SYNOPSIS

Name of Sponsor/Company Daiichi Sankyo Co., Ltd. Name of Finished Product INAVIR® DRY POWDER INHALER 20mg Name of Active Ingredient Laninamivir Octanoate Hydrate (JAN) Title of Study A randomized, double-blind, placebo-controlled, multi-center phase II study for the evaluation of efficacy and safety of CS-8958 in patients with influenza virus infection Investigators Study Centre(s) Publication (reference) Not published. Studied Period Phase II Objectives The primary objective of this study was to evaluate the efficacy after a single dose of 10 mg or 20 mg of CS-8958 in patients with influenza virus A or B infection using the time to resolution of fever after treatment as the primary endpoint. Methodology Randomized double-blind, placebo controlled, parallel group, multi-center study of a single dose of CS-8958 at 10 mg or 20 mg Number of Patients (planned and analyzed) Planned number of patients: 180 patients CS-8958 10 mg group, 60 patients; CS-8958 20 mg group, 60 patients: Placebo group, 60 patients Diagnosis and Main Criteria Patients with a group, 60 patients; CS-8958 20 mg group, 59 patients; Placebo group, 59 patients Diagnosis and Main Criteria Patients with a positive rapid diagnostic test result for influenza virus A and/or B. Diagnosis and Main Criteria Patients win a positive rapid diagnostic test re		
Name of Active Ingredient Laninamivir Octanoate Hydrate (JAN) Title of Study A randomized, double-blind, placebo-controlled, multi-center phase II study for the evaluation of efficacy and safety of CS-8958 in patients with influenza virus infection Investigators Study Centre(s) Publication (reference) Not published. Studied Period Phase II Objectives The primary objective of this study was to evaluate the efficacy after a single dose of 10 mg or 20 mg of CS-8958 in patients with influenza virus A or B infection using the time to resolution of fever after treatment as the primary endpoint. Methodology Randomized double-blind, placebo controlled, parallel group, multi-center study of a single dose of CS-8958 at 10 mg or 20 mg Number of Patients (planned and analyzed) Planned number of patients : 180 patients CS-8958 10 mg group, 60 patients: CS-8958 20 mg group, 60 patients; Placebo group, 60 patients; CS-8958 20 mg group, 50 patients; Placebo group, 59 patients. Diagnosis and Main Criteria for Inclusion Patients who met following criteria were enrolled. 1. Male or fenale patients aged 18 to 64 years. 2. Outpatients. 3. Providing written informed consent. 4. Patients with a positive rapid diagnostic test result for influenza virus A and/or B. 5. Patients with an ear temperature of ≥ 37.8°C. 6. Patients who presented the onset of influenza symptoms (Name of Sponsor/Company	Daiichi Sankyo Co., Ltd.
Title of Study A randomized, double-blind, placebo-controlled, multi-center phase II study for the evaluation of efficacy and safety of CS-8958 in patients with influenza virus infection Study Centre(s) Publication (reference) Not published. Studied Period Phase of Development Objectives The primary objective of this study was to evaluate the efficacy after a single dose of 10 mg or 20 mg of CS-8958 in patients with influenza virus A or B infection using the time to resolution of fever after treatment as the primary endpoint. Methodology Randomized double-blind, placebo controlled, parallel group, multi-center study of a single dose of CS-8958 at 10 mg or 20 mg Planned number of patients: 180 patients CS-8958 10 mg group, 60 patients; CS-8958 20 mg group, 60 patients; Placebo group, 60 patients Full analysis et (FAS):174 patients CS-8958 10 mg group. 59 patients CS-8958 10 mg group. 59 patients Patients who met following criteria were enrolled. 1. Male or female patients aged 18 to 64 years. 2. Outpatients. 3. Providing written informed consent. 4. Patients with a positive rapid diagnostic test result for influenza virus A and/or B. 5. Patients with an ear temperature of ≥ 37.8°C. 6. Patients with an ear temperature of ≥ 37.8°C. 6. Patients who presented the onset of influenza symptoms (fever, headache, myalgia/arthralgia, fatigue, chill/perspiration, nasal symptom, sore throat, cough, etc.) within 36 hours. Test Product, Dose and Mode of Administration CS-8958 CS-8958 placebo	Name of Finished Product	INAVIR® DRY POWDER INHALER 20mg
phase II study for the evaluation of efficacy and safety of CS-8958 in patients with influenza virus infection Investigators Study Centre(s) Publication (reference) Not published. Studied Period Phase of Development Objectives The primary objective of this study was to evaluate the efficacy after a single dose of 10 mg or 20 mg of CS-8958 in patients with influenza virus A or B infection using the time to resolution of fever after treatment as the primary endpoint. Methodology Randomized double-blind, placebo controlled, parallel group, multi-center study of a single dose of CS-8958 at 10 mg or 20 mg Planned number of patients: 180 patients CS-8958 10 mg group, 60 patients; CS-8958 20 mg group, 60 patients is Placebo group, 60 patients Full analysis set (FAS):174 patients CS-8958 10 mg group. 59 patients Full analysis set (FAS):174 patients CS-8958 10 mg group. 59 patients Patients who met following criteria were enrolled. 1. Male or female patients aged 18 to 64 years. 2. Outpatients. 3. Providing written informed consent. 4. Patients with a positive rapid diagnostic test result for influenza virus A and/or B. 5. Patients with an ear temperature of ≥ 37.8°C. 6. Patients who presented the onset of influenza symptoms (fever, headache, myalgia/arthralgia, fatigue, chill/perspiration, nasal symptom, sore throat, cough, etc.) within 36 hours. Test Product, Dose and Mode of Administration CS-8958 CS-8958 placebo	Name of Active Ingredient	Laninamivir Octanoate Hydrate (JAN)
Investigators Study Centre(s) Publication (reference) Not published. Studied Period Phase of Development Objectives The primary objective of this study was to evaluate the efficacy after a single dose of 10 mg or 20 mg of CS-8958 in patients with influenza virus A or B infection using the time to resolution of fever after treatment as the primary endpoint. Methodology Randomized double-blind, placebo controlled, parallel group, multi-center study of a single dose of CS-8958 at 10 mg or 20 mg Number of Patients (planned and analyzed) Planned number of patients: 180 patients CS-8958 10 mg group, 60 patients; CS-8958 20 mg group, 60 patients; Placebo group, 60 patients Full analysis set (FAS):174 patients CS-8958 10 mg group. 56 patients; CS-8958 20 mg group, 59 patients; Placebo group. 59 patients Diagnosis and Main Criteria for Inclusion Patients who met following criteria were enrolled. 1. Male or female patients aged 18 to 64 years. 2. Outpatients. 3. Providing written informed consent. 4. Patients with a positive rapid diagnostic test result for influenza virus A and/or B. 5. Patients with an ear temperature of ≥ 37.8°C. 6. Patients with an ear temperature of ≥ 37.8°C. 6. Patients with an ear temperature of ≥ 37.8°C. 6. Patients with an ear temperature of ≥ 37.8°C. 6. Patients with an ear temperature of ≥ 37.8°C. 6. Patients with an ear temperature of ≥ 37.8°C. 6. Patients with an ear temperature of ≥ 37.8°C. 6. Patients with an ear temperature of ≥ 37.8°C. 6. Patients with an ear temperature of ≥ 37.8°C. 6. Patients with an ear temperature of ≥ 37.8°C. 6. Patients with an ear temperature of ≥ 37.8°C. 6. Patients with an ear temperature of ≥ 37.8°C. 6. Patients with an ear temperature of ≥ 37.8°C. 6. Patients with an ear temperature of ≥ 37.8°C. 6. Patients with an ear temperature of ≥ 37.8°C. 6. Patients with an ear temperature of ≥ 37.8°C. 6. Patients with an ear temperature of ≥ 37.8°C.	Title of Study	A randomized, double-blind, placebo-controlled, multi-center
Investigators Study Centre(s) Publication (reference) Not published. Studied Period Phase of Development Phase of Development Phase II Objectives The primary objective of this study was to evaluate the efficacy after a single dose of 10 mg or 20 mg of CS-8958 in patients with influenza virus A or B infection using the time to resolution of fever after treatment as the primary endpoint. Methodology Randomized double-blind, placebo controlled, parallel group, multi-center study of a single dose of CS-8958 at 10 mg or 20 mg Number of Patients (planned and analyzed) Planned number of patients : 180 patients CS-8958 10 mg group, 60 patients; CS-8958 20 mg group, 60 patients; Full analysis set (FAS):174 patients CS-8958 10 mg group. 59 patients Diagnosis and Main Criteria for Inclusion Patients who met following criteria were enrolled. Di America for Inclusion Patients who met following criteria were enrolled. Di America for Emale patients aged 18 to 64 years. Coutpatients. Di Providing written informed consent. Patients with a positive rapid diagnostic test result for influenza virus A and/or B. Patients with an ear temperature of ≥ 37.8°C. Evaluation for Emale for Influence for influenc		phase II study for the evaluation of efficacy and safety of CS-8958
Study Centre(s) Not published. Studied Period Phase of Development Phase of Development Phase II Objectives The primary objective of this study was to evaluate the efficacy after a single dose of 10 mg or 20 mg of CS-8958 in patients with influenza virus A or B infection using the time to resolution of fever after treatment as the primary endpoint. Methodology Randomized double-blind, placebo controlled, parallel group, multi-center study of a single dose of CS-8958 at 10 mg or 20 mg Number of Patients (planned and analyzed) Planned number of patients : 180 patients CS-8958 10 mg group, 60 patients; CS-8958 20 mg group, 60 patients; Full analysis set (FAS):174 patients CS-8958 10 mg group, 59 patients CS-8958 10 mg group, 59 patients Diagnosis and Main Criteria Patients who met following criteria were enrolled. 1. Male or female patients aged 18 to 64 years. 2. Outpatients. 2. Outpatients. 3. Providing written informed consent. 4. Patients with a positive rapid diagnostic test result for influenza virus A and/or B. 5. Patients with an ear temperature of ≥ 37.8°C. 6. Patients who presented the onset of influenza symptoms (fever, headache, myalgia/arthralgia, fatigue, chill/perspiration, nasal symptom, sore throat, cough, etc.) within 36 hours. Test Product, Dose and Mode of Administration CS-8958		in patients with influenza virus infection
Publication (reference) Not published. Studied Period Phase of Development Phase of Development Phase II Objectives The primary objective of this study was to evaluate the efficacy after a single dose of 10 mg or 20 mg of CS-8958 in patients with influenza virus A or B infection using the time to resolution of fever after treatment as the primary endpoint. Methodology Randomized double-blind, placebo controlled, parallel group, multi-center study of a single dose of CS-8958 at 10 mg or 20 mg Number of Patients (planned and analyzed) Planned number of patients : 180 patients CS-8958 10 mg group, 60 patients; CS-8958 20 mg group, 60 patients; Placebo group, 60 patients; Placebo group, 59 patients; Placebo group. 59 patients; Placebo group. 59 patients; Placebo group. 59 patients Diagnosis and Main Criteria for Inclusion Patients who met following criteria were enrolled. 1. Male or female patients aged 18 to 64 years. 2. Outpatients. 2. Outpatients. 3. Providing written informed consent. 4. Patients with a positive rapid diagnostic test result for influenza virus A and/or B. 5. Patients with an ear temperature of ≥ 37.8°C. 6. Patients who presented the onset of influenza symptoms (fever, headache, myalgia/arthralgia, fatigue, chill/perspiration, nasal symptom, sore throat, cough, etc.) within 36 hours. Test Product, Dose and Mode of Administration CS-8958	Investigators	
Studied Period Phase II Objectives The primary objective of this study was to evaluate the efficacy after a single dose of 10 mg or 20 mg of CS-8958 in patients with influenza virus A or B infection using the time to resolution of fever after treatment as the primary endpoint. Methodology Randomized double-blind, placebo controlled, parallel group, multi-center study of a single dose of CS-8958 at 10 mg or 20 mg Number of Patients (planned and analyzed) Planned number of patients : 180 patients CS-8958 10 mg group, 60 patients; CS-8958 20 mg group, 60 patients; Placebo group, 60 patients CS-8958 10 mg group, 60 patients; CS-8958 20 mg group, 59 patients; Placebo group, 59 patients; Placebo group. 59 patients; Placebo group. 59 patients Diagnosis and Main Criteria for Inclusion Patients who met following criteria were enrolled. 1. Male or female patients aged 18 to 64 years. 2. Outpatients. 3. Providing written informed consent. 4. Patients with a positive rapid diagnostic test result for influenza virus A and/or B. 5. Patients with an ear temperature of ≥ 37.8°C. 6. Patients who presented the onset of influenza symptoms (fever, headache, myalgia/arthralgia, fatigue, chill/perspiration, nasal symptom, sore throat, cough, etc.) within 36 hours. Test Product, Dose and Mode of Administration CS-8958 placebo	Study Centre(s)	
Phase of Development Phase II Objectives The primary objective of this study was to evaluate the efficacy after a single dose of 10 mg or 20 mg of CS-8958 in patients with influenza virus A or B infection using the time to resolution of fever after treatment as the primary endpoint. Methodology Randomized double-blind, placebo controlled, parallel group, multi-center study of a single dose of CS-8958 at 10 mg or 20 mg Number of Patients (planned and analyzed) Planned number of patients: 180 patients CS-8958 10 mg group, 60 patients: CS-8958 20 mg group, 60 patients; Placebo group, 60 patients Full analysis set (FAS):174 patients CS-8958 10 mg group. 56 patients; CS-8958 20 mg group, 59 patients; Placebo group. 59 patients Diagnosis and Main Criteria Patients who met following criteria were enrolled. 1. Male or female patients aged 18 to 64 years. 2. Outpatients. 3. Providing written informed consent. 4. Patients with a positive rapid diagnostic test result for influenza virus A and/or B. 5. Patients with an ear temperature of ≥ 37.8°C. 6. Patients who presented the onset of influenza symptoms (fever, headache, myalgia/arthralgia, fatigue, chill/perspiration, nasal symptom, sore throat, cough, etc.) within 36 hours. Test Product, Dose and Mode of Administration CS-8958	Publication (reference)	Not published.
Objectives The primary objective of this study was to evaluate the efficacy after a single dose of 10 mg or 20 mg of CS-8958 in patients with influenza virus A or B infection using the time to resolution of fever after treatment as the primary endpoint. Methodology Randomized double-blind, placebo controlled, parallel group, multi-center study of a single dose of CS-8958 at 10 mg or 20 mg Number of Patients (planned and analyzed) Planned number of patients: 180 patients CS-8958 10 mg group, 60 patients; CS-8958 20 mg group, 60 patients; Placebo group, 60 patients Full analysis set (FAS):174 patients CS-8958 10 mg group. 56 patients; CS-8958 20 mg group, 59 patients; Placebo group. 59 patients Test Product, Dose and Mode of Administration	Studied Period	
after a single dose of 10 mg or 20 mg of CS-8958 in patients with influenza virus A or B infection using the time to resolution of fever after treatment as the primary endpoint. Methodology Randomized double-blind, placebo controlled, parallel group, multi-center study of a single dose of CS-8958 at 10 mg or 20 mg Number of Patients (planned and analyzed) Planned number of patients: 180 patients CS-8958 10 mg group, 60 patients; CS-8958 20 mg group, 60 patients; Placebo group, 60 patients Full analysis set (FAS):174 patients CS-8958 10 mg group. 56 patients; CS-8958 20 mg group, 59 patients; Placebo group. 59 patients Diagnosis and Main Criteria for Inclusion Patients who met following criteria were enrolled. 1. Male or female patients aged 18 to 64 years. 2. Outpatients. 3. Providing written informed consent. 4. Patients with a positive rapid diagnostic test result for influenza virus A and/or B. 5. Patients with an ear temperature of ≥ 37.8°C. 6. Patients who presented the onset of influenza symptoms (fever, headache, myalgia/arthralgia, fatigue, chill/perspiration, nasal symptom, sore throat, cough, etc.) within 36 hours. Test Product, Dose and Mode of Administration CS-8958 placebo	Phase of Development	Phase II
influenza virus A or B infection using the time to resolution of fever after treatment as the primary endpoint. Methodology Randomized double-blind, placebo controlled, parallel group, multi-center study of a single dose of CS-8958 at 10 mg or 20 mg Number of Patients (planned and analyzed) Planned number of patients: 180 patients CS-8958 10 mg group, 60 patients; CS-8958 20 mg group, 60 patients; Placebo group, 60 patients Full analysis set (FAS):174 patients CS-8958 10 mg group. 56 patients; CS-8958 20 mg group, 59 patients; Placebo group. 59 patients Diagnosis and Main Criteria for Inclusion Patients who met following criteria were enrolled. 1. Male or female patients aged 18 to 64 years. 2. Outpatients. 3. Providing written informed consent. 4. Patients with a positive rapid diagnostic test result for influenza virus A and/or B. 5. Patients with an ear temperature of ≥ 37.8°C. 6. Patients with an ear temperature of influenza symptoms (fever, headache, myalgia/arthralgia, fatigue, chill/perspiration, nasal symptom, sore throat, cough, etc.) within 36 hours. Test Product, Dose and Mode of Administration CS-8958 placebo	Objectives	The primary objective of this study was to evaluate the efficacy
MethodologyRandomized double-blind, placebo controlled, parallel group, multi-center study of a single dose of CS-8958 at 10 mg or 20 mgNumber of Patients (planned and analyzed)Planned number of patients : 180 patientsCS-8958 10 mg group, 60 patients; CS-8958 20 mg group, 60 patients; Full analysis set (FAS):174 patientsCS-8958 10 mg group, 50 patients; CS-8958 20 mg group, 59 patients; Placebo group, 59 patientsDiagnosis and Main CriteriaPatients who met following criteria were enrolled.for Inclusion1. Male or female patients aged 18 to 64 years.2. Outpatients.3. Providing written informed consent.4. Patients with a positive rapid diagnostic test result for influenza virus A and/or B.5. Patients with an ear temperature of ≥ 37.8°C.6. Patients who presented the onset of influenza symptoms (fever, headache, myalgia/arthralgia, fatigue, chill/perspiration, nasal symptom, sore throat, cough, etc.) within 36 hours.Test Product, Dose and Mode of AdministrationCS-8958CS-8958 placebo		after a single dose of 10 mg or 20 mg of CS-8958 in patients with
Methodology Randomized double-blind, placebo controlled, parallel group, multi-center study of a single dose of CS-8958 at 10 mg or 20 mg Number of Patients (planned and analyzed) Planned number of patients: 180 patients CS-8958 10 mg group, 60 patients; CS-8958 20 mg group, 60 patients; Placebo group, 60 patients Full analysis set (FAS):174 patients CS-8958 10 mg group, 56 patients; CS-8958 20 mg group, 59 patients; Placebo group, 59 patients Patients who met following criteria were enrolled. 1. Male or female patients aged 18 to 64 years. 2. Outpatients. 3. Providing written informed consent. 4. Patients with a positive rapid diagnostic test result for influenza virus A and/or B. 5. Patients with an ear temperature of ≥ 37.8°C. 6. Patients who presented the onset of influenza symptoms (fever, headache, myalgia/arthralgia, fatigue, chill/perspiration, nasal symptom, sore throat, cough, etc.) within 36 hours. Test Product, Dose and Mode of Administration CS-8958		influenza virus A or B infection using the time to resolution of
multi-center study of a single dose of CS-8958 at 10 mg or 20 mg Number of Patients (planned and analyzed) Planned number of patients : 180 patients CS-8958 10 mg group, 60 patients; CS-8958 20 mg group, 60 patients; Placebo group, 60 patients Full analysis set (FAS):174 patients CS-8958 10 mg group. 56 patients; CS-8958 20 mg group, 59 patients; Placebo group. 59 patients Patients who met following criteria were enrolled. 1. Male or female patients aged 18 to 64 years. 2. Outpatients. 3. Providing written informed consent. 4. Patients with a positive rapid diagnostic test result for influenza virus A and/or B. 5. Patients with an ear temperature of ≥ 37.8°C. 6. Patients who presented the onset of influenza symptoms (fever, headache, myalgia/arthralgia, fatigue, chill/perspiration, nasal symptom, sore throat, cough, etc.) within 36 hours. Test Product, Dose and Mode of Administration CS-8958		fever after treatment as the primary endpoint.
Number of Patients (planned and analyzed) Planned number of patients: 180 patients CS-8958 10 mg group, 60 patients; CS-8958 20 mg group, 60 patients; Placebo group, 60 patients Full analysis set (FAS):174 patients CS-8958 10 mg group. 56 patients; CS-8958 20 mg group, 59 patients; Placebo group. 59 patients Diagnosis and Main Criteria for Inclusion Patients who met following criteria were enrolled. 1. Male or female patients aged 18 to 64 years. 2. Outpatients. 3. Providing written informed consent. 4. Patients with a positive rapid diagnostic test result for influenza virus A and/or B. 5. Patients with an ear temperature of ≥ 37.8°C. 6. Patients who presented the onset of influenza symptoms (fever, headache, myalgia/arthralgia, fatigue, chill/perspiration, nasal symptom, sore throat, cough, etc.) within 36 hours. Test Product, Dose and Mode of Administration CS-8958 placebo	Methodology	Randomized double-blind, placebo controlled, parallel group,
and analyzed) CS-8958 10 mg group, 60 patients; CS-8958 20 mg group, 60 patients; Placebo group, 60 patients Full analysis set (FAS):174 patients CS-8958 10 mg group. 56 patients; CS-8958 20 mg group, 59 patients; Placebo group. 59 patients Diagnosis and Main Criteria Patients who met following criteria were enrolled. 1. Male or female patients aged 18 to 64 years. 2. Outpatients. 3. Providing written informed consent. 4. Patients with a positive rapid diagnostic test result for influenza virus A and/or B. 5. Patients with an ear temperature of ≥ 37.8°C. 6. Patients who presented the onset of influenza symptoms (fever, headache, myalgia/arthralgia, fatigue, chill/perspiration, nasal symptom, sore throat, cough, etc.) within 36 hours. Test Product, Dose and Mode of Administration CS-8958 placebo		multi-center study of a single dose of CS-8958 at 10 mg or 20 mg
60 patients; Placebo group, 60 patients Full analysis set (FAS):174 patients CS-8958 10 mg group. 56 patients; CS-8958 20 mg group, 59 patients; Placebo group. 59 patients Diagnosis and Main Criteria for Inclusion Patients who met following criteria were enrolled. 1. Male or female patients aged 18 to 64 years. 2. Outpatients. 3. Providing written informed consent. 4. Patients with a positive rapid diagnostic test result for influenza virus A and/or B. 5. Patients with an ear temperature of ≥ 37.8°C. 6. Patients who presented the onset of influenza symptoms (fever, headache, myalgia/arthralgia, fatigue, chill/perspiration, nasal symptom, sore throat, cough, etc.) within 36 hours. Test Product, Dose and Mode of Administration CS-8958 placebo	Number of Patients (planned	Planned number of patients: 180 patients
Full analysis set (FAS):174 patients CS-8958 10 mg group. 56 patients; CS-8958 20 mg group, 59 patients; Placebo group. 59 patients Diagnosis and Main Criteria Patients who met following criteria were enrolled. 1. Male or female patients aged 18 to 64 years. 2. Outpatients. 3. Providing written informed consent. 4. Patients with a positive rapid diagnostic test result for influenza virus A and/or B. 5. Patients with an ear temperature of ≥ 37.8°C. 6. Patients who presented the onset of influenza symptoms (fever, headache, myalgia/arthralgia, fatigue, chill/perspiration, nasal symptom, sore throat, cough, etc.) within 36 hours. Test Product, Dose and Mode of Administration CS-8958 placebo	and analyzed)	CS-8958 10 mg group, 60 patients; CS-8958 20 mg group,
CS-8958 10 mg group. 56 patients; CS-8958 20 mg group, 59 patients; Placebo group. 59 patients Diagnosis and Main Criteria for Inclusion Patients who met following criteria were enrolled. 1. Male or female patients aged 18 to 64 years. 2. Outpatients. 3. Providing written informed consent. 4. Patients with a positive rapid diagnostic test result for influenza virus A and/or B. 5. Patients with an ear temperature of ≥ 37.8°C. 6. Patients who presented the onset of influenza symptoms (fever, headache, myalgia/arthralgia, fatigue, chill/perspiration, nasal symptom, sore throat, cough, etc.) within 36 hours. Test Product, Dose and Mode of Administration CS-8958 placebo		60 patients; Placebo group, 60 patients
Diagnosis and Main Criteria Patients who met following criteria were enrolled. 1. Male or female patients aged 18 to 64 years. 2. Outpatients. 3. Providing written informed consent. 4. Patients with a positive rapid diagnostic test result for influenza virus A and/or B. 5. Patients with an ear temperature of ≥ 37.8°C. 6. Patients who presented the onset of influenza symptoms (fever, headache, myalgia/arthralgia, fatigue, chill/perspiration, nasal symptom, sore throat, cough, etc.) within 36 hours. Test Product, Dose and Mode of Administration CS-8958 placebo		Full analysis set (FAS):174 patients
Diagnosis and Main Criteria for Inclusion Patients who met following criteria were enrolled. 1. Male or female patients aged 18 to 64 years. 2. Outpatients. 3. Providing written informed consent. 4. Patients with a positive rapid diagnostic test result for influenza virus A and/or B. 5. Patients with an ear temperature of ≥ 37.8°C. 6. Patients who presented the onset of influenza symptoms (fever, headache, myalgia/arthralgia, fatigue, chill/perspiration, nasal symptom, sore throat, cough, etc.) within 36 hours. Test Product, Dose and Mode of Administration CS-8958 placebo		CS-8958 10 mg group. 56 patients; CS-8958 20 mg group, 59
for Inclusion 1. Male or female patients aged 18 to 64 years. 2. Outpatients. 3. Providing written informed consent. 4. Patients with a positive rapid diagnostic test result for influenza virus A and/or B. 5. Patients with an ear temperature of ≥ 37.8°C. 6. Patients who presented the onset of influenza symptoms (fever, headache, myalgia/arthralgia, fatigue, chill/perspiration, nasal symptom, sore throat, cough, etc.) within 36 hours. Test Product, Dose and Mode of Administration CS-8958 placebo		patients; Placebo group. 59 patients
2. Outpatients. 3. Providing written informed consent. 4. Patients with a positive rapid diagnostic test result for influenza virus A and/or B. 5. Patients with an ear temperature of ≥ 37.8°C. 6. Patients who presented the onset of influenza symptoms (fever, headache, myalgia/arthralgia, fatigue, chill/perspiration, nasal symptom, sore throat, cough, etc.) within 36 hours. Test Product, Dose and Mode of Administration CS-8958 placebo	Diagnosis and Main Criteria	Patients who met following criteria were enrolled.
3. Providing written informed consent. 4. Patients with a positive rapid diagnostic test result for influenza virus A and/or B. 5. Patients with an ear temperature of ≥ 37.8°C. 6. Patients who presented the onset of influenza symptoms (fever, headache, myalgia/arthralgia, fatigue, chill/perspiration, nasal symptom, sore throat, cough, etc.) within 36 hours. Test Product, Dose and Mode of Administration CS-8958 CS-8958 placebo	for Inclusion	1. Male or female patients aged 18 to 64 years.
4. Patients with a positive rapid diagnostic test result for influenza virus A and/or B. 5. Patients with an ear temperature of ≥ 37.8°C. 6. Patients who presented the onset of influenza symptoms (fever, headache, myalgia/arthralgia, fatigue, chill/perspiration, nasal symptom, sore throat, cough, etc.) within 36 hours. Test Product, Dose and Mode of Administration CS-8958 CS-8958 placebo		2. Outpatients.
virus A and/or B. 5. Patients with an ear temperature of ≥ 37.8°C. 6. Patients who presented the onset of influenza symptoms (fever, headache, myalgia/arthralgia, fatigue, chill/perspiration, nasal symptom, sore throat, cough, etc.) within 36 hours. Test Product, Dose and Mode of Administration CS-8958 CS-8958 placebo		3. Providing written informed consent.
5. Patients with an ear temperature of ≥ 37.8°C. 6. Patients who presented the onset of influenza symptoms (fever, headache, myalgia/arthralgia, fatigue, chill/perspiration, nasal symptom, sore throat, cough, etc.) within 36 hours. Test Product, Dose and Mode of Administration CS-8958 placebo		4. Patients with a positive rapid diagnostic test result for influenza
6. Patients who presented the onset of influenza symptoms (fever, headache, myalgia/arthralgia, fatigue, chill/perspiration, nasal symptom, sore throat, cough, etc.) within 36 hours. Test Product, Dose and Mode of Administration CS-8958 CS-8958 placebo		virus A and/or B.
headache, myalgia/arthralgia, fatigue, chill/perspiration, nasal symptom, sore throat, cough, etc.) within 36 hours. Test Product, Dose and Mode of Administration CS-8958 CS-8958 placebo		5. Patients with an ear temperature of \geq 37.8°C.
symptom, sore throat, cough, etc.) within 36 hours. Test Product, Dose and Mode of Administration CS-8958 placebo		6. Patients who presented the onset of influenza symptoms (fever,
Test Product, Dose and Mode CS-8958 of Administration CS-8958 placebo		headache, myalgia/arthralgia, fatigue, chill/perspiration, nasal
of Administration CS-8958 placebo		symptom, sore throat, cough, etc.) within 36 hours.
·	Test Product, Dose and Mode	CS-8958
Patient received a single inhalation of CS-8958 10 mg, 20 mg or	of Administration	CS-8958 placebo
		Patient received a single inhalation of CS-8958 10 mg, 20 mg or

	placebo using a inhaler.
Duration of Treatment	Single dose
Reference Therapy, Dose and	None
Mode of Administration	
Criteria for Evaluation	Primary Endpoint: Time to Resolution of Fever (≤ 37.2°C)
	Secondary Endpoints: Time to alleviation of influenza illness
Statistical Method	Efficacy Analysis;
	Primary analysis: The time to resolution of fever was analyzed
	using the generalized Wilcoxon test, and its 95% confidence
	interval for the difference of median time to resolution of fever
	between treatment groups were estimated. And median time to
	resolution of fever, its 95% confidence interval, and other summary
	statistics were calculated for each treatment group.
	Secondary analysis:The difference in the median of the CS-8958
	treatment groups and its 95% confidence interval was calculated,
	and the generalized Wilcoxon test was conducted.
	Safety Analysis;
	Adverse Events: The number of patients and the incidence in each
	treatment group were obtained for study drug-related adverse
	events and all adverse events. Similar analysis was also performed
	for each event and severity.
Summary - Conclusion	Efficacy (primary endpoint):
	Primary analysis:
	The Kaplan-Meier plot was comparable between the treatment
	groups. The median of the primary endpoint "time to resolution of
	fever" was 39.7 h in CS-8958 10 mg group, 38.5 h in CS-8958 20
	mg group, and 41.0 h in placebo group, and there were no
	statistically significant differences between each CS-8958 group
	and the placebo group. The differences (95% confidence interval)
	of the median time to resolution of fever between each CS-8958
	group and placebo group were -1.3 h (-13.5 to 7.5) in CS-8958 10
	mg group and -2.5 h (-12.2 to 9.8) in CS-8958 20 mg group.
	Secondary analysis:
	The median of the secondary endpoint "time to alleviation of
	influenza illness" was 62.0 h in CS-8958 10 mg group, 49.9 h in
	CS-8958 20 mg group, and 84.0 h in placebo group, and there were
	no statistically significant differences between each CS-8958 group

	and the placebo group. The differences (95% confidence interval)
	of the median time to alleviation of influenza illness between the
	CS-8958 groups and placebo group were -22.0 h (-44.7 to 5.6) in
	CS-8958 10 mg group, and -34.1 h (-43.8 to 4.4) in CS-8958 20
	mg group. Although there was no statistically significant difference,
	all of the doses tested shortened the time to alleviation of influenza
	illness when compared with placebo.
	Safety:
	AEs occurred in 25.9% (15/58) of patients in CS-8958 10 mg
	group, 21.7% (13/60) in CS-8958 20 mg group, and 22.6% (14/62)
	in placebo group. No significant safety concerns were raised
	in all CS-8958 groups.
Date of Report	August 30, 2011