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The human rotavirus vaccine Rotarix™ in infants: An integrated analysis of safety and reactogenicity

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ONLINE SUPPLEMENTARY MATERIAL

Table S1. Overview of the *Rotarix*™ double-blind, randomized, placebo-controlled studies included in this integrated clinical safety summary

Study ID (Phase)	**Country**	**Age at vaccination (No. of doses)**	**Concomitant vaccination**	**HRV viral concentration**	**No. of subjects Vaccine (Placebo)**	**Ref**
444563/003 (Phase II)	Finland	2, 4 months (2 doses)	None	$10^{4.7}$ ffu $10^{4.1}$ ffu $10^{4.7}$ ffu $10^{5.8}$ ffu	128 (64)	1
444563/004 (Phase II)	Finland	2, 4 months (2 doses)	None	$10^{4.7}$ ffu	270 (135)	2
444563/005 (Phase II)	USA, Canada	2, 4 months (2 doses)	DTPa, IPV, *S. pneumoniae,* Hib	$10^{5.2}$ ffu $10^{6.4}$ ffu	421 (108)	3
444563/006 (Phase II)	Brazil, Mexico, Venezuela	2, 4, months (2 or 3 doses)[a]	DTPw-HBV/Hib OPV deferred	$10^{4.7}$ ffu $10^{5.2}$ ffu $10^{5.8}$ ffu	1709 (567)	4
444563/007 (Phase II)	Singapore	3, 4 months (2 doses)	DTPa-IPV/Hib, HBV	$10^{4.7}$ ffu $10^{5.2}$ ffu $10^{6.1}$ ffu	1811 (653)	5
444563/013 (Phase II)	South Africa	6, 10, 14 weeks (3 doses) 10, 14 weeks (2 doses)	DTPw-HBV/Hib OPV	$10^{6.0}$ $CCID_{50}$	379 (96)	6
444563/014 (Phase II)	South Africa	6, 10 weeks 10, 14 weeks (2 doses)	DTPa/Hib + OPV or DTPa/IPV/Hib	$10^{5.2}$ ffu $10^{5.6}$ ffu	297 (150)	7
444563/021 (Phase II)	Panama	2, 4, 6 months (3 doses)	DTPw-HBV/Hib OPV delayed	$10^{5.2}$ ffu	177 (25)	8

444563/022 (Phase II)	South Africa	6, 10, 14 weeks (3 doses)	DTPw-HBV/Hib + OPV	$10^{6.4}$ $CCID_{50}$ $10^{6.5}$ $CCID_{50}$	50 (50)	9
444563/023 (Phase III)	Argentina, Brazil, Chile, Columbia, Dominican Republic, Honduras, Mexico, Nicaragua, Panama, Peru, Venezuela, Finland	2, 3 to 4 months (2 doses)	Routine vaccinations per national schedule OPV deferred if used	$10^{6.5}$ $CCID_{50}$	31673 (31552)	10
444563/024 (Phase III)	Brazil, Columbia, Panama, Argentina	2, 3 to 4 months (2 doses)	DTPw-HBV/Hib + OPV	$10^{6.0}$ $CCID_{50}$	4376 (2192)	11
444563/028/029/030 (Phase III)	Singapore (028) Hong Kong (029) Taiwan (030)	2 or 3, 4 months (2 doses)	DTPa-IPV/Hib + HBV OPV deferred if used	$10^{6.0}$ $CCID_{50}$	5359 (5349)	12
444563/033 (Phase III)	Mexico, Columbia, Peru	2, 4 months (2 doses)	DTPw-HBV/Hib OPV deferred	$10^{6.5}$ $CCID_{50}$	730 (124)	13
102247/Rota-036 (Phase III)	Czech Republic Finland France Germany Italy Spain	3, 4 months 3, 5 months 2, 3 months 2, 3 months 3, 5 months 2, 4 months (2 doses)	DTPa-HBV-IPV/Hib[b] Meningitec in Spain Prevenar in France & Germany	$10^{6.5}$ $CCID_{50}$	2646 (1348)	14
102248/Rota-037 (Phase III)	South Africa, Malawi	6, 10, 14 weeks (3 doses) 10, 14 weeks (2 doses)	DTPw-HBV/Hib + OPV	$10^{6.4}$ $CCID_{50}$ $10^{6.5}$ $CCID_{50}$	3298 (1641)	15
103477/Rota-039 (Phase III)	Thailand	2, 4 months (2 doses)	None	$10^{6.4}$ $CCID_{50}$	174 (52)	16
103478/Rota-041 (Phase II)	Korea	2, 4 months (2 doses)	None	$10^{6.5}$ $CCID_{50}$	103 (52)	17
103792/Rota-044	India	8, 12 weeks	OPV	$10^{6.0}$ $CCID_{50}$	182 (181)	18

(Phase II)		(2 doses)	Deferred DTPw-HBV/Hib			
103992/Rota-045 (Phase II)	Bangladesh	12, 16 weeks (2 doses)	None OPV	$10^{6.5}$ $CCID_{50}$ $10^{6.5}$ $CCID_{50}$	196 (98)	19
104480/Rota-048 (Phase II)	Finland	2, 3 months (2 doses)	None	At least $10^{6.0}$ $CCID_{50}$	200 (50)	20
106260/Rota-052 (Phase III)	Dominican Republic	2, 4 months (2 doses)	DTPa-HBV-IPV/Hib	At least $10^{6.0}$ $CCID_{50}$	100 (100)	21
106481/Rota-054 (Phase III)	France, Portugal, Spain, Poland	6, 10/14 weeks (2 doses)	Routine vaccinations per national schedule	At least $10^{6.0}$ $CCID_{50}$	670 (339)	22
107625/Rota-056 (Phase III)	Japan	6, 14 weeks (2 doses)	DTPa, HBV	At least $10^{6.0}$ $CCID_{50}$	508 (257)	23
105722/Rota-051 (Phase II)	Vietnam	8, 12/16 weeks (2 doses)	DTPw, HBV, OPV	At least $10^{6.0}$ $CCID_{50}$	297 (78)	24
109216/Rota-063 (Phase II)	Philippines	6, 10/14 weeks (2 doses)	DTPw, HBV, OPV	At least $10^{6.0}$ $CCID_{50}$	300 (75)	24
112269/Rota-068 (Phase IV)	Korea	2, 4 months (2 doses)	DTPa, Hib, HBV, IPV	At least $10^{6.0}$ $CCID_{50}$	508 (176)	25

[a]A subset of 121 subjects in Brazil received 3 doses of study vaccine/placebo
[b]Subjects in each country received 3 doses of DTPa-HBV-IPV/Hib with the first two doses co-administered with study vaccine or placebo, except in France where DTPa-IPV/Hib was co-administered with the second study vaccine/placebo dose

Table S2. Overview of cases of intussusception reported (total vaccinated cohort)

Group	Dose	Age at onset (weeks)	Sex	Day of onset	Duration (days)	Outcome
Human RV vaccine	1	12	Male	29	49	Recovered with sequelae
	1	14	Male	18	2	Recovered
	1	14	Male	6	5	Recovered
	2	11	Female	3	10	Recovered
	2	14	Female	22	4	Recovered
	2	18	Female	7	20	Fatal
	2	19	Male	8	7	Recovered
	2	20	Female	3	13	Recovered
	2	20	Female	17	7	Recovered
	2	21	Male	25	3	Recovered
	2	22	Male	16	4	Recovered
Placebo	1	9	Male	22	3	Recovered
	1	14	Female	16	17	Recovered
	2	16	Female	6	4	Recovered
	2	16	Female	9	6	Recovered
	2	19	Female	18	4	Recovered
	2	22	Female	28	12	Recovered
	2	24	Male	24	14	Recovered

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