize growth opportunities across the value chain. For more information, please visit www.daiichisankyo.com

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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-own a range of second generation influenza antivirals, of which the lead product Inavir®, is approved for marketing 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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