SYNOPSIS

Name of Sponsor/Company	Daiichi Sankyo Co., Ltd.
Name of Finished Product	Influenza HA Vaccine “Kitasatodaiichisankyo”
Name of Active Ingredient	VN-0104 (Seasonal influenza quadrivalent vaccine)
Title of Study	Clinical trial of VN-0104 in Japanese healthy adult volunteers
Investigators	-
Study Centre(s)	1 site
Publication (reference)	-
Studied Period	Study initiation date: August, 2014 Study completion date: October, 2014
Phase of Development	Phase 2
Objectives	To evaluate the safety and the immunogenicity of VN-0104 in Japanese healthy adult volunteers
Methodology	Single-center, uncontrolled, open-label study
Number of Patients (planned and analyzed)	Planned: 50 subjects Analyzed (Safety): 50 subjects Analyzed (Immunogenicity): 50 subjects
Diagnosis and Main Criteria for Inclusion	Main Inclusion: ・ Healthy Japanese adults aged 20 to 64 years Main Exclusion: ・ Subjects with a history of seasonal influenza within the past 6 months ・ Subjects with a history of seasonal influenza vaccinations in the past 6 months
Test Product, Dose and Mode of Administration, Batch Number	Test product: VN-0104 Dosage and administration: Two doses of subcutaneous administration of VN-0104 (0.5 mL) containing 15 μg of HA per strain, 7-28 days apart
Duration of Treatment	6 weeks
Reference Therapy, Dose and Mode of Administration, Batch Number	None
Criteria for Evaluation	・ Safety endpoints: Adverse events and body temperature ・ Immunology endpoints: HI antibody titer, SRH antibody titer, and neutralizing antibody titer
Statistical Method	Safety endpoints:

	The number and the incidence of subjects with adverse events which occurred within 6 weeks after the 1st vaccination Immunogenicity endpoints: Seroconversion rates, geometric mean titer (GMT), geometric mean titer ratio (GMTR), and seroprotection rates of HI, SRH, and neutralizing antibody titer were calculated respectively.
Summary - Conclusion	Safety summary: The incidence of adverse reactions was 80.0% (40/50). The incidence of local adverse reactions was 80.0% (40/50), and that of systematic adverse reactions was 10.0% (5/50). The adverse reactions whose incidences were higher than 5.0% are as follows: injection site erythema was 64.0% (32/50), injection site pain was 50.0% (25/50), injection site warmth was 40.0% (20/50), injection site swelling was 30.0% (15/50), injection site pruritus was 30.0% (15/50), injection site induration was 14.0% (7/50), headache was 6.0% (3/50), and malaise was 6.0% (3/50). There were no serious adverse events reported. Immunogenicity summary: VN-0104 increased HI, SRH, and neutralizing antibody titer for all four strains (A/H1N1, A/H3N2, B/Yamagata, and B/Victoria). Conclusion: The results of this study showed the acceptable safety profile and the immune response for all four strains.
Date of Report	February 18, 2015