For Immediate Release

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Positive top line results from Phase III study (MARVEL) of anti-influenza virus agent 'CS-8958'

TOKYO, Japan (August 10, 2009) – Daiichi Sankyo Company, Limited announced today the top line results from a Phase III study of the anti-influenza virus agent 'CS-8958' (generic name; laninamivir).

This study, named MARVEL (Multinational Asian Clinical Research for Influenza Virus Extermination on Long-Acting Neuraminidase-Inhibitor study), was performed as a randomized, double-blind, and active-controlled study in order to confirm the efficacy and safety of CS-8958 administered as a single inhaled dose of 20 or 40 mg compared to oseltamivir phosphate 75 mg (Tamiflu® capsule) orally administered twice daily for 5 days (total of 10 times) in adult patients with influenza A or B virus infection. According to the results, non-inferiority to oseltamivir phosphate was confirmed in both the 20 mg group and 40 mg group of CS-8958 in terms of the primary endpoint, which was the time to alleviation of influenza illness. In the comparison between the dose groups of CS-8958, 40 mg group was superior to 20 mg group in efficacy. Both 20 mg and 40 mg of CS-8958 were well tolerated.
In addition, Daiichi Sankyo conducted a randomized, double-blind, active-controlled Phase II/III study for pediatric use in parallel with MARVEL study, and the efficacy and safety of CS-8958 administered as a single inhaled dose of 20 or 40 mg was compared to oseltamivir phosphate (Tamiflu® for oral suspension) as well. According to the results, both the 20 mg group and 40 mg group of CS-8958 were better than oseltamivir phosphate group in efficacy. Both 20 mg and 40 mg of CS-8958 were well tolerated in pediatric patients.

Daiichi Sankyo is now preparing to file its NDA for a treatment indication in fiscal year 2009. Furthermore, Daiichi Sankyo is also preparing to start a clinical study for a prophylaxis indication in autumn of 2009.

①About CS-8958

CS-8958 (generic name; laninamivir) is an anti-influenza virus agent, originated by Daiichi Sankyo Co.,Ltd., and is expected to be effective after a single dose due to its long action as a neuraminidase inhibitor. After inhalation, CS-8958 is retained for a long time in the target organ. Non-clinical studies conducted so far have shown that this agent was effective not only against seasonal influenza, but also against new type influenza (swine A/H1N1) *in-vitro* and *in-vivo* (Y. Itoh,et al, Nature, 2009). Additionally, CS-8958 shows efficacy against H5N1 avian influenza virus in non-clinical tests.

②About phase III study in adult patients

MARVEL study (Multinational Asian Clinical Research for Influenza Virus Extermination on Long Acting Neuraminidase Inhibitor)

Study design	A randomized, double-blind, active-controlled, multi-center study to confirm the efficacy and safety of CS-8958 20 mg and 40 mg compared to oseltamivir phosphate in approximately 1,000 adult (age ≥20 yr) patients with influenza A or B virus infection. It was conducted as a multinational study in Japan, Taiwan, Hong Kong, and Korea.
Efficacy	To confirm the non-inferiority of CS-8958 to oseltamivir phosphate in terms of the primary endpoint, which was the time to alleviation of influenza illness
Safety	To make between-group comparisons with regard to incidence of adverse events and other safety measures
Secondary objective	To evaluate the optimum dosage of CS-8958 based on the efficacy and safety of single inhaled doses of 20 mg and 40 mg

③About phase II/III study in pediatric patients

Study design	A randomized, double-blind, active-controlled, multi-center study for the evaluation of efficacy and safety of CS-8958 20 mg and 40 mg compared to oral formulation of oseltamivir phosphate 2 mg/kg (Tamiflu® for oral suspension) administered twice daily for 5 days in approximately 180 pediatric (age ≤9 yr) patients with influenza A or B virus infection
Efficacy	To evaluate by the primary endpoint, which was the time to alleviation of influenza illness
Safety	To make between-group comparisons with regard to incidence of adverse events and other safety measures
Secondary objective	To evaluate the optimum dosage of CS-8958 based on the efficacy and safety of single inhaled doses of 20 mg and 40 mg.