SYNOPSIS

Name of Sponsor/Company	Daiichi Sankyo Co., Ltd.
Name of Finished Product	Squarekids Subcutaneous Injection Syringe
Name of Active Ingredient	Purified diphtheria toxoid, Purified tetanus toxoid, Purified *Bordetella pertussis* antigens, and inactivated polioviruses type 1, 2 and 3.
Title of Study	Phase II Clinical Study of DD-687 (An open, single arm, safety and immunogenicity study in healthy Japanese infants)
Investigators	
Study Centre(s)	8 sites
Publication (reference)	None
Studied Period	
Phase of Development	Phase 2
Objectives	To assess the safety and the immunogenicity of DD-687 after primary and booster vaccination in healthy Japanese infants
Methodology	Open, single-arm, non-comparative, multi-center study
Number of Patients (planned and analyzed)	Planned: 110 subjects Analyzed: 115 subjects for safety analyses 114 subjects for immunogenicity analyses (primary series) 110 subjects for immunogenicity analyses (booster)
Diagnosis and Main Criteria for Inclusion	Healthy Japanese infants who fulfill all of the following criteria: 1) Aged 3 months to 8 months inclusive on the day of inclusion 2) Informed consent form signed by the parent(s) or other legal representative 3) Able to attend all scheduled visits and to comply with all trial procedures
Test Product, Dose and Mode of Administration, Batch Number	Test product (Batch number) DD-687 (DD687I0H09T01A) Dosage and administration 0.5 mL of DD-687 as a three-dose primary vaccination every 30 days, starting at 3-8 months of age followed by DD-687 booster dose 12 months after the three-dose primary vaccination
Duration of Treatment	Approximately 16 months
Reference Therapy, Dose and Mode of Administration,	Not applicable

Batch Number	
Criteria for Evaluation	Seroprotection rate, seroconversion rate and GMT for anti-D, anti-T, anti-PT, anti-FHA, anti-polio 1, 2 and 3 antibodies after three-dose primary vaccination and booster vaccination
Statistical Method	Seroprotection rates with their 95% confidence intervals (CIs) were calculated at pre-injection1, post-injection3, pre-injection4 and post-injection4. Seroconversion rates with their 95% CIs were calculated at post-injection3 and post-injection4. GMTs with their 95% CIs were calculated, at pre-injection1, post-injection3, pre-injection4 and post-injection4. Reverse cumulative distribution curves were also presented.
Summary - Conclusion	DD-687 was highly immunogenic for all antigens when given as a three-dose primary vaccination and booster vaccination approximately 1 year after primary series for Japanese infants. DD-687 was well tolerated without any clinically significant adverse reactions.
Date of Report	24/June/2015