2 SYNOPSIS

SPONSOR:	**Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc.**	
COMPOUND NAME:	**V260** (ROTATEQ®)**:** Rotavirus Vaccine, Live, Oral, Pentavalent **Dosage and formulation**: Three (3) doses of the clinical material were administered to each subject orally. The volume of each vaccination was 2.0 mL of vaccine or placebo. **Clinical Material:** ROTATEQ® (Lot No. WL00052360, and WL00057321) consisted of a 2 mL, oral solution of 5 live human-bovine reassortant rotavirus strains (G1, G2, G3, G4, and P1A[8]), which contained a minimum of 2.0 to 2.8 × 10^6 infectious units (IU) per reassortant dose, depending on the serotype, and not greater than 116 × 10^6 IU per dose in the aggregate. The reassortants were suspended in a buffered stablilizer solution which contained sucrose, sodium citrate, sodium phosphate monobasic monohydrate, sodium hydroxide, polysorbate 80, culture media (containing inorganic salts, amino acids and vitamins), and also purified water. Placebo (Lot No. WL00052361) was 2 mL per dose which contained sucrose, sodium citrate, sodium dihydrogen phosphate monohydrate, sodium hydroxide, polysorbate-80, culture media (containing inorganic salts, amino acids and vitamins), and purified water.	
INDICATION:	Prevention of rotavirus gastroenteritis (RVGE) in infants and children caused by the serotypes G1, G2, G3, G4, and G serotypes that contain P1A[8] (e.g., G9)	
PROTOCOL TITLE:	A Randomized, Double-Blind, Placebo-Controlled Study to Evaluate Efficacy, Safety, and Immunogenicity of V260 in Healthy Chinese Infants	
TRIAL IDENTIFIERS:	Protocol Number:	V260-024
	Clinical Phase:	III
	National Clinical Trial Registry Number:	NCT02062385
TRIAL CENTERS:	This trial was conducted at 7 trial centers: Five (5) of them allocated subjects to study treatment, and 2 centers were for trial administration. All these centers are under the jurisdiction of Guangxi Autonomous Center for Disease Control and Prevention, China.	

DESIGN:	This is a randomized, double-blind, placebo-controlled, multicentered study conducted in conformance with Good Clinical Practices. The purpose was to investigate clinical efficacy, immunogenicity, and safety/tolerability of a 3-dose regimen of V260 (ROTATEQ®) in healthy Chinese infants. Approximately 4040 eligible infants, at least 6 weeks (42 days) and up to 12 weeks (84 days) of age at time of the first vaccination of ROTATEQ®/placebo, were randomly assigned in a 1:1 ratio to receive either ROTATEQ® or placebo. In this study, administration of oral poliovirus vaccine (OPV) and diphtheria, tetanus, acellular pertussis vaccine (DTaP) were allowed according to China Expanded Program on Immunization (EPI). OPV and DTaP were administered either in a concomitant-use or in a staggered-use dosing schedule with ROTATEQ®/placebo. All subjects were followed for efficacy and safety. Antibody responses to OPV, DTaP, and ROTATEQ® were evaluated in a subset of subjects.	
	Planned Duration of Main Phase:	15 months

Objectives	**Primary Objective**: To evaluate the efficacy of 3 doses of V260 against rotavirus gastroenteritis caused by naturally-occurring rotavirus (regardless of serotype or disease severity), occurring at least 14 days following the third dose. **Secondary Objective(s)** : **(1)** To assess the safety of V260 with respect to all adverse experiences (AEs) within 30 days after each dose of V260/placebo. [Note: Safety assessment in the context of V260 concomitant-use with OPV and DTaP are also to be summarized for the Concomitant Use Cohort (both the Immunogenicity and Non-Immunogenicity Subgroups]. **(2)** To evaluate the efficacy of 3 doses of V260 against severe rotavirus gastroenteritis caused by naturally occurring rotavirus (regardless of serotype) occurring at least 14 days following the third dose. **(3)** To evaluate the efficacy of V260 against any rotavirus gastroenteritis that occurs at least 14 days after the first dose in all subjects receiving at least one dose of V260. **(4)** To evaluate the efficacy of 3 doses of V260 against i) severe and ii) any severity rotavirus gastroenteritis caused by rotavirus serotypes G1, G2, G3, G4, and G-serotypes that contain P1A[8] (e.g., G9) that occurs at least 14 days following the third dose. **(5)** To evaluate the impact of V260 on occurrence of any and severe all cause gastroenteritis. **(6)** To characterize the antibody responses against OPV antigens. **(7)** To characterize the antibody responses against DTaP antigens. **(8)** To characterize the immune response to V260 as measured by anti-rotavirus IgA **(9)** To characterize the immune response to V260 as measured by serum neutralizing antibody (SNA).

Hypotheses	**Primary Hypothesis**: Oral ROTATEQ® would be efficacious (based on the lower bound of the confidence interval [CI] for efficacy being > 0%) against rotavirus gastroenteritis caused by naturally occurring rotavirus (of any serotype or disease severity) that occurs at least 14 days following the third dose. **Secondary Hypothesis**: Proportion of subjects who achieve the OPV seroprotection criteria: neutralizing antibody titers ([NA] ≥1:8) for poliovirus types 1, 2, and 3, measured at Postdose 3 of OPV, in subjects receiving OPV concomitantly with V260 is non -inferior to that in subjects receiving OPV concomitantly with placebo. [*Noninferiority criterion corresponds to the lower bound of the two-sided 95% confidence interval on the difference in proportions, excluding a decrease of ≥10 percentage points*].	
Treatments Groups	**Staggered Use Cohort**	ROTATEQ®/placebo was given in a staggered fashion with OPV + DTaP (includes non-immunogenicity subgroup and immunogenicity subgroup). A total of 3240 subjects received 3 doses of ROTATEQ®/placebo in a 1:1 ratio, administered approximately 4 weeks apart.
	Concomitant Use Cohort	ROTATEQ®/placebo given concomitantly with OPV + DTaP (includes non-immunogenicity subgroup and immunogenicity subgroup). A total of 800 subjects received 3 doses of ROTATEQ®/placebo in a 1:1 ratio, administered approximately 4 weeks apart.

Endpoints and Definitions	**Primary efficacy endpoint**	Incidence	Efficacy against any severity of RVGE regardless of serotype that occurs ≥ 14 days Postdose 3
	Secondary immunogenicity endpoint	Seroconversion rates	Postdose 3 antibody seroconversion rates for poliovirus types 1, 2, and 3 in Concomitant Use Immunogenicity Subgroup
		Geometric Mean Titers (GMT) and seroconversion rates	In Concomitant Use Immunogenicity Subgroup, Summary of Postdose 3 antibody responses by GMTs and seroconversion rates of OPV and DTaP.
		GMT and percent ≥ 3-fold rise from baseline	In Concomitant Use Immunogenicity Subgroup, Summary of Postdose 3 IgA Response: GMT and percent ≥ 3-fold rise from baseline
		GMT and percent ≥ 3-fold rise from baseline	In Staggered Use Immunogenicity Subgroup, Summary of Postdose 3 IgA, SNA for G1, G2,G3, G4, P1A[8] Response: GMT and percent ≥ 3-fold rise from Baseline
	Safety endpoint	Incidence	Safety endpoints include incidence of adverse events [AEs] collected for 30 days following each dose (Days 1 to 14 via Vaccine Report Card [VRC]). In addition, any serious AEs (SAEs), any deaths, and reports of intussusception, were to be reported from the time of written consent until the end of the entire study (defined as last subject's last study visit).
Database Lock	13-OCT-2015	Trial status	30-MAY-2014 (first subject first visit) to 11-JUN-2015 (last subject last visit)

Disposition of Subjects
(All Randomized Subjects)

	ROTATEQ®		Placebo		Total	
	n	(%)	n	(%)	n	(%)
Not Randomized					133	
Subjects in population	2,020		2,020		4,040	
Vaccinated at						
Vaccination 1	2,018	(99.9)	2,019	(100.0)	4,037	(99.9)
Vaccination 2	1,946	(96.3)	1,959	(97.0)	3,905	(96.7)
Vaccination 3	1,932	(95.6)	1,946	(96.3)	3,878	(96.0)
Trial Disposition						
Completed	1,930	(95.5)	1,946	(96.3)	3,876	(95.9)
Discontinued	90	(4.5)	74	(3.7)	164	(4.1)
Adverse Event	20	(1.0)	13	(0.6)	33	(0.8)
Death	0	(0.0)	1	(0.0)	1	(0.0)
Lost To Follow-Up	1	(0.0)	0	(0.0)	1	(0.0)
Protocol Violation	1	(0.0)	0	(0.0)	1	(0.0)
Study Terminated By Sponsor†	2	(0.1)	0	(0.0)	2	(0.0)
Subject Moved	11	(0.5)	11	(0.5)	22	(0.5)
Withdrawal By Parent/Guardian	55	(2.7)	49	(2.4)	104	(2.6)

Each subject is counted once for Trial Disposition based on the latest corresponding disposition record.
† Subjects did not complete vaccination with OPV/DTaP prior to database lock

ANALYSIS DESCRIPTION	**Efficacy:** Primary Analysis Statistical methodology: For the primary hypothesis, ROTATEQ® was considered efficacious if the lower bound of the 2-sided CI for efficacy was > 0% at the final analysis. To calculate the CI and associated p-value, an exact conditional method based on a Poisson distribution was used, which evaluates the number of subjects with RVGE in the group that received ROTATEQ® conditional on the total number of subjects with RVGE, accounting for any potential differential follow-up between the 2 vaccination groups. The Clopper-Pearson method was used for the CI. Key Secondary Analysis The statistical methodology was the same as the primary analysis. **Immunogenicity:** For the OPV components, the statistical criterion was that the difference in the percentage with seroconversion between subjects receiving ROTATEQ® concomitantly with OPV/ DTaP versus subjects receiving placebo concomitantly with OPV/ DTaP (ROTATEQ® minus placebo) excluded a decrease of 10 percentage points or more. One-sided tests of H0: P_{V260}-$P_{Placebo} \leq -0.10$ versus H1: P_{V260}-$P_{Placebo} > -0.10$ was performed at the 0.025 Confidential significance level for each of the poliovirus components. The statistical criterion for non-inferiority corresponded to the 2-sided 95% CI for the difference in the seroprotection rates (ROTATEQ® minus placebo) excluding a decrease of 10%. The 95% CI was calculated using the method proposed by Miettinen and Nurminen. **Safety:** The analysis of safety results followed a tiered approach. The tiers differed with respect to the analyses that were performed. Safety parameters or adverse experiences of special interest that were identified a priori constitute "Tier 1" safety endpoints that were subjected to inferential testing for statistical significance with p-values and 95% CIs provided for between-group comparisons. Other safety parameters were considered Tier 2 or Tier 3.Tier 2 parameters were assessed via point estimates with 95% CIs provided for between group comparisons; only point estimates by vaccination group were provided for Tier 3 safety parameters.

Analysis Population and Time Point Description	**Efficacy:** The Per-Protocol for efficacy (PPE) population served as the primary population for the analysis of efficacy in this study. The PPE population was defined as subjects who received the 3 scheduled doses of study vaccine, adhered to guidelines for the administration of the study vaccine, and did not have important deviations from the protocol that may substantially affect the results of the primary efficacy endpoint. **Immunogenicity:** The Per-Protocol for Immunogenicity (PPI) population served as the primary population for the analysis of immunogenicity in this study. The PPI population was antigen specific. Evaluable subjects were those who received their scheduled doses without intervening laboratory-confirmed disease specific to the antigen earlier than the blood sample collection Postdose 3, adhered to the guidelines for administration of vaccine, and had valid values available for analysis within specified day ranges. **Safety:** The All-Subjects-as-Treated (ASaT) population was used for the analysis of safety data in this study. The ASaT population consisted of all randomized subjects who received at least 1 dose of ROTATEQ® or placebo.
RESULTS AND ANALYSIS:	**Efficacy**: The primary analysis of PPE for 3 doses of ROTATEQ® against RVGE caused by any serotype regardless of severity, is presented in the table below. The point estimate and 95% CI for the primary efficacy against RVGE was 69.3% with a 95% CI (54.5, 79.7). ROTATEQ® met the statistical criterion for efficacy, because the lower bound of the 95% CI was > 0%. The key secondary efficacy analysis was that 3 doses of ROTATEQ® would be efficacious against severe RVGE caused by any serotype. The point estimate and 95% CI for efficacy against severe RVGE was 78.9% (59.1%, 90.1%). Thus, ROTATEQ® met the statistical criterion for efficacy, because the lower bound on the 95% CI was > 0%.

Primary Efficacy Analysis of Naturally Occurring Rotavirus Gastroenteritis Cases at Least 14 Days Postdose 3 Through the Entire Efficacy Follow-up Period in the Per-Protocol Population Using Per-Protocol Case Definition

	ROTATEQ®	Placebo
Subjects vaccinated	2018	2019
Protocol violators[†]	87	73
Subjects with no follow-up	0	0
Subjects classified as unevaluable per per-protocol case definition[‡]	4	9
Subjects contributing to efficacy analysis	1927	1937
Days of efficacy follow-up	428477	422252
Subjects classified as rotavirus gastroenteritis cases per protocol case definition	34	109
Efficacy estimate(%) and 95% CI	69.3 (54.5 ,79.7)	
P-value for efficacy > 0%	<.0001	
Conclusion[§]	Efficacious	

[†] Subjects identified in Protocol Violator Memo, including subjects with less than 3 doses; subjects with medical history of temporary immunoglobuline decreased; subjects who did not give the appropriate Informed Consent.

[‡] Subjects where classified as unevaluable due to rotavirus gastroenteritis occurred prior to 14 days Postdose 3, incomplete clinical and/or laboratory results, or stool samples collected out of day range.

[§] A conclusion of "efficacious" indicates that the criterion for efficacy was met (i.e., the lower bound of the 95%CI was > 0%)

NOTE: Rotavirus gastroenteritis cases consist of all subjects with at least 1 episode classified as positive for specific serotype. Multiple positive episodes for 1 subject are counted as a single case, and the first positive episode is used as the date of the case.

CI = Confidence Interval

Efficacy Analysis of Naturally Occurring Severe Rotavirus Gastroenteritis Cases (Severity Score ≥11 on the Vesikari Scoring System)
at Least 14 Days Postdose 3 Through the Entire Efficacy Follow-up Period
in the Per-Protocol Population Using Per-Protocol Case Definition

	ROTATEQ®	Placebo
Subjects vaccinated	2018	2019
Protocol violators[†]	87	73
Subjects with no follow-up	0	0
Subjects classified as unevaluable per per-protocol case definition[‡]	5	9
Subjects contributing to efficacy analysis	1926	1937
Days of efficacy follow-up	431061	429345
Subjects classified as rotavirus gastroenteritis cases per protocol case definition with severity score ≥11	11	52
Efficacy estimate(%) and 95% CI	78.9 (59.1 ,90.1)	
P-value for efficacy > 0%	<.0001	
Conclusion[§]	Efficacious	

[†] Subjects identified in Protocol Violator Memo, including subjects with less than 3 doses; subjects with medical history of temporary immunoglobuline decreased; subjects who did not give the appropriate Informed Consent.

[‡] Subjects where classified as unevaluable due to rotavirus gastroenteritis occurred prior to 14 days Postdose 3, incomplete clinical and/or laboratory results, or stool samples collected out of day range, or due to missing severity scoring items

[§] A conclusion of "efficacious" indicates that the criterion for efficacy was met (i.e., the lower bound of the 95%CI was > 0%)

NOTE: Rotavirus gastroenteritis cases consist of all subjects with at least 1 episode classified as positive and having a severity score ≥11 on the Vesikari grading scale. Multiple positive episodes for 1 subject are counted as a single case, and the first positive episode is used as the date of the case.

CI = Confidence Interval

RESULTS AND ANALYSIS:	**Immunogenicity** • A secondary immunogenicity hypothesis was that the proportion of subjects who achieved the OPV seroprotection criteria: neutralizing antibody (NA) titers ≥1:8 for poliovirus types 1, 2, and 3, measured at Postdose 3 of OPV, in subjects receiving OPV concomitantly with ROTATEQ® would be non-inferior to that in subjects receiving OPV concomitantly with placebo, in that 95% CIs for the difference in the seroprotection rates would exclude a decrease of 10 percentage points or more. The results showed that the estimated difference of anti-poliovirus 1, 2 and 3 between the 2 vaccination groups are -1.07% (-3.82%, 0.91%), 0.00% (-2.02%, 1.97%) and -0.03% (-2.89%, 2.77%). Therefore, the immune responses to poliovirus 1, 2 and 3 in the subjects who received OPV concomitantly with ROTATEQ® were non-inferior to those subjects who received OPV concomitantly with placebo. • To characterize the antibody responses against DTaP antigens, a descriptive analysis on the antibody responses to DTaP was performed. GMTs and seroconversion rates to DTaP antigens were comparable between the group that received ROTATEQ® and the placebo group. • Immune response following 3 doses of ROTATEQ® was determined using total IgA. The proportion of infants with ≥ 3-fold rise in anti-rotavirus total IgA from baseline to Postdose 3 in the group that received ROTATEQ® (89.40%) was higher than that in the placebo group (10.11%). • For SNA responses to human rotavirus serotypes G1, G2, G3, G4, and P1A[8] in the Staggered Use Group, the results indicated that all serotypes had higher GMTs Postdose 3 and the proportion of subjects with a ≥ 3-fold rise to each serotype was higher in the group that received ROTATEQ® than in the placebo group.

Statistical Analysis of Non-inferiority of Poliovirus Type 1, 2 and 3 Seroprotection Rates Postdose 3
(Per-Protocol Immunogenicity for OPV Population, Concomitant Use Group)

Antigen	ROTATEQ® (N=187)		Placebo (N=192)		Estimated Difference[†] [§] (Percentage Points) (95% CI)[‡]	P-value [‡]	Non-inferiority Conclusion
	n	Observed Response	n	Observed Response			
Poliovirus Type 1	187	98.93%	192	100.00%	-1.07% (-3.82%, 0.91%)	<.0001	Non-inferior[‡]
Poliovirus Type 2	187	100.00%	192	100.00%	0.00% (-2.02%, 1.97%)	<.0001	Non-inferior[‡]
Poliovirus Type 3	187	98.93%	192	98.96%	-0.03% (-2.89%, 2.77%)	<.0001	Non-inferior[‡]

PPI: Evaluable subjects are those who receive their scheduled doses without intervening laboratory-confirmed disease specific to the antigen earlier than the blood sample collection Postdose 3, adhere to the guidelines for administration of vaccine, and have valid values available for analysis within specified day ranges.

[†] Based on Miettinen & Nurminen method.

[‡] A 95% CI on the difference excluding a decrease of 10 percentage points or more and associated one sided p-value < 0.025 implies that the difference is statistically significantly less than the pre-specified clinically relevant decrease of 10 percentage points and allows for a conclusion of non-inferiority.

[§] [ROTATEQ® + OPV] - [Placebo + OPV].

N = Number of subjects in Per-Protocol Immunogenicity for OPV population.

n = Number of subjects contributing to the per-protocol analyses.

CI = Confidence interval.

Seroprotection Rate = Proportion of subjects who achieve the seroprotection criteria: neutralizing antibody titers [NA] ≥ 1:8.

Immunogenicity Summary for Serum Anti-Rotavirus Total IgA
(Per-Protocol Immunogenicity for ROTATEQ® Population)

Antigen (Assay)	Parameter	ROTATEQ® (N=361)			Placebo (N=372)		
		n	Observed Response	95% CI	n	Observed Response	95% CI
Serum Anti-rotavirus Total IgA	Predose 1 GMT	349	0.15	(0.13, 0.18)	356	0.17	(0.14, 0.21)
	Postdose 3 GMT	361	82.42	(66.19, 102.63)	372	0.33	(0.26, 0.42)
	Proportion of subjects with a ≥ 3-fold rise	349	89.40%	(85.68%, 92.42%)	356	10.11%	(7.18%, 13.72%)

PPI: Evaluable subjects are those who receive their scheduled doses without intervening laboratory-confirmed disease specific to the antigen earlier than the blood sample collection Postdose 3, adhere to the guidelines for administration of vaccine, and have valid values available for analysis within specified day ranges.

N = Number of subjects in Per-Protocol Immunogenicity for ROTATEQ® population.

n = Number of subjects contributing to the per-protocol analyses (for ≥ 3 fold rise, limited to per-protocol subjects with both Predose 1 and Postdose 3 serology).

GMT = Geometric mean titer.

CI = Confidence interval. The two-sided 95% CI for the GMTs is based on the natural log-transformed titers and t-distribution.The two-sided 95% CI for binomial responses is provided using the exact method by Clopper-Pearson.

Immunogenicity Summary of Response to Serum Neutralizing Antibody Serotypes G1, G2, G3, G4 and P1A[8]
(Per-Protocol Immunogenicity for ROTATEQ® Population, Staggered Use Group)

Antigen (Assay)	Parameter	ROTATEQ® (N=175)			Placebo (N=180)		
		n	Observed Response	95% CI	n	Observed Response	95% CI
Serotypes G1	Predose 1 GMT	175	43.41	(38.69, 48.71)	180	49.65	(44.33, 55.60)
	Postdose 3 GMT	175	141.88	(120.49, 167.07)	180	17.94	(15.93, 20.20)
	Proportion of subjects with a ≥ 3-fold rise	175	51.43%	(43.77%, 59.04%)	180	0.00%	(0.00%, 2.03%)
Serotypes G2	Predose 1 GMT	175	24.03	(20.76, 27.81)	180	30.35	(25.62, 35.95)
	Postdose 3 GMT	175	25.16	(20.96, 30.21)	180	10.67	(9.37, 12.17)
	Proportion of subjects with a ≥ 3-fold rise	175	19.43%	(13.85%, 26.08%)	180	0.56%	(0.01%, 3.06%)
Serotypes G3	Predose 1 GMT	175	23.93	(20.11, 28.47)	180	23.73	(19.87, 28.34)
	Postdose 3 GMT	175	21.97	(18.64, 25.89)	180	8.33	(7.39, 9.38)
	Proportion of subjects with a ≥ 3-fold rise	175	13.71%	(8.99%, 19.72%)	180	0.00%	(0.00%, 2.03%)
Serotypes G4	Predose 1 GMT	175	33.82	(29.99, 38.14)	180	43.34	(37.23, 50.44)
	Postdose 3 GMT	175	76.94	(67.25, 88.01)	180	14.84	(13.18, 16.72)
	Proportion of subjects with a ≥ 3-fold rise	175	37.14%	(29.97%, 44.76%)	180	0.00%	(0.00%, 2.03%)
Serotypes P1A[8]	Predose 1 GMT	175	39.18	(33.88, 45.31)	180	43.73	(37.69, 50.72)
	Postdose 3 GMT	175	125.01	(103.00, 151.72)	180	11.98	(10.44, 13.74)
	Proportion of subjects with a ≥ 3-fold rise	175	46.86%	(39.29%, 54.53%)	180	0.56%	(0.01%, 3.06%)

PPI: Evaluable subjects are those who receive their scheduled doses without intervening laboratory-confirmed disease specific to the antigen earlier than the blood sample collection Postdose 3, adhere to the guidelines for administration of vaccine, and have valid values available for analysis within specified day ranges.

N = Number of subjects in Per-Protocol Immunogenicity for ROTATEQ® population.

n = Number of subjects contributing to the per-protocol analyses (for ≥ 3 fold rise, limited to per-protocol subjects with both Predose 1 and Postdose 3 serology).

GMT = Geometric mean titer.

CI = Confidence interval. The two-sided 95% CI for the GMTs is based on the natural log-transformed titers and t-distribution.The two-sided 95% CI for binomial responses is provided using the exact method by Clopper-Pearson.

RESULTS AND ANALYSIS:	**Safety** The statistical analysis of the secondary safety objective regarding AEs occurring within 30 days following any vaccination is presented in the following table, showing that the 2 vaccination groups were comparable with respect to the safety profile.

Adverse Event Summary
(within 30 Days Following any Vaccination Visit)
(All Subjects as Treated Population)

	ROTATEQ®		Placebo		Total	
	n	(%)	n	(%)	n	(%)
Subjects in population with follow-up	2,015		2,019		4,034	
with one or more adverse events	1,079	(53.5)	1,077	(53.3)	2,156	(53.4)
with no adverse event	936	(46.5)	942	(46.7)	1,878	(46.6)
with vaccine-related† adverse events	359	(17.8)	354	(17.5)	713	(17.7)
with serious adverse events	116	(5.8)	116	(5.7)	232	(5.8)
with serious vaccine-related adverse events	0	(0.0)	3	(0.1)	3	(0.1)
who died	0	(0.0)	0	(0.0)	0	(0.0)
discontinued‡ due to an adverse event	17	(0.8)	12	(0.6)	29	(0.7)
discontinued due to a vaccine-related adverse event	4	(0.2)	4	(0.2)	8	(0.2)
discontinued due to a serious adverse event	10	(0.5)	5	(0.2)	15	(0.4)
discontinued due to a serious vaccine-related adverse event	0	(0.0)	0	(0.0)	0	(0.0)

† Determined by the investigator to be related to the vaccine.
‡ Study medication withdrawn.
All events were collected within 30 days after any vaccination and before next vaccination.

CONCLUSIONS:	Among healthy Chinese infants, 6 to 12 weeks of age at enrollment, who received ROTATEQ® or placebo, the following conclusions can be drawn: 1. The vaccine is efficacious against naturally-occurring RVGE regardless of serotype and severity that occurs at least 14 days following the third vaccination. 2. The vaccine is efficacious against naturally-occurring severe RVGE regardless of serotype that occurs at least 14 days following the third vaccination. 3. The vaccine is immunogenic with respect to anti-rotavirus total IgA response and SNA responses to G1, G2, G3, G4, P1A[8]. 4. The vaccine is generally well-tolerated with respect to all clinical AEs. 5. Immune responses induced by OPV and DTaP are not affected by the concomitant use of ROTATEQ®.
REPORT DATE:	12-JAN-2016