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Study No.: 113482 (FLU Q-PAN H1N1-003 PRI)
Title: A study to evaluate the safety and immunogenicity of A/California/7/2009 (H1N1)v-like vaccines GSK2340274A and GSK2340273A in children 6 months to less than 9 years of age
GSK2340274A (Flu1): GlaxoSmithKline (GSK) Biologicals' adjuvanted A/California/7/2009 (H1N1)v-like vaccine. GSK2340273A (Flu2): GSK Biologicals' unadjuvanted A/California/7/2009 (H1N1)v-like vaccine.
Rationale: The aim of the study was to evaluate the safety and immunogenicity of 2 doses of different formulations of Flu1 and Flu2 vaccines when administered in children 6 months to less than 9 years of age. This summary presents results up to Day 42 and will be updated when additional data become available.
Phase: I/II
Study Period: From 20 October 2009 to 23 April 2010 (data lock point Day 42)
Study Design: Observer-blind, randomized study with four parallel groups.
Centers: 14 centers in Canada.
Indication: Immunization against A/California/7/2009 (H1N1)v-like influenza in children 6 months to <9 years of age.
Treatment: The study groups were as follows: <ul style="list-style-type: none"> – Flu1/F1 Group: subjects received 2 doses of Flu1-formulation 1 vaccine administered at a 21-day interval. – Flu1/F2 Group: Subjects received 2 doses of Flu1-formulation 2 vaccine administered at a 21-day interval. – Flu2/F1 Group: Subjects received 2 doses of Flu2-formulation 1 vaccine administered at a 21-day interval. – Flu2/F2 Group: Subjects received 2 doses of Flu2-formulation 2 vaccine administered at a 21-day interval. Enrollment was performed in a 2-step process. First, approximately 240 subjects were enrolled and randomized in an observer-blind manner to the 4 groups. Before proceeding to the second enrollment period, safety data through Day 6 (Day 7 analysis) was reviewed for approximately the first 120 subjects randomized. After completing both safety data review for the first 120 subjects and enrollment of all 240 subjects in this first period, the second enrollment period will begin. During the second period, approximately 120 subjects were to be enrolled in an open-label manner into Flu1/F2 Group. This summary presents results up to Day 42 from subjects enrolled during the first enrollment period. The first dose of each series of vaccines was administered intramuscularly in the deltoid region of the non-dominant arm (or left arm if dominance was not yet identified) or left anterolateral thigh (for children < 12 months of age). The second dose of vaccines was administered in the deltoid region of the dominant arm (or right arm) or right anterolateral thigh (children < 12 months of age).
Objectives: To assess whether vaccination with Flu1 or Flu2 vaccines results in an immune response to the vaccine-homologous virus that meets or exceeds the Committee for Medicinal Products for Human Use (CHMP) guidance targets for pandemic vaccine seroconversion rate (SCR), rate of induction of vaccine-homologous reciprocal hemagglutination inhibition (HI) titers ≥ 40 (potential seroprotection rate, or SPR), and geometric mean fold rise (GMFR) at 21 days after the second dose of Flu1 or Flu2 vaccine (Day 21 or 42) in children 6 months to <9 years of age. <i>The CHMP Criteria was fulfilled if:</i> <ul style="list-style-type: none"> – the point estimate for SCR was > 40%, and – the post-vaccination point estimate for SPR was > 70%, and – the point estimate for GMFR was > 2.5.
Primary Outcome/Efficacy Variable: <ul style="list-style-type: none"> • Evaluation of the humoral immune response in subjects receiving any H1N1 vaccine as demonstrated by the HI antibody titers before initial vaccination (Screening/Day 0) and 21 days after the first or second dose of H1N1 vaccine (Day 21 or 42). The following aggregate variables were derived based on the primary outcome result to evaluate the primary objective: <ul style="list-style-type: none"> – Seroconversion rate (SCR)* – Seroprotection rate (SPR)** – Geometric mean fold-rise (GMFR or seroconversion factor [SCF])*** * SCR is defined as the proportion of subjects who have either a prevaccination reciprocal HI titer < 10 and a post-vaccination reciprocal titer ≥ 40 , or a pre-vaccination reciprocal HI titer ≥ 10 and at least a 4-fold increase in post vaccination reciprocal titer against the vaccine virus. ** SPR is defined as the proportion of subjects with reciprocal HI titers ≥ 40 against the tested virus.

***GMFR also known as the Seroconversion Factor (or SCF) is defined as the geometric mean of the within-subject ratios of the postvaccination reciprocal HI titer to the pre-vaccination reciprocal HI titer for the vaccine virus.

Secondary Outcome/Efficacy Variable(s):

Immunogenicity

- Vaccine-virus homologous antibody response in subjects receiving any H1N1 vaccine as demonstrated by the HI antibody titers at Screening/Day 0 and Days 21, 42, and 182[#].
- Vaccine virus heterologous HI antibody response in a subcohort of subjects for all groups at Screening/Day 0 and Days 21, 42, and 182. [§]

The following aggregate variables were derived based on the outcome results:

- Seroconversion rate (SCR)
- Seroprotection rate (SPR)
- Geometric mean fold-rise (GMFR or seroconversion factor [SCF])
 - A/California/7/2009 (H1N1)v-like virus vaccine-homologous and heterologous virus antibody response measured by microneutralization[§] (MN) at Screening/Day 0 and Days 21, 42, and 182.

The aggregate variables included:

- Geometric mean titers (GMTs) of serum neutralizing antibodies at Screening/Day 0 and Days 21, 42, and 182.
- Seropositivity rates of serum neutralizing antibodies at Screening/Day 0 and Days 21, 42, and 182.
- Vaccine response rates (VRR*) on Days 21, 42, and 182.

* VRR is defined as the incidence rate of vaccinees with at least a 4-fold increase in post vaccination reciprocal titer relative to that prior to first vaccination.

Safety:

- The occurrence of specifically-solicited local and general signs and symptoms during a 7-day follow-up period (i.e., day of vaccination and 6 subsequent days) after each dose of vaccine.
- The occurrence of all unsolicited adverse events (AEs) during a 21-day follow-up period following each dose of vaccine and Days 0 to 84[#].
- Clinical laboratory (complete blood count [CBC], alanine aminotransferase [ALT], aspartate aminotransferase [AST], creatinine, serum urea nitrogen [SUN][%], bilirubin) abnormalities at Screening/Day 0 and Days 7, 21, 42, and 182[#].
- The occurrence of medically attended visit (MAEs), potential immune-mediated disease (pIMDs), and serious adverse events (SAEs) throughout the study[#].

[%] Blood urea nitrogen parameter (BUN) was reported instead of Serum urea nitrogen [SUN]

[#] This summary presents preliminary results up to Day 42 only. It will be updated when additional data become available.

[§] Not available at the time of writing this summary.

Statistical Methods:

The analyses were performed on the Total Vaccinated cohort and the According-To-Protocol (ATP) cohort for immunogenicity.

- The Total Vaccinated cohort included all subjects who received at least 1 study vaccination.
- The ATP cohort for immunogenicity included all evaluable subjects (i.e., those meeting all eligibility criteria, complying with the procedures defined in the protocol, with no elimination criteria during the study) for whom no immunoglobulins and/or any blood products were administered during the relevant study period (Days 0 - 42), for whom there was no chronic administration of immunosuppressants (e.g., prednisone \geq 0.5 mg/kg/day, or \geq 10 mg/day [whichever is less], for more than 14 consecutive days) or administration of other immune-modifying drugs during the relevant study period, who received the vaccine doses on both Day 0 and Day 21 per protocol treatment assignment and for whom assay results for antibodies against A/California-like HA antigen for the blood samples taken 21 days after the first and second vaccinations were available.

Analysis of immunogenicity

The analyses of immunogenicity were performed on the ATP cohort for immunogenicity.

The objective was evaluated by examining the immunogenicity response in all treatment groups 21 days after each dose. Point estimates for SCR, SPR, GMFR and the associated 95 % confidence interval (CI) were computed at Day 21 and Day 42.

Analysis of safety

The incidence of solicited local and general symptoms occurring during 7 days after each dose was tabulated with exact 95% CI for each treatment group and per age stratum. The same calculations were performed for symptoms of any intensity and those with intensity of Grade 3, as well as for solicited general symptoms assessed by the investigator as related to

vaccination. All solicited local symptoms were considered causally related to study vaccination. The percentage of subjects with at least one report of an unsolicited AE classified by the Medical Dictionary for Regulatory Activities (MedDRA) Preferred Term up to Day 42 was tabulated for each treatment group. Safety laboratory data were summarized by vaccine treatment group and tabulated over time. MAEs, SAEs, and pIMDs were collected and summarized up to Day 42.							
Study Population: Healthy male or female children 6 months to less than 9 years of age at the time of the first vaccination. Female subjects were to be of non-childbearing potential (pre-menarche). Written informed consent was obtained from the subject's parent/ legally acceptable representative prior to any study procedure and a written informed assent was obtained from the subject when appropriate.							
Number of subjects	Flu1/F1 Group	Flu1/F2 Group	Flu2/F1 Group	Flu2/F2 Group			
Planned, N	60	60	60	60			
Randomized, N (Total Vaccinated cohort)	67	64	64	63			
Completed to Day 42, n (%)	65 (97.0)	60 (93.8)	63 (98.4)	60 (95.2)			
Total Number Subjects Withdrawn, n (%)	2 (3.0)	4 (6.3)	1 (1.6)	3 (4.8)			
Withdrawn due to Adverse Events, n (%)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)			
Withdrawn due to Lack of Efficacy, n (%)	Not applicable	Not applicable	Not applicable	Not applicable			
Withdrawn for other reasons, n (%)	2 (3.0)	4 (6.3)	1 (1.6)	3 (4.8)			
Demographics	Flu1/F1 Group	Flu1/F2 Group	Flu2/F1 Group	Flu2/F2 Group			
N (Total Vaccinated cohort)	67	64	64	63			
Females:Males	27:40	34:30	33:31	30:33			
Mean Age, months (SD)	53.6 (31.57)	47.4 (28.24)	50.3 (28.97)	54.4 (30.45)			
White - caucasian / european heritage, n (%)	46 (68.7)	41 (64.1)	44 (68.8)	38 (60.3)			
Primary Efficacy Results: SCR for HI antibodies against A/California strain at Day 21 (ATP cohort for immunogenicity)							
			SCR				
			95% CI				
Antibody against	Group	N	n	%	LL	UL	
Flu A/CAL/7/09	Flu1/F1	57	54	94.7	85.4	98.9	
	Flu1/F2	47	45	95.7	85.5	99.5	
	Flu2/F1	55	41	74.5	61.0	85.3	
	Flu2/F2	57	34	59.6	45.8	72.4	
Seroconversion defined as: For initially seronegative subjects, antibody titer \geq 1:40 after vaccination For initially seropositive subjects, antibody titer after vaccination \geq 4 fold the pre-vaccination antibody titer N = Number of subjects with pre- and post-vaccination results available n/% = Number/percentage of seroconverted subjects 95% CI = 95% confidence interval, LL = Lower Limit, UL = Upper Limit							
Primary Efficacy Results: SCR for HI antibodies against A/California strain at Day 42 (ATP cohort for immunogenicity)							
			SCR				
			95% CI				
Antibody against	Group	N	n	%	LL	UL	
Flu A/CAL/7/09	Flu1/F1	43	43	100	91.8	100	
	Flu1/F2	40	39	97.5	86.8	99.9	
	Flu2/F1	46	46	100	92.3	100	
	Flu2/F2	44	38	86.4	72.6	94.8	
Seroconversion defined as: For initially seronegative subjects, antibody titer \geq 1:40 after vaccination For initially seropositive subjects, antibody titer after vaccination \geq 4 fold the pre-vaccination antibody titer N = Number of subjects with pre- and post-vaccination results available n/% = Number/percentage of seroconverted subjects 95% CI = 95% confidence interval, LL = Lower Limit, UL = Upper Limit							
Primary Efficacy Results: SPR for HI antibodies against A/California strain at Screening and Day 21 (ATP cohort for immunogenicity)							
			SPR				
			95% CI				
Antibody against	Group	Timing	N	n	%	LL	UL
Flu A/CAL/7/09	Flu1/F1	Screening	57	12	21.1	11.4	33.9

	PI(D21)	57	56	98.2	90.6	100
Flu1/F2	Screening	49	2	4.1	0.5	14.0
	PI(D21)	49	48	98.0	89.1	99.9
Flu2/F1	Screening	55	12	21.8	11.8	35.0
	PI(D21)	55	42	76.4	63.0	86.8
Flu2/F2	Screening	58	14	24.1	13.9	37.2
	PI(D21)	57	37	64.9	51.1	77.1

N = Number of subjects with available results
n/% = Number/percentage of seroprotected subjects (HI titer \geq 1:40)
95% CI = 95% confidence interval, LL = Lower Limit, UL = Upper Limit
PI(D21) = Post-vaccination at Day 21
Screening = Day 0

Primary Efficacy Results: SPR for HI antibodies against A/California strain at Screening and Day 42 (ATP cohort for immunogenicity)

				SPR			
						95% CI	
Antibody against	Group	Timing	N	n	%	LL	UL
Flu A/CAL/7/09	Flu1/F1	Screening	43	8	18.6	8.4	33.4
		PII(D42)	43	43	100	91.8	100
	Flu1/F2	Screening	40	1	2.5	0.1	13.2
		PII(D42)	42	42	100	91.6	100
	Flu2/F1	Screening	46	9	19.6	9.4	33.9
		PII(D42)	46	46	100	92.3	100
	Flu2/F2	Screening	44	9	20.5	9.8	35.3
		PII(D42)	44	41	93.2	81.3	98.6

N = Number of subjects with available results
n/% = Number/percentage of seroprotected subjects (HI titer \geq 1:40)
95% CI = 95% confidence interval, LL = Lower Limit, UL = Upper Limit
PII(D42) = Post-vaccination at Day 42
Screening = Day 0

Primary Efficacy Results: GMFR for HI antibodies against A/California strain at Day 21 (ATP cohort for immunogenicity)

				GMFR		
				95% CI		
Antibody against	Group	N	Value	LL	UL	
Flu A/CAL/7/09 (1/DIL)	Flu1/F1	57	35.9	26.4	49.0	
	Flu1/F2	47	40.8	29.7	56.2	
	Flu2/F1	55	13.2	9.2	18.8	
	Flu2/F2	57	7.6	5.4	10.6	

N = Number of subjects with pre- and post-vaccination results available
GMFR = Geometric mean of the within-subject ratios of the post-vaccination reciprocal HI titer to the Day 0 reciprocal HI titer
95% CI = 95% confidence interval, LL = Lower Limit, UL = Upper Limit

Primary Efficacy Results: GMFR for HI antibodies against A/California strain at Day42 (ATP cohort for immunogenicity)

				GMFR		
				95% CI		
Antibody against	Group	N	Value	LL	UL	
Flu A/CAL/7/09 (1/DIL)	Flu1/F1	43	155.3	105.7	228.2	
	Flu1/F2	40	217.2	163.9	287.9	
	Flu2/F1	46	44.2	30.6	63.9	
	Flu2/F2	44	24.1	15.9	36.5	

N = Number of subjects with pre- and post-vaccination results available
GMFR = Geometric mean of the within-subject ratios of the post-vaccination reciprocal HI titer to the Day 0 reciprocal HI titer
95% CI = 95% confidence interval, LL = Lower Limit, UL = Upper Limit

Primary Efficacy Results: Seropositivity rates and GMTs for HI antibodies against A/California strain at Screening and Day 21 (ATP cohort for immunogenicity)

		\geq 1:10	GMT	
		95% CI	95% CI	

Antibody against	Group	Timing	N	n	%	LL	UL	value	LL	UL
Flu A/CAL/7/09	Flu1/F1	Screening	57	15	26.3	15.5	39.7	10.8	7.4	15.6
		PI(D21)	57	57	100	93.7	100	386.4	280.3	532.6
	Flu1/F2	Screening	49	3	6.1	1.3	16.9	6.1	4.7	7.8
		PI(D21)	49	49	100	92.7	100	270.1	194.2	375.5
	Flu2/F1	Screening	55	13	23.6	13.2	37.0	10.5	7.2	15.5
		PI(D21)	55	53	96.4	87.5	99.6	138.4	86.3	222.0
	Flu2/F2	Screening	58	14	24.1	13.9	37.2	10.9	7.5	15.8
		PI(D21)	57	54	94.7	85.4	98.9	83.4	52.9	131.4

GMT = geometric mean antibody titer calculated on all subjects

N = number of subjects with available results

n/% = number/percentage of subjects with titer within the specified range

95% CI = 95% confidence interval; LL = Lower Limit, UL = Upper Limit

PI(D21) = Post-vaccination at Day 21

Screening = Day 0

Primary Efficacy Results: Seropositivity rates and GMTs for HI antibodies against A/California strain at Screening and Day 42 (ATP cohort for immunogenicity)

Antibody against	Group	Timing	N	n	%	≥ 1:10		GMT		
						LL	UL	value	95% CI	
						LL	UL		LL	UL
Flu A/CAL/7/09	Flu1/F1	Screening	43	10	23.3	11.8	38.6	9.3	6.4	13.5
		PII(D42)	43	43	100	91.8	100	1444.4	1146.0	1820.6
	Flu1/F2	Screening	40	2	5.0	0.6	16.9	5.7	4.6	7.1
		PII(D42)	42	42	100	91.6	100	1238.5	1050.2	1460.5
	Flu2/F1	Screening	46	10	21.7	10.9	36.4	9.3	6.4	13.6
		PII(D42)	46	46	100	92.3	100	413.5	296.6	576.4
	Flu2/F2	Screening	44	9	20.5	9.8	35.3	9.5	6.4	14.0
		PII(D42)	44	44	100	92.0	100	228.0	156.9	331.3

GMT = geometric mean antibody titer calculated on all subjects

N = number of subjects with available results

n/% = number/percentage of subjects with titer within the specified range

95% CI = 95% confidence interval; LL = Lower Limit, UL = Upper Limit

PII(D42) = Post-vaccination at Day 42

Screening = Day 0

Secondary Outcome Variable(s): Incidence of solicited local symptoms reported during the 7-day (Days 0-6) post-vaccination period following each dose and overall (Total Vaccinated cohort)

		Flu1/F1 Group														
		6m-5y					6y-<9y					out				
		95 % CI					95 % CI					95 % CI				
Symptom	Intensity	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL
Dose 1																
Pain	Any	47	27	57.4	42.2	71.7	18	14	77.8	52.4	93.6	1	1	100	2.5	100
	Grade 3	47	4	8.5	2.4	20.4	18	1	5.6	0.1	27.3	1	0	0.0	0.0	97.5
Redness	Any	47	5	10.6	3.5	23.1	18	4	22.2	6.4	47.6	1	0	0.0	0.0	97.5
	>100mm	47	0	0.0	0.0	7.5	18	0	0.0	0.0	18.5	1	0	0.0	0.0	97.5
Swelling	Any	47	1	2.1	0.1	11.3	18	2	11.1	1.4	34.7	1	0	0.0	0.0	97.5
	>100mm	47	0	0.0	0.0	7.5	18	0	0.0	0.0	18.5	1	0	0.0	0.0	97.5
Dose 2																
Pain	Any	41	22	53.7	37.4	69.3	17	13	76.5	50.1	93.2	-	-	-	-	-
	Grade 3	41	4	9.8	2.7	23.1	17	0	0.0	0.0	19.5	-	-	-	-	-
Redness	Any	41	5	12.2	4.1	26.2	17	1	5.9	0.1	28.7	-	-	-	-	-
	>100mm	41	0	0.0	0.0	8.6	17	0	0.0	0.0	19.5	-	-	-	-	-
Swelling	Any	41	1	2.4	0.1	12.9	17	1	5.9	0.1	28.7	-	-	-	-	-
	>100mm	41	0	0.0	0.0	8.6	17	0	0.0	0.0	19.5	-	-	-	-	-
Across doses																
Pain	Any	47	35	74.5	59.7	86.1	18	15	83.3	58.6	96.4	1	1	100	2.5	100

	Grade 3	47	7	14.9	6.2	28.3	18	1	5.6	0.1	27.3	1	0	0.0	0.0	97.5
Redness	Any	47	7	14.9	6.2	28.3	18	4	22.2	6.4	47.6	1	0	0.0	0.0	97.5
	>100mm	47	0	0.0	0.0	7.5	18	0	0.0	0.0	18.5	1	0	0.0	0.0	97.5
Swelling	Any	47	2	4.3	0.5	14.5	18	2	11.1	1.4	34.7	1	0	0.0	0.0	97.5
	>100mm	47	0	0.0	0.0	7.5	18	0	0.0	0.0	18.5	1	0	0.0	0.0	97.5
		Flu1/F2 Group										Flu2/F1 Group				
		6m-5y					6y-<9y					6m-5y				
		95 % CI					95 % CI					95 % CI				
Symptom	Intensity	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL
Dose 1																
Pain	Any	48	26	54.2	39.2	68.6	12	9	75.0	42.8	94.5	46	19	41.3	27.0	56.8
	Grade 3	48	0	0.0	0.0	7.4	12	0	0.0	0.0	26.5	46	1	2.2	0.1	11.5
Redness	Any	48	4	8.3	2.3	20.0	12	2	16.7	2.1	48.4	46	1	2.2	0.1	11.5
	>100mm	48	0	0.0	0.0	7.4	12	0	0.0	0.0	26.5	46	0	0.0	0.0	7.7
Swelling	Any	48	1	2.1	0.1	11.1	12	1	8.3	0.2	38.5	46	1	2.2	0.1	11.5
	>100mm	48	0	0.0	0.0	7.4	12	0	0.0	0.0	26.5	46	0	0.0	0.0	7.7
Dose 2																
Pain	Any	44	25	56.8	41.0	71.7	11	7	63.6	30.8	89.1	41	11	26.8	14.2	42.9
	Grade 3	44	1	2.3	0.1	12.0	11	2	18.2	2.3	51.8	41	0	0.0	0.0	8.6
Redness	Any	44	3	6.8	1.4	18.7	11	0	0.0	0.0	28.5	41	0	0.0	0.0	8.6
	>100mm	44	0	0.0	0.0	8.0	11	0	0.0	0.0	28.5	41	0	0.0	0.0	8.6
Swelling	Any	44	2	4.5	0.6	15.5	11	0	0.0	0.0	28.5	41	0	0.0	0.0	8.6
	>100mm	44	0	0.0	0.0	8.0	11	0	0.0	0.0	28.5	41	0	0.0	0.0	8.6
Across doses																
Pain	Any	49	33	67.3	52.5	80.1	12	9	75.0	42.8	94.5	46	22	47.8	32.9	63.1
	Grade 3	49	1	2.0	0.1	10.9	12	2	16.7	2.1	48.4	46	1	2.2	0.1	11.5
Redness	Any	49	6	12.2	4.6	24.8	12	2	16.7	2.1	48.4	46	1	2.2	0.1	11.5
	>100mm	49	0	0.0	0.0	7.3	12	0	0.0	0.0	26.5	46	0	0.0	0.0	7.7
Swelling	Any	49	3	6.1	1.3	16.9	12	1	8.3	0.2	38.5	46	1	2.2	0.1	11.5
	>100mm	49	0	0.0	0.0	7.3	12	0	0.0	0.0	26.5	46	0	0.0	0.0	7.7
		Flu2/F1 Group					Flu2/F2 Group									
		6y-<9y					6m-5y					6y-<9y				
		95 % CI					95 % CI					95 % CI				
Symptom	Intensity	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL
Dose 1																
Pain	Any	17	12	70.6	44.0	89.7	44	15	34.1	20.5	49.9	18	10	55.6	30.8	78.5
	Grade 3	17	1	5.9	0.1	28.7	44	0	0.0	0.0	8.0	18	0	0.0	0.0	18.5
Redness	Any	17	0	0.0	0.0	19.5	44	1	2.3	0.1	12.0	18	1	5.6	0.1	27.3
	>100mm	17	0	0.0	0.0	19.5	44	0	0.0	0.0	8.0	18	0	0.0	0.0	18.5
Swelling	Any	17	0	0.0	0.0	19.5	44	1	2.3	0.1	12.0	18	0	0.0	0.0	18.5
	>100mm	17	0	0.0	0.0	19.5	44	0	0.0	0.0	8.0	18	0	0.0	0.0	18.5
Dose 2																
Pain	Any	17	8	47.1	23.0	72.2	41	9	22.0	10.6	37.6	16	7	43.8	19.8	70.1
	Grade 3	17	0	0.0	0.0	19.5	41	0	0.0	0.0	8.6	16	1	6.3	0.2	30.2
Redness	Any	17	0	0.0	0.0	19.5	41	0	0.0	0.0	8.6	16	0	0.0	0.0	20.6
	>100mm	17	0	0.0	0.0	19.5	41	0	0.0	0.0	8.6	16	0	0.0	0.0	20.6
Swelling	Any	17	0	0.0	0.0	19.5	41	0	0.0	0.0	8.6	16	0	0.0	0.0	20.6
	>100mm	17	0	0.0	0.0	19.5	41	0	0.0	0.0	8.6	16	0	0.0	0.0	20.6
Across doses																
Pain	Any	17	12	70.6	44.0	89.7	44	18	40.9	26.3	56.8	18	12	66.7	41.0	86.7
	Grade 3	17	1	5.9	0.1	28.7	44	0	0.0	0.0	8.0	18	1	5.6	0.1	27.3
Redness	Any	17	0	0.0	0.0	19.5	44	1	2.3	0.1	12.0	18	1	5.6	0.1	27.3
	>100mm	17	0	0.0	0.0	19.5	44	0	0.0	0.0	8.0	18	0	0.0	0.0	18.5
Swelling	Any	17	0	0.0	0.0	19.5	44	1	2.3	0.1	12.0	18	0	0.0	0.0	18.5
	>100mm	17	0	0.0	0.0	19.5	44	0	0.0	0.0	8.0	18	0	0.0	0.0	18.5

6m-5y = 6 months - 5 years																
6y-<9y = 6 years to less than 9 years																
Out = out-of-age interval																
N= number of subjects with at least one documented dose																
n/%= number/percentage of subjects reporting at least once the symptom																
95%CI= Exact 95% confidence interval; LL = lower limit, UL = upper limit																
Any= occurrence of any local symptoms regardless of their intensity grade																
Grade 3 pain (subjects aged 6 months to 5 years)= cried when limb was moved/spontaneously painful																
Grade 3 pain (subjects aged 6 years to less than 9 years)= pain that prevented normal activity																
Secondary Outcome Variable(s): Incidence of solicited general symptoms reported during the 7-day (Days 0-6) post-vaccination period following each dose and overall on subjects between and including 6 months to 5 years old (Total Vaccinated cohort)																
		Flu1/F1 Group					Flu1/F2 Group					Flu2/F1 Group				
		95 % CI					95 % CI					95 % CI				
Symptom	Intensity/Relationship	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL
Dose 1																
Drowsiness	Any	47	11	23.4	12.3	38.0	48	11	22.9	12.0	37.3	46	8	17.4	7.8	31.4
	Grade 3	47	2	4.3	0.5	14.5	48	1	2.1	0.1	11.1	46	0	0.0	0.0	7.7
	Related	47	5	10.6	3.5	23.1	48	8	16.7	7.5	30.2	46	5	10.9	3.6	23.6
Irritability	Any	47	22	46.8	32.1	61.9	48	18	37.5	24.0	52.6	46	15	32.6	19.5	48.0
	Grade 3	47	3	6.4	1.3	17.5	48	3	6.3	1.3	17.2	46	1	2.2	0.1	11.5
	Related	47	19	40.4	26.4	55.7	48	15	31.3	18.7	46.3	46	12	26.1	14.3	41.1
Loss of appetite	Any	47	16	34.0	20.9	49.3	48	17	35.4	22.2	50.5	46	6	13.0	4.9	26.3
	Grade 3	47	1	2.1	0.1	11.3	48	1	2.1	0.1	11.1	46	0	0.0	0.0	7.7
	Related	47	9	19.1	9.1	33.3	48	12	25.0	13.6	39.6	46	3	6.5	1.4	17.9
Temperature/ (Axillary)	≥ 38.0°C	47	9	19.1	9.1	33.3	48	6	12.5	4.7	25.2	46	2	4.3	0.5	14.8
	≥ 39.0°C	47	1	2.1	0.1	11.3	48	0	0.0	0.0	7.4	46	0	0.0	0.0	7.7
	Related	47	8	17.0	7.6	30.8	48	3	6.3	1.3	17.2	46	1	2.2	0.1	11.5
Dose 2																
Drowsiness	Any	41	13	31.7	18.1	48.1	44	6	13.6	5.2	27.4	41	7	17.1	7.2	32.1
	Grade 3	41	5	12.2	4.1	26.2	44	0	0.0	0.0	8.0	41	0	0.0	0.0	8.6
	Related	41	9	22.0	10.6	37.6	44	2	4.5	0.6	15.5	41	5	12.2	4.1	26.2
Irritability	Any	41	19	46.3	30.7	62.6	44	12	27.3	15.0	42.8	41	13	31.7	18.1	48.1
	Grade 3	41	3	7.3	1.5	19.9	44	1	2.3	0.1	12.0	41	2	4.9	0.6	16.5
	Related	41	18	43.9	28.5	60.3	44	11	25.0	13.2	40.3	41	12	29.3	16.1	45.5
Loss of appetite	Any	41	18	43.9	28.5	60.3	44	10	22.7	11.5	37.8	41	7	17.1	7.2	32.1
	Grade 3	41	1	2.4	0.1	12.9	44	2	4.5	0.6	15.5	41	0	0.0	0.0	8.6
	Related	41	15	36.6	22.1	53.1	44	8	18.2	8.2	32.7	41	5	12.2	4.1	26.2
Temperature/ (Axillary)	≥ 38.0°C	41	13	31.7	18.1	48.1	44	7	15.9	6.6	30.1	41	3	7.3	1.5	19.9
	≥ 39.0°C	41	5	12.2	4.1	26.2	44	0	0.0	0.0	8.0	41	0	0.0	0.0	8.6
	Related	41	11	26.8	14.2	42.9	44	6	13.6	5.2	27.4	41	2	4.9	0.6	16.5
Across doses																
Drowsiness	Any	47	17	36.2	22.7	51.5	49	15	30.6	18.3	45.4	46	13	28.3	16.0	43.5
	Grade 3	47	6	12.8	4.8	25.7	49	1	2.0	0.1	10.9	46	0	0.0	0.0	7.7
	Related	47	10	21.3	10.7	35.7	49	9	18.4	8.8	32.0	46	9	19.6	9.4	33.9
Irritability	Any	47	28	59.6	44.3	73.6	49	22	44.9	30.7	59.8	46	21	45.7	30.9	61.0
	Grade 3	47	6	12.8	4.8	25.7	49	4	8.2	2.3	19.6	46	3	6.5	1.4	17.9
	Related	47	25	53.2	38.1	67.9	49	20	40.8	27.0	55.8	46	17	37.0	23.2	52.5
Loss of appetite	Any	47	25	53.2	38.1	67.9	49	23	46.9	32.5	61.7	46	11	23.9	12.6	38.8
	Grade 3	47	2	4.3	0.5	14.5	49	3	6.1	1.3	16.9	46	0	0.0	0.0	7.7
	Related	47	17	36.2	22.7	51.5	49	17	34.7	21.7	49.6	46	7	15.2	6.3	28.9
Temperature/ (Axillary)	≥ 38.0°C	47	19	40.4	26.4	55.7	49	11	22.4	11.8	36.6	46	4	8.7	2.4	20.8
	≥ 39.0°C	47	6	12.8	4.8	25.7	49	0	0.0	0.0	7.3	46	0	0.0	0.0	7.7
	Related	47	16	34.0	20.9	49.3	49	8	16.3	7.3	29.7	46	2	4.3	0.5	14.8
Flu2/F2 Group																

					95 % CI											
Symptom	Intensity/ Relationship	N	n	%	LL	UL										
Dose 1																
Drowsiness	Any	44	9	20.5	9.8	35.3										
	Grade 3	44	0	0.0	0.0	8.0										
	Related	44	7	15.9	6.6	30.1										
Irritability	Any	44	8	18.2	8.2	32.7										
	Grade 3	44	0	0.0	0.0	8.0										
	Related	44	8	18.2	8.2	32.7										
Loss of appetite	Any	44	9	20.5	9.8	35.3										
	Grade 3	44	1	2.3	0.1	12.0										
	Related	44	8	18.2	8.2	32.7										
Temperature/(Axillary)	≥ 38.0°C	44	1	2.3	0.1	12.0										
	≥ 39.0°C	44	0	0.0	0.0	8.0										
	Related	44	1	2.3	0.1	12.0										
Dose 2																
Drowsiness	Any	41	7	17.1	7.2	32.1										
	Grade 3	41	0	0.0	0.0	8.6										
	Related	41	7	17.1	7.2	32.1										
Irritability	Any	41	11	26.8	14.2	42.9										
	Grade 3	41	2	4.9	0.6	16.5										
	Related	41	11	26.8	14.2	42.9										
Loss of appetite	Any	41	5	12.2	4.1	26.2										
	Grade 3	41	0	0.0	0.0	8.6										
	Related	41	5	12.2	4.1	26.2										
Temperature/(Axillary)	≥ 38.0°C	41	3	7.3	1.5	19.9										
	≥ 39.0°C	41	0	0.0	0.0	8.6										
	Related	41	0	0.0	0.0	8.6										
Across doses																
Drowsiness	Any	44	14	31.8	18.6	47.6										
	Grade 3	44	0	0.0	0.0	8.0										
	Related	44	12	27.3	15.0	42.8										
Irritability	Any	44	17	38.6	24.4	54.5										
	Grade 3	44	2	4.5	0.6	15.5										
	Related	44	17	38.6	24.4	54.5										
Loss of appetite	Any	44	11	25.0	13.2	40.3										
	Grade 3	44	1	2.3	0.1	12.0										
	Related	44	10	22.7	11.5	37.8										
Temperature/(Axillary)	≥ 38.0°C	44	4	9.1	2.5	21.7										
	≥ 39.0°C	44	0	0.0	0.0	8.0										
	Related	44	1	2.3	0.1	12.0										
<p>N= number of subjects with at least one documented dose n/%= number/percentage of subjects reporting at least once the symptom 95%CI= Exact 95% confidence interval; LL = lower limit, UL = upper limit Any= occurrence of any general symptoms regardless of their intensity grade or relation to vaccination Grade 3 drowsiness= drowsiness that prevented normal activity Grade 3 irritability= crying that could not be comforted/prevented normal activity Grade 3 loss of appetite= not eating at all Related= general symptom assessed by the investigator as causally related to the study vaccination</p>																
Secondary Outcome Variable(s): Incidence of solicited general symptoms reported during the 7-day (Days 0-6) post-vaccination period following each dose and overall on subjects between 6 years to less than 9 years (Total Vaccinated cohort)																
		Flu1/F1 Group			Flu1/F2 Group			Flu2/F1 Group								
		95 % CI			95 % CI			95 % CI								
Symptom	Intensity/ Relationship	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL

Dose 1																
Fatigue	Any	18	3	16.7	3.6	41.4	12	4	33.3	9.9	65.1	17	4	23.5	6.8	49.9
	Grade 3	18	0	0.0	0.0	18.5	12	0	0.0	0.0	26.5	17	1	5.9	0.1	28.7
	Related	18	2	11.1	1.4	34.7	12	3	25.0	5.5	57.2	17	4	23.5	6.8	49.9
Gastro-intestinal	Any	18	1	5.6	0.1	27.3	12	2	16.7	2.1	48.4	17	3	17.6	3.8	43.4
	Grade 3	18	0	0.0	0.0	18.5	12	0	0.0	0.0	26.5	17	1	5.9	0.1	28.7
	Related	18	0	0.0	0.0	18.5	12	1	8.3	0.2	38.5	17	3	17.6	3.8	43.4
Headache	Any	18	4	22.2	6.4	47.6	12	4	33.3	9.9	65.1	17	2	11.8	1.5	36.4
	Grade 3	18	0	0.0	0.0	18.5	12	0	0.0	0.0	26.5	17	0	0.0	0.0	19.5
	Related	18	3	16.7	3.6	41.4	12	2	16.7	2.1	48.4	17	1	5.9	0.1	28.7
Joint pain at other location	Any	18	0	0.0	0.0	18.5	12	0	0.0	0.0	26.5	17	2	11.8	1.5	36.4
	Grade 3	18	0	0.0	0.0	18.5	12	0	0.0	0.0	26.5	17	0	0.0	0.0	19.5
	Related	18	0	0.0	0.0	18.5	12	0	0.0	0.0	26.5	17	2	11.8	1.5	36.4
Muscle aches	Any	18	4	22.2	6.4	47.6	12	2	16.7	2.1	48.4	17	3	17.6	3.8	43.4
	Grade 3	18	0	0.0	0.0	18.5	12	0	0.0	0.0	26.5	17	0	0.0	0.0	19.5
	Related	18	4	22.2	6.4	47.6	12	2	16.7	2.1	48.4	17	3	17.6	3.8	43.4
Shivering	Any	18	0	0.0	0.0	18.5	12	0	0.0	0.0	26.5	17	1	5.9	0.1	28.7
	Grade 3	18	0	0.0	0.0	18.5	12	0	0.0	0.0	26.5	17	0	0.0	0.0	19.5
	Related	18	0	0.0	0.0	18.5	12	0	0.0	0.0	26.5	17	1	5.9	0.1	28.7
Sweating	Any	18	1	5.6	0.1	27.3	12	1	8.3	0.2	38.5	17	2	11.8	1.5	36.4
	Grade 3	18	0	0.0	0.0	18.5	12	0	0.0	0.0	26.5	17	0	0.0	0.0	19.5
	Related	18	1	5.6	0.1	27.3	12	0	0.0	0.0	26.5	17	2	11.8	1.5	36.4
Temperature/ (Axillary)	≥ 38.0°C	18	5	27.8	9.7	53.5	12	2	16.7	2.1	48.4	17	1	5.9	0.1	28.7
	≥ 39.0°C	18	0	0.0	0.0	18.5	12	0	0.0	0.0	26.5	17	0	0.0	0.0	19.5
	Related	18	3	16.7	3.6	41.4	12	2	16.7	2.1	48.4	17	1	5.9	0.1	28.7
Dose 2																
Fatigue	Any	17	3	17.6	3.8	43.4	11	3	27.3	6.0	61.0	17	3	17.6	3.8	43.4
	Grade 3	17	0	0.0	0.0	19.5	11	1	9.1	0.2	41.3	17	0	0.0	0.0	19.5
	Related	17	3	17.6	3.8	43.4	11	2	18.2	2.3	51.8	17	3	17.6	3.8	43.4
Gastro-intestinal	Any	17	0	0.0	0.0	19.5	11	2	18.2	2.3	51.8	17	1	5.9	0.1	28.7
	Grade 3	17	0	0.0	0.0	19.5	11	0	0.0	0.0	28.5	17	0	0.0	0.0	19.5
	Related	17	0	0.0	0.0	19.5	11	2	18.2	2.3	51.8	17	1	5.9	0.1	28.7
Headache	Any	17	8	47.1	23.0	72.2	11	3	27.3	6.0	61.0	17	2	11.8	1.5	36.4
	Grade 3	17	0	0.0	0.0	19.5	11	0	0.0	0.0	28.5	17	0	0.0	0.0	19.5
	Related	17	8	47.1	23.0	72.2	11	3	27.3	6.0	61.0	17	2	11.8	1.5	36.4
Joint pain at other location	Any	17	2	11.8	1.5	36.4	11	4	36.4	10.9	69.2	17	0	0.0	0.0	19.5
	Grade 3	17	0	0.0	0.0	19.5	11	1	9.1	0.2	41.3	17	0	0.0	0.0	19.5
	Related	17	2	11.8	1.5	36.4	11	4	36.4	10.9	69.2	17	0	0.0	0.0	19.5
Muscle aches	Any	17	7	41.2	18.4	67.1	11	2	18.2	2.3	51.8	17	1	5.9	0.1	28.7
	Grade 3	17	0	0.0	0.0	19.5	11	1	9.1	0.2	41.3	17	0	0.0	0.0	19.5
	Related	17	7	41.2	18.4	67.1	11	2	18.2	2.3	51.8	17	1	5.9	0.1	28.7
Shivering	Any	17	4	23.5	6.8	49.9	11	2	18.2	2.3	51.8	17	2	11.8	1.5	36.4
	Grade 3	17	0	0.0	0.0	19.5	11	0	0.0	0.0	28.5	17	0	0.0	0.0	19.5
	Related	17	4	23.5	6.8	49.9	11	2	18.2	2.3	51.8	17	2	11.8	1.5	36.4
Sweating	Any	17	1	5.9	0.1	28.7	11	1	9.1	0.2	41.3	17	0	0.0	0.0	19.5
	Grade 3	17	0	0.0	0.0	19.5	11	0	0.0	0.0	28.5	17	0	0.0	0.0	19.5
	Related	17	1	5.9	0.1	28.7	11	1	9.1	0.2	41.3	17	0	0.0	0.0	19.5
Temperature/ (Axillary)	≥ 38.0°C	17	5	29.4	10.3	56.0	11	2	18.2	2.3	51.8	17	0	0.0	0.0	19.5
	≥ 39.0°C	17	2	11.8	1.5	36.4	11	0	0.0	0.0	28.5	17	0	0.0	0.0	19.5
	Related	17	5	29.4	10.3	56.0	11	2	18.2	2.3	51.8	17	0	0.0	0.0	19.5
Across doses																
Fatigue	Any	18	6	33.3	13.3	59.0	12	5	41.7	15.2	72.3	17	4	23.5	6.8	49.9
	Grade 3	18	0	0.0	0.0	18.5	12	1	8.3	0.2	38.5	17	1	5.9	0.1	28.7
	Related	18	5	27.8	9.7	53.5	12	4	33.3	9.9	65.1	17	4	23.5	6.8	49.9
Gastro-	Any	18	1	5.6	0.1	27.3	12	3	25.0	5.5	57.2	17	3	17.6	3.8	43.4

intestinal	Grade 3	18	0	0.0	0.0	18.5	12	0	0.0	0.0	26.5	17	1	5.9	0.1	28.7
	Related	18	0	0.0	0.0	18.5	12	3	25.0	5.5	57.2	17	3	17.6	3.8	43.4
Headache	Any	18	9	50.0	26.0	74.0	12	5	41.7	15.2	72.3	17	4	23.5	6.8	49.9
	Grade 3	18	0	0.0	0.0	18.5	12	0	0.0	0.0	26.5	17	0	0.0	0.0	19.5
	Related	18	9	50.0	26.0	74.0	12	4	33.3	9.9	65.1	17	3	17.6	3.8	43.4
Joint pain at other location	Any	18	2	11.1	1.4	34.7	12	4	33.3	9.9	65.1	17	2	11.8	1.5	36.4
	Grade 3	18	0	0.0	0.0	18.5	12	1	8.3	0.2	38.5	17	0	0.0	0.0	19.5
	Related	18	2	11.1	1.4	34.7	12	4	33.3	9.9	65.1	17	2	11.8	1.5	36.4
Muscle aches	Any	18	8	44.4	21.5	69.2	12	3	25.0	5.5	57.2	17	3	17.6	3.8	43.4
	Grade 3	18	0	0.0	0.0	18.5	12	1	8.3	0.2	38.5	17	0	0.0	0.0	19.5
	Related	18	8	44.4	21.5	69.2	12	3	25.0	5.5	57.2	17	3	17.6	3.8	43.4
Shivering	Any	18	4	22.2	6.4	47.6	12	2	16.7	2.1	48.4	17	2	11.8	1.5	36.4
	Grade 3	18	0	0.0	0.0	18.5	12	0	0.0	0.0	26.5	17	0	0.0	0.0	19.5
	Related	18	4	22.2	6.4	47.6	12	2	16.7	2.1	48.4	17	2	11.8	1.5	36.4
Sweating	Any	18	2	11.1	1.4	34.7	12	1	8.3	0.2	38.5	17	2	11.8	1.5	36.4
	Grade 3	18	0	0.0	0.0	18.5	12	0	0.0	0.0	26.5	17	0	0.0	0.0	19.5
	Related	18	2	11.1	1.4	34.7	12	1	8.3	0.2	38.5	17	2	11.8	1.5	36.4
Temperature/ (Axillary)	≥ 38.0°C	18	9	50.0	26.0	74.0	12	4	33.3	9.9	65.1	17	1	5.9	0.1	28.7
	≥ 39.0°C	18	2	11.1	1.4	34.7	12	0	0.0	0.0	26.5	17	0	0.0	0.0	19.5
	Related	18	7	38.9	17.3	64.3	12	4	33.3	9.9	65.1	17	1	5.9	0.1	28.7
											Flu2/F2 Group					
											95 % CI					
Symptom		Intensity/ Relationship					N	n	%			LL	UL			
Dose 1																
Fatigue	Any						18	4	22.2			6.4	47.6			
	Grade 3						18	0	0.0			0.0	18.5			
	Related						18	3	16.7			3.6	41.4			
Gastrointestinal	Any						18	2	11.1			1.4	34.7			
	Grade 3						18	0	0.0			0.0	18.5			
	Related						18	0	0.0			0.0	18.5			
Headache	Any						18	2	11.1			1.4	34.7			
	Grade 3						18	0	0.0			0.0	18.5			
	Related						18	2	11.1			1.4	34.7			
Joint pain at other location	Any						18	1	5.6			0.1	27.3			
	Grade 3						18	0	0.0			0.0	18.5			
	Related						18	0	0.0			0.0	18.5			
Muscle aches	Any						18	1	5.6			0.1	27.3			
	Grade 3						18	0	0.0			0.0	18.5			
	Related						18	1	5.6			0.1	27.3			
Shivering	Any						18	0	0.0			0.0	18.5			
	Grade 3						18	0	0.0			0.0	18.5			
	Related						18	0	0.0			0.0	18.5			
Sweating	Any						18	1	5.6			0.1	27.3			
	Grade 3						18	0	0.0			0.0	18.5			
	Related						18	0	0.0			0.0	18.5			
Temperature/(Axillary)	≥ 38.0°C						18	0	0.0			0.0	18.5			
	≥ 39.0°C						18	0	0.0			0.0	18.5			
	Related						18	0	0.0			0.0	18.5			
Dose 2																
Fatigue	Any						16	4	25.0			7.3	52.4			
	Grade 3						16	0	0.0			0.0	20.6			
	Related						16	3	18.8			4.0	45.6			
Gastrointestinal	Any						16	5	31.3			11.0	58.7			
	Grade 3						16	1	6.3			0.2	30.2			
	Related						16	4	25.0			7.3	52.4			

Headache	Any	16	4	25.0	7.3	52.4
	Grade 3	16	1	6.3	0.2	30.2
	Related	16	3	18.8	4.0	45.6
Joint pain at other location	Any	16	1	6.3	0.2	30.2
	Grade 3	16	0	0.0	0.0	20.6
	Related	16	0	0.0	0.0	20.6
Muscle aches	Any	16	2	12.5	1.6	38.3
	Grade 3	16	0	0.0	0.0	20.6
	Related	16	1	6.3	0.2	30.2
Shivering	Any	16	1	6.3	0.2	30.2
	Grade 3	16	0	0.0	0.0	20.6
	Related	16	0	0.0	0.0	20.6
Sweating	Any	16	2	12.5	1.6	38.3
	Grade 3	16	0	0.0	0.0	20.6
	Related	16	1	6.3	0.2	30.2
Temperature/(Axillary)	≥ 38.0°C	16	2	12.5	1.6	38.3
	≥ 39.0°C	16	0	0.0	0.0	20.6
	Related	16	1	6.3	0.2	30.2
Across doses						
Fatigue	Any	18	8	44.4	21.5	69.2
	Grade 3	18	0	0.0	0.0	18.5
	Related	18	6	33.3	13.3	59.0
Gastrointestinal	Any	18	7	38.9	17.3	64.3
	Grade 3	18	1	5.6	0.1	27.3
	Related	18	4	22.2	6.4	47.6
Headache	Any	18	5	27.8	9.7	53.5
	Grade 3	18	1	5.6	0.1	27.3
	Related	18	4	22.2	6.4	47.6
Joint pain at other location	Any	18	2	11.1	1.4	34.7
	Grade 3	18	0	0.0	0.0	18.5
	Related	18	0	0.0	0.0	18.5
Muscle aches	Any	18	3	16.7	3.6	41.4
	Grade 3	18	0	0.0	0.0	18.5
	Related	18	2	11.1	1.4	34.7
Shivering	Any	18	1	5.6	0.1	27.3
	Grade 3	18	0	0.0	0.0	18.5
	Related	18	0	0.0	0.0	18.5
Sweating	Any	18	3	16.7	3.6	41.4
	Grade 3	18	0	0.0	0.0	18.5
	Related	18	1	5.6	0.1	27.3
Temperature/(Axillary)	≥ 38.0°C	18	2	11.1	1.4	34.7
	≥ 39.0°C	18	0	0.0	0.0	18.5
	Related	18	1	5.6	0.1	27.3

N= number of subjects with at least one documented dose

n/%= number/percentage of subjects reporting at least once the symptom

95%CI= Exact 95% confidence interval; LL = lower limit, UL = upper limit

Any= occurrence of any general symptoms regardless of their intensity grade or relation to vaccination

Grade 3= general symptom that prevented normal activity

Related= general symptom assessed by the investigator as causally related to the study vaccination

Secondary Outcome Variable(s): Distribution of hematology with respect to normal laboratory ranges (Total Vaccinated cohort)

		Flu1/F1 Group N = 67									Flu1/F2 Group N = 64								
		Unknown		Below		Within		Above		Unknown		Below		Within		Above			
Laboratory	Timing	N	n	%	n	%	n	%	n	%	N	n	%	n	%	n	%		

parameter																			
Basophils	Screening	66	1	1.5	0	0.0	65	98.5	0	0.0	63	3	4.8	0	0.0	60	95.2	0	0.0
	PI(D7)	66	5	7.6	0	0.0	61	92.4	0	0.0	60	4	6.7	0	0.0	56	93.3	0	0.0
	PI(D21)	65	1	1.5	0	0.0	64	98.5	0	0.0	57	3	5.3	0	0.0	54	94.7	0	0.0
	PII(D42)	58	3	5.2	0	0.0	55	94.8	0	0.0	56	2	3.6	0	0.0	54	96.4	0	0.0
Eosinophils	Screening	66	4	6.1	12	18.2	46	69.7	4	6.1	63	2	3.2	5	7.9	53	84.1	3	4.8
	PI(D7)	66	5	7.6	7	10.6	50	75.8	4	6.1	60	4	6.7	8	13.3	42	70.0	6	10.0
	PI(D21)	65	1	1.5	5	7.7	54	83.1	5	7.7	57	3	5.3	6	10.5	42	73.7	6	10.5
	PII(D42)	58	3	5.2	4	6.9	42	72.4	9	15.5	56	2	3.6	3	5.4	46	82.1	5	8.9
Hematocrit	Screening	66	5	7.6	5	7.6	53	80.3	3	4.5	63	5	7.9	8	12.7	44	69.8	6	9.5
	PI(D7)	66	5	7.6	6	9.1	52	78.8	3	4.5	60	4	6.7	7	11.7	47	78.3	2	3.3
	PI(D21)	65	1	1.5	7	10.8	54	83.1	3	4.6	57	3	5.3	10	17.5	41	71.9	3	5.3
	PII(D42)	58	3	5.2	9	15.5	45	77.6	1	1.7	56	2	3.6	12	21.4	41	73.2	1	1.8
Hemoglobin	Screening	66	3	4.5	1	1.5	58	87.9	4	6.1	63	6	9.5	5	7.9	45	71.4	7	11.1
	PI(D7)	66	5	7.6	4	6.1	55	83.3	2	3.0	60	3	5.0	5	8.3	50	83.3	2	3.3
	PI(D21)	65	1	1.5	5	7.7	55	84.6	4	6.2	57	3	5.3	3	5.3	48	84.2	3	5.3
	PII(D42)	58	3	5.2	2	3.4	49	84.5	4	6.9	56	2	3.6	8	14.3	43	76.8	3	5.4
Lymphocytes	Screening	66	2	3.0	0	0.0	46	69.7	18	27.3	63	4	6.3	0	0.0	38	60.3	21	33.3
	PI(D7)	66	5	7.6	1	1.5	38	57.6	22	33.3	60	4	6.7	2	3.3	28	46.7	26	43.3
	PI(D21)	65	1	1.5	0	0.0	43	66.2	21	32.3	57	3	5.3	1	1.8	27	47.4	26	45.6
	PII(D42)	58	3	5.2	1	1.7	36	62.1	18	31.0	56	2	3.6	1	1.8	31	55.4	22	39.3
Monocytes	Screening	66	4	6.1	10	15.2	52	78.8	0	0.0	63	5	7.9	10	15.9	48	76.2	0	0.0
	PI(D7)	66	5	7.6	13	19.7	48	72.7	0	0.0	60	4	6.7	10	16.7	46	76.7	0	0.0
	PI(D21)	65	1	1.5	19	29.2	45	69.2	0	0.0	57	3	5.3	8	14.0	46	80.7	0	0.0
	PII(D42)	58	3	5.2	13	22.4	41	70.7	1	1.7	56	2	3.6	17	30.4	37	66.1	0	0.0
Neutrophils	Screening	66	5	7.6	5	7.6	54	81.8	2	3.0	63	4	6.3	6	9.5	52	82.5	1	1.6
	PI(D7)	66	5	7.6	10	15.2	50	75.8	1	1.5	60	4	6.7	3	5.0	52	86.7	1	1.7
	PI(D21)	65	1	1.5	1	1.5	62	95.4	1	1.5	57	3	5.3	3	5.3	51	89.5	0	0.0
	PII(D42)	58	3	5.2	5	8.6	50	86.2	0	0.0	56	2	3.6	5	8.9	48	85.7	1	1.8
Platelets	Screening	66	4	6.1	0	0.0	51	77.3	11	16.7	63	8	12.7	0	0.0	49	77.8	6	9.5
	PI(D7)	66	6	9.1	0	0.0	51	77.3	9	13.6	60	3	5.0	0	0.0	49	81.7	8	13.3
	PI(D21)	65	2	3.1	0	0.0	57	87.7	6	9.2	57	4	7.0	1	1.8	43	75.4	9	15.8
	PII(D42)	58	3	5.2	0	0.0	50	86.2	5	8.6	56	3	5.4	0	0.0	47	83.9	6	10.7
Red Blood Cells	Screening	66	4	6.1	1	1.5	59	89.4	2	3.0	63	4	6.3	4	6.3	54	85.7	1	1.6
	PI(D7)	66	5	7.6	2	3.0	56	84.8	3	4.5	60	4	6.7	3	5.0	52	86.7	1	1.7
	PI(D21)	65	1	1.5	1	1.5	62	95.4	1	1.5	57	3	5.3	3	5.3	51	89.5	0	0.0
	PII(D42)	58	3	5.2	1	1.7	51	87.9	3	5.2	56	2	3.6	2	3.6	52	92.9	0	0.0
White Blood Cells	Screening	66	6	9.1	3	4.5	55	83.3	2	3.0	63	5	7.9	0	0.0	57	90.5	1	1.6
	PI(D7)	66	5	7.6	6	9.1	54	81.8	1	1.5	60	4	6.7	2	3.3	53	88.3	1	1.7
	PI(D21)	65	1	1.5	2	3.1	61	93.8	1	1.5	57	3	5.3	1	1.8	53	93.0	0	0.0
	PII(D42)	58	3	5.2	3	5.2	52	89.7	0	0.0	56	2	3.6	3	5.4	51	91.1	0	0.0
		Flu2/F1 Group N = 64										Flu2/F2 Group N = 63							
		Unknown		Below		Within		Above		Unknown		Below		Within		Above			
Laboratory parameter	Timing	N	n	%	n	%	n	%	n	%	N	n	%	n	%	n	%	n	%
Basophils	Screening	63	7	11.1	0	0.0	56	88.9	0	0.0	63	2	3.2	0	0.0	61	96.8	0	0.0
	PI(D7)	60	4	6.7	0	0.0	56	93.3	0	0.0	61	3	4.9	0	0.0	58	95.1	0	0.0
	PI(D21)	59	6	10.2	0	0.0	53	89.8	0	0.0	61	0	0.0	0	0.0	61	100	0	0.0
	PII(D42)	60	1	1.7	0	0.0	59	98.3	0	0.0	58	1	1.7	0	0.0	57	98.3	0	0.0
Eosinophils	Screening	63	6	9.5	7	11.1	45	71.4	5	7.9	63	1	1.6	6	9.5	51	81.0	5	7.9
	PI(D7)	60	4	6.7	8	13.3	46	76.7	2	3.3	61	3	4.9	6	9.8	45	73.8	7	11.5
	PI(D21)	59	6	10.2	5	8.5	47	79.7	1	1.7	61	0	0.0	7	11.5	51	83.6	3	4.9
	PII(D42)	60	1	1.7	5	8.3	50	83.3	4	6.7	58	1	1.7	3	5.2	47	81.0	7	12.1
Hematocrit	Screening	63	6	9.5	4	6.3	48	76.2	5	7.9	63	2	3.2	5	7.9	52	82.5	4	6.3

	PI(D7)	60	4	6.7	4	6.7	48	80.0	4	6.7	61	3	4.9	6	9.8	49	80.3	3	4.9
	PI(D21)	59	6	10.2	7	11.9	43	72.9	3	5.1	61	0	0.0	7	11.5	53	86.9	1	1.6
	PII(D42)	60	1	1.7	5	8.3	48	80.0	6	10.0	58	1	1.7	10	17.2	46	79.3	1	1.7
Hemoglobin	Screening	63	4	6.3	3	4.8	52	82.5	4	6.3	63	2	3.2	3	4.8	55	87.3	3	4.8
	PI(D7)	60	4	6.7	1	1.7	51	85.0	4	6.7	61	3	4.9	2	3.3	52	85.2	4	6.6
	PI(D21)	59	6	10.2	3	5.1	47	79.7	3	5.1	61	0	0.0	3	4.9	56	91.8	2	3.3
	PII(D42)	60	1	1.7	4	6.7	49	81.7	6	10.0	58	1	1.7	4	6.9	50	86.2	3	5.2
Lymphocytes	Screening	63	6	9.5	1	1.6	35	55.6	21	33.3	63	2	3.2	0	0.0	43	68.3	18	28.6
	PI(D7)	60	4	6.7	0	0.0	33	55.0	23	38.3	61	3	4.9	0	0.0	44	72.1	14	23.0
	PI(D21)	59	6	10.2	0	0.0	36	61.0	17	28.8	61	0	0.0	1	1.6	38	62.3	22	36.1
	PII(D42)	60	1	1.7	0	0.0	36	60.0	23	38.3	58	1	1.7	0	0.0	40	69.0	17	29.3
Monocytes	Screening	63	6	9.5	4	6.3	53	84.1	0	0.0	63	1	1.6	15	23.8	46	73.0	1	1.6
	PI(D7)	60	4	6.7	11	18.3	44	73.3	1	1.7	61	3	4.9	7	11.5	51	83.6	0	0.0
	PI(D21)	59	6	10.2	10	16.9	43	72.9	0	0.0	61	0	0.0	13	21.3	48	78.7	0	0.0
	PII(D42)	60	1	1.7	21	35.0	38	63.3	0	0.0	58	1	1.7	16	27.6	41	70.7	0	0.0
Neutrophils	Screening	63	4	6.3	4	6.3	51	81.0	4	6.3	63	1	1.6	6	9.5	56	88.9	0	0.0
	PI(D7)	60	4	6.7	2	3.3	54	90.0	0	0.0	61	3	4.9	6	9.8	50	82.0	2	3.3
	PI(D21)	59	6	10.2	3	5.1	50	84.7	0	0.0	61	0	0.0	2	3.3	59	96.7	0	0.0
	PII(D42)	60	1	1.7	10	16.7	48	80.0	1	1.7	58	1	1.7	13	22.4	40	69.0	4	6.9
Platelets	Screening	63	8	12.7	1	1.6	48	76.2	6	9.5	63	3	4.8	0	0.0	56	88.9	4	6.3
	PI(D7)	60	4	6.7	1	1.7	50	83.3	5	8.3	61	3	4.9	0	0.0	51	83.6	7	11.5
	PI(D21)	59	6	10.2	0	0.0	52	88.1	1	1.7	61	0	0.0	0	0.0	57	93.4	4	6.6
	PII(D42)	60	1	1.7	0	0.0	59	98.3	0	0.0	58	2	3.4	1	1.7	53	91.4	2	3.4
Red Blood Cells	Screening	63	5	7.9	0	0.0	56	88.9	2	3.2	63	2	3.2	3	4.8	55	87.3	3	4.8
	PI(D7)	60	4	6.7	1	1.7	54	90.0	1	1.7	61	3	4.9	1	1.6	54	88.5	3	4.9
	PI(D21)	59	6	10.2	2	3.4	49	83.1	2	3.4	61	0	0.0	1	1.6	57	93.4	3	4.9
	PII(D42)	60	1	1.7	2	3.3	55	91.7	2	3.3	58	1	1.7	3	5.2	52	89.7	2	3.4
White Blood Cells	Screening	63	6	9.5	1	1.6	54	85.7	2	3.2	63	2	3.2	2	3.2	59	93.7	0	0.0
	PI(D7)	60	4	6.7	1	1.7	55	91.7	0	0.0	61	3	4.9	1	1.6	56	91.8	1	1.6
	PI(D21)	59	6	10.2	0	0.0	53	89.8	0	0.0	61	0	0.0	1	1.6	60	98.4	0	0.0
	PII(D42)	60	1	1.7	2	3.3	56	93.3	1	1.7	58	1	1.7	5	8.6	50	86.2	2	3.4

N = number of subjects with laboratory results for the specified time point and laboratory parameter

n/% = number/percentage of subjects in a given category

Unknown = value unknown for the specified time point and laboratory parameter

Below = value below the laboratory reference range defined for the specified time point and laboratory parameter

Within = value within the laboratory reference range defined for the specified time point and laboratory parameter

Above = value above the laboratory reference range defined for the specified time point and laboratory parameter

Screening = Day 0

PI(D7) = Post-vaccination at Day 7

PI(D21) = Post-vaccination at Day 21

PII(D42) = Post-vaccination at Day 42

Secondary Outcome Variable(s): Distribution of biochemistry with respect to normal laboratory ranges (Total Vaccinated cohort)

		Flu1/F1 Group N = 67								Flu1/F2 Group N = 64									
		Unknown		Below		Within		Above		Unknown		Below		Within		Above			
Laboratory parameter	Timing	N	n	%	n	%	n	%	n	%	N	n	%	n	%	n	%		
ALAT	Screening	66	2	3.0	0	0.0	64	97.0	0	0.0	63	2	3.2	0	0.0	61	96.8	0	0.0
	PI(D7)	66	1	1.5	0	0.0	64	97.0	1	1.5	60	1	1.7	0	0.0	59	98.3	0	0.0
	PI(D21)	65	2	3.1	0	0.0	63	96.9	0	0.0	57	0	0.0	0	0.0	57	100	0	0.0
	PII(D42)	58	3	5.2	0	0.0	55	94.8	0	0.0	56	2	3.6	0	0.0	53	94.6	1	1.8
ASAT	Screening	66	5	7.6	0	0.0	61	92.4	0	0.0	63	6	9.5	0	0.0	57	90.5	0	0.0
	PI(D7)	66	1	1.5	0	0.0	63	95.5	2	3.0	60	3	5.0	0	0.0	57	95.0	0	0.0
	PI(D21)	65	4	6.2	0	0.0	61	93.8	0	0.0	57	0	0.0	0	0.0	56	98.2	1	1.8
	PII(D42)	58	4	6.9	0	0.0	54	93.1	0	0.0	56	2	3.6	0	0.0	53	94.6	1	1.8

Bilirubin	Screening	66	2	3.0	0	0.0	64	97.0	0	0.0	63	1	1.6	0	0.0	62	98.4	0	0.0
	PI(D7)	66	1	1.5	0	0.0	65	98.5	0	0.0	60	1	1.7	0	0.0	59	98.3	0	0.0
	PI(D21)	65	2	3.1	0	0.0	63	96.9	0	0.0	57	0	0.0	0	0.0	57	100	0	0.0
	PII(D42)	58	3	5.2	0	0.0	55	94.8	0	0.0	56	2	3.6	0	0.0	53	94.6	1	1.8
Bilirubin Conjugated / Direct	Screening	66	2	3.0	0	0.0	64	97.0	0	0.0	63	2	3.2	0	0.0	61	96.8	0	0.0
	PI(D7)	66	1	1.5	0	0.0	65	98.5	0	0.0	60	1	1.7	0	0.0	59	98.3	0	0.0
	PI(D21)	65	2	3.1	0	0.0	63	96.9	0	0.0	57	0	0.0	0	0.0	57	100	0	0.0
	PII(D42)	58	3	5.2	0	0.0	55	94.8	0	0.0	56	2	3.6	0	0.0	54	96.4	0	0.0
Creatinine	Screening	66	2	3.0	19	28.8	45	68.2	0	0.0	63	2	3.2	22	34.9	39	61.9	0	0.0
	PI(D7)	66	1	1.5	18	27.3	47	71.2	0	0.0	60	1	1.7	23	38.3	36	60.0	0	0.0
	PI(D21)	65	2	3.1	22	33.8	41	63.1	0	0.0	57	0	0.0	23	40.4	34	59.6	0	0.0
	PII(D42)	58	3	5.2	18	31.0	37	63.8	0	0.0	56	2	3.6	20	35.7	34	60.7	0	0.0
BUN	Screening	66	2	3.0	2	3.0	58	87.9	4	6.1	63	2	3.2	0	0.0	55	87.3	6	9.5
	PI(D7)	66	1	1.5	0	0.0	62	93.9	3	4.5	60	1	1.7	0	0.0	55	91.7	4	6.7
	PI(D21)	65	2	3.1	0	0.0	59	90.8	4	6.2	57	0	0.0	0	0.0	54	94.7	3	5.3
	PII(D42)	58	3	5.2	1	1.7	49	84.5	5	8.6	56	2	3.6	0	0.0	49	87.5	5	8.9
		Flu2/F1 Group N = 64										Flu2/F2 Group N = 63							
			Unknown		Below		Within		Above			Unknown		Below		Within		Above	
Laboratory parameter	Timing	N	n	%	n	%	n	%	n	%	N	n	%	n	%	n	%	n	%
ALAT	Screening	63	3	4.8	0	0.0	59	93.7	1	1.6	63	0	0.0	0	0.0	63	100	0	0.0
	PI(D7)	60	0	0.0	0	0.0	59	98.3	1	1.7	61	1	1.6	0	0.0	59	96.7	1	1.6
	PI(D21)	59	4	6.8	0	0.0	55	93.2	0	0.0	61	0	0.0	0	0.0	61	100	0	0.0
	PII(D42)	60	0	0.0	0	0.0	59	98.3	1	1.7	58	1	1.7	0	0.0	56	96.6	1	1.7
ASAT	Screening	63	3	4.8	0	0.0	59	93.7	1	1.6	63	0	0.0	0	0.0	63	100	0	0.0
	PI(D7)	60	0	0.0	0	0.0	57	95.0	3	5.0	61	1	1.6	0	0.0	58	95.1	2	3.3
	PI(D21)	59	4	6.8	0	0.0	53	89.8	2	3.4	61	1	1.6	0	0.0	60	98.4	0	0.0
	PII(D42)	60	0	0.0	0	0.0	57	95.0	3	5.0	58	1	1.7	0	0.0	57	98.3	0	0.0
Bilirubin	Screening	63	3	4.8	0	0.0	60	95.2	0	0.0	63	0	0.0	0	0.0	63	100	0	0.0
	PI(D7)	60	0	0.0	0	0.0	60	100	0	0.0	61	1	1.6	0	0.0	60	98.4	0	0.0
	PI(D21)	59	4	6.8	0	0.0	55	93.2	0	0.0	61	0	0.0	0	0.0	61	100	0	0.0
	PII(D42)	60	0	0.0	0	0.0	60	100	0	0.0	58	1	1.7	0	0.0	57	98.3	0	0.0
Bilirubin Conjugated / Direct	Screening	63	3	4.8	0	0.0	60	95.2	0	0.0	63	0	0.0	0	0.0	63	100	0	0.0
	PI(D7)	60	0	0.0	0	0.0	60	100	0	0.0	61	1	1.6	0	0.0	60	98.4	0	0.0
	PI(D21)	59	4	6.8	0	0.0	55	93.2	0	0.0	61	0	0.0	0	0.0	61	100	0	0.0
	PII(D42)	60	0	0.0	0	0.0	60	100	0	0.0	58	1	1.7	0	0.0	57	98.3	0	0.0
Creatinine	Screening	63	3	4.8	17	27.0	43	68.3	0	0.0	63	0	0.0	15	23.8	48	76.2	0	0.0
	PI(D7)	60	0	0.0	19	31.7	41	68.3	0	0.0	61	1	1.6	17	27.9	43	70.5	0	0.0
	PI(D21)	59	4	6.8	15	25.4	40	67.8	0	0.0	61	0	0.0	17	27.9	44	72.1	0	0.0
	PII(D42)	60	0	0.0	16	26.7	44	73.3	0	0.0	58	1	1.7	13	22.4	44	75.9	0	0.0
BUN	Screening	63	3	4.8	0	0.0	55	87.3	5	7.9	63	0	0.0	0	0.0	58	92.1	5	7.9
	PI(D7)	60	0	0.0	0	0.0	51	85.0	9	15.0	61	1	1.6	1	1.6	51	83.6	8	13.1
	PI(D21)	59	4	6.8	0	0.0	49	83.1	6	10.2	61	0	0.0	0	0.0	52	85.2	9	14.8
	PII(D42)	60	0	0.0	0	0.0	54	90.0	6	10.0	58	1	1.7	0	0.0	50	86.2	7	12.1
<p>N = number of subjects with laboratory results for the specified time point and laboratory parameter n/% = number/percentage of subjects in a given category Unknown = value unknown for the specified time point and laboratory parameter Below = value below the laboratory reference range defined for the specified time point and laboratory parameter Within = value within the laboratory reference range defined for the specified time point and laboratory parameter Above = value above the laboratory reference range defined for the specified time point and laboratory parameter Screening = Day 0 PI(D7) = Post-vaccination at Day 7 PI(D21) = Post-vaccination at Day 21 PII(D42) = Post-vaccination at Day 42 ALAT= Alanine aminotransferase</p>																			

ASAT= Aspartate aminotransferase				
BUN= Blood urea nitrogen				
Secondary Outcome Variable(s): Percentage of subjects reporting the occurrence of unsolicited adverse events with medically attended visit, within the 42-day (Days 0-41) post-vaccination period (Total Vaccinated cohort)				
	Flu1/F1 Group N = 67	Flu1/F2 Group N = 64	Flu2/F1 Group N = 64	Flu2/F2 Group N = 63
Subjects with any MAE(s), n (%)	18 (26.9)	14 (21.9)	8 (12.5)	9 (14.3)
Pancytopenia	-	-	-	1 (1.6)
Eye discharge	1 (1.5)	-	-	-
Chapped lips	1 (1.5)	-	-	-
Diarrhoea	-	1 (1.6)	1 (1.6)	-
Gingival swelling	1 (1.5)	-	-	-
Vomiting	-	1 (1.6)	-	2 (3.2)
Chills	-	-	-	1 (1.6)
Influenza like illness	-	-	1 (1.6)	-
Pyrexia	1 (1.5)	1 (1.6)	2 (3.1)	1 (1.6)
Food allergy	-	-	-	1 (1.6)
Bronchitis	3 (4.5)	-	-	-
Croup infectious	2 (3.0)	-	1 (1.6)	-
Ear infection	1 (1.5)	-	-	-
Eye infection	1 (1.5)	1 (1.6)	-	-
Gingival infection	1 (1.5)	-	-	-
Lower respiratory tract infection	-	1 (1.6)	-	1 (1.6)
Mycoplasma infection	-	-	1 (1.6)	-
Otitis media	-	3 (4.7)	-	3 (4.8)
Pharyngitis streptococcal	1 (1.5)	-	-	-
Pneumonia	-	1 (1.6)	-	-
Respiratory tract infection viral	-	1 (1.6)	-	-
Swine influenza	1 (1.5)	-	1 (1.6)	-
Tonsillitis	1 (1.5)	1 (1.6)	-	-
Upper respiratory tract infection	3 (4.5)	2 (3.1)	-	1 (1.6)
Viral infection	1 (1.5)	1 (1.6)	-	-
Viral upper respiratory tract infection	-	1 (1.6)	1 (1.6)	-
Wound	-	1 (1.6)	-	-
Hepatic enzyme increased	-	-	1 (1.6)	-
Neutrophil count increased	-	-	-	1 (1.6)
Sleep disorder	-	-	1 (1.6)	-
Vaginal discharge	-	2 (3.1)	-	-
Asthma	-	-	-	1 (1.6)
Cough	2 (3.0)	4 (6.3)	-	1 (1.6)
Dyspnoea	1 (1.5)	-	-	-
Oropharyngeal pain	1 (1.5)	-	-	-
Rhinorrhoea	-	1 (1.6)	-	-
Eczema	-	-	1 (1.6)	-
-: Adverse event absent				
Secondary Outcome Variable(s): Percentage of subjects reporting the occurrence of unsolicited adverse events with potential Immune-Mediated Disorders, within the 42-day (Days 0-41) post-vaccination period (Total Vaccinated cohort)				
	Flu1/F1 Group N = 67	Flu1/F2 Group N = 64	Flu2/F1 Group N = 64	Flu2/F2 Group N = 63
Subjects with any pIMDs, n (%)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Safety results: Number (%) of subjects with unsolicited adverse events (Total Vaccinated cohort)				
Most frequent adverse events - On-Therapy (occurring within day 0-41 following vaccination)	Flu1/F1 Group N = 67	Flu1/F2 Group N = 64	Flu2/F1 Group N = 64	Flu2/F2 Group N = 63
Subjects with any AE(s), n (%)	33 (49.3)	35 (54.7)	25 (39.1)	23 (36.5)

Cough	4 (6.0)	7 (10.9)	6 (9.4)	6 (9.5)
Vomiting	3 (4.5)	5 (7.8)	2 (3.1)	5 (7.9)
Nasopharyngitis	-	7 (10.9)	2 (3.1)	5 (7.9)
Pyrexia	-	5 (7.8)	4 (6.3)	3 (4.8)
Rhinorrhoea	3 (4.5)	6 (9.4)	-	3 (4.8)
Diarrhoea	-	-	2 (3.1)	3 (4.8)
Upper respiratory tract infection	3 (4.5)	-	2 (3.1)	-
Bronchitis	3 (4.5)	-	-	-
Nasal congestion	3 (4.5)	-	-	-
Otitis media	-	-	-	3 (4.8)
Oropharyngeal pain	-	-	2 (3.1)	-
- : Adverse event absent or not meeting the selected rule: more than 30 subjects per treatment group and > 3 groups: only the 5 most frequent events in each treatment group are to be listed.				
Safety results: Number (%) of subjects with serious adverse events (Total Vaccinated cohort)				
Serious adverse event, n (%) [n considered by the investigator to be related to study medication]				
All SAEs	Flu1/F1 Group N = 67	Flu1/F2 Group N = 64	Flu2/F1 Group N = 64	Flu2/F2 Group N = 63
Subjects with any SAE(s), n (%) [n assessed by investigator as related]	*1* [0]	*1* [0]	*1* [0]	*1* [0]
Fatal SAEs	Flu1/F1 Group N = 67	Flu1/F2 Group N = 64	Flu2/F1 Group N = 64	Flu2/F2 Group N = 63
Subjects with fatal SAE(s), n (%) [n assessed by investigator as related]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]
n = n subjects reported in one group and none in the other groups. The case remains blinded since the study is ongoing. SAE preferred term : Tonsillitis				

Conclusion:
21 days after the first dose (Day 21), the SCR was 94.7%, 95.7%, 74.5%, and 59.6% in groups Flu1/F1, Flu1/F2, Flu2/F1, and Flu2/F2 Groups, respectively. The SPR was 98.2%, 98.0%, 76.4%, and 64.9% in groups Flu1/F1, Flu1/F2, Flu2/F1, and Flu2/F2 Groups, respectively. The GMFR was 35.9, 40.8, 13.2 and 7.6, in groups Flu1/F1, Flu1/F2, Flu2/F1 and Flu2/F2 Groups, respectively. At the same timepoint, the GMTs of HI antibodies against the vaccine-homologous virus were 386.4, 270.1, 138.4 and 83.4 in groups Flu1/F1, Flu1/F2, Flu2/F1 and Flu2/F2 Groups, respectively.
21 days after the second dose (Day 42), the SCR was 100%, 97.5%, 100%, and 86.4% in groups Flu1/F1, Flu1/F2, Flu2/F1, and Flu2/F2 Groups, respectively. The SPR was 100%, 100%, 100%, and 93.2% in groups Flu1/F1, Flu1/F2, Flu2/F1, and Flu2/F2 Groups, respectively. The GMFR was 155.3, 217.2, 44.2 and 24.1, in groups Flu1/F1, Flu1/F2, Flu2/F1 and Flu2/F2 Groups, respectively. At the same timepoint, the GMTs of HI antibodies against the vaccine-homologous virus were 1444.4, 1238.5, 413.5 and 228.0 in groups Flu1/F1, Flu1/F2, Flu2/F1 and Flu2/F2 Groups, respectively.
During the 21-day follow-up period after each dose, at least one unsolicited AE was reported for 33 (49.3%) subjects of Flu1/F1 Group, 35 (54.7%) subjects of Flu1/F2 Group, 25 (39.1%) subjects of Flu2/F1 Group and 23 (36.5%) subjects of Flu2/F2 Group.
Up to Day 42, one SAE was reported and was assessed by the investigator as unrelated to study vaccination.

Publications: None

Date updated: 31 May 2010