SYNOPSIS

Name of Sponsor/Company Datichi Sankyo Co., Ltd. Name of Finished Product INAVIR® DRY POWDER INHALER 20mg Name of Active Ingredient Laninamivir Octanoate Hydrate (JAN) Title of St. udy A Phase 3 Study of CS-8958 A randomized study of CS-8958 comparing two inhalers in patients with influenza virus infection − Investigators Study Centre(s) Publication (reference) Not published. Studied Period Phase 3 Objectives The objective of this study is to assess and compare the efficacy, safety and pharmacokinetics of a single inhalation of CS-8958 40 mg between an inhaler for commercial use (TwinCaps) and an inhaler for investigational use in patients with type A or B influenza virus infection. Methodology A multicenter, randomized, open-label comparative study Number of Patients (planned and analyzed) Planned number of patients : 140 subjects (70 in the TwinCaps group and 70 in the investigational use group) The target number of subjects required for pharmacokinetic evaluation was 10 for each group. Full analysis set (FAS): 182 subjects (90 in the TwinCaps group and 92 in the investigational use group) Diagnosis and Main Criteria for Inclusion Influenza virus-positive by an influenza rapid diagnostic kit, and diagnosed with influenza virus infection by the investigators 2) Body temperature (axillary) ≥ 37.5°C at the time of informed consent (fever [feeling	Name of C	Delial: Control Control
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Test Product, Dose and Mode CS-8958-20TC		4) Aged ≥ 20 years as of informed consent drug using the inhaler
	Test Product, Dose and Mode	CS-8958-20TC

of Administration	CS-8958
	Subjects received a single inhalation of CS-8958 40 mg using
	either TwinCaps or the investigational use inhalers.
Duration of Treatment	Single dose
Reference Therapy, Dose and	None
Mode of Administration	
Criteria for Evaluation	Primary Endpoint: Time to Alleviation of Influenza Illness
Statistical Method	Efficacy Analysis;
	Primary analysis: The TwinCaps and the investigational use groups
	were compared using the generalized Wilcoxon test. The median
	difference (the TwinCaps group - the investigational use group)
	and the 95% CI was calculated based on the generalized Wilcoxon
	test statistics.
	Safety Analysis;
	Adverse Events:
	The number of subjects and the incidence by treatment group were
	calculated for all adverse events and adverse events considered
	related to the study drug. They were also summarized by event and
	severity. The number of subjects with serious adverse events and
	adverse events considered related to the study drug and their
	incidences were calculated by treatment group.
Summary - Conclusion	Efficacy (primary endpoint):
	A Kaplan-Meier plot of the time to alleviation of influenza illness,
	the primary endpoint, showed that recovery from influenza illness
	was similar in the TwinCaps and the investigational use groups.
	The median time to alleviation of influenza illness was 72.0 hours
	in the TwinCaps group and 78.0 hours in the investigational use
	group. The median difference (95% CI) was -6.0 (-23.9 to 6.7)
	hours and the time to alleviation of influenza illness was
	comparable between the two groups.
	Safety:
	The incidence of adverse events was 20.9% (19/91) in the
	TwinCaps group and 12.1% (11/91) in the investigational use
	group.
Date of Report	August 30, 2011