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Study No.: 113519 (FLU Q-PAN H1N1-016)
Title: Immunogenicity and safety study of GSK Biologicals' influenza candidate vaccine GSK2340274A. GSK2340274A (Flu): GlaxoSmithKline (GSK) Biologicals' A/California/7/2009 (H1N1)v-like vaccine adjuvanted with AS03A.
Rationale: The aim of the study was to assess the immunogenicity and safety of Flu vaccine in healthy Japanese adults between the ages of 20 and 64. This summary presents results up to Day 42 and will be updated when additional data become available.
Phase: II
Study Period: 13 October 2009 to 16 December 2009 (Data lock point Day 42)
Study Design: Open, multicentre, single group study. Subjects were stratified by age: between 20 and 40 years inclusive and 41 to 64 years inclusive (ratio 1:1).
Centres: 2 centres in Japan
Indication: Immunization against A/California/7/2009 (H1N1)v-like influenza
Treatment: There was one study group. All subjects in the Flu Group received 2 vaccine doses, injected intramuscularly in the deltoid region of the non-dominant arm at Day 0 and of the dominant arm at Day 21.
Objectives: To demonstrate that administration of Flu vaccine results in an immune response to the vaccine-homologous virus that meets or exceeds the U.S. Food and Drug Administration (FDA), Centre for Biologics Evaluation and Research (CBER) and the European Medicines Agency (EMA), 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) titres ≥ 40 (potential seroprotection rate or SPR), and geometric mean fold rise (GMFR) at 21 days after one or two doses of Flu vaccine in adults 20 to 64 (or 20 to 60 for CHMP criteria) years of age. The CBER Criteria was fulfilled for this study if after dose 1 or dose 2: <ul style="list-style-type: none"> the lower 97.5% confidence interval for SCR was $> 40\%$ in subjects 20 to 64 years of age, and the lower 97.5% confidence interval for SPR was $> 70\%$ in subjects 20 to 64 years of age. The CHMP Criteria was fulfilled for this study if after dose 1 or dose 2: <ul style="list-style-type: none"> the point estimate for SCR was $> 40\%$ in subjects 20 to 60 years of age, and the post-vaccination point estimate for SPR was $> 70\%$ in subjects 20 to 60 years of age, and the point estimate for GMFR was > 2.5 in subjects 20 to 60 years of age.
Primary Outcome/Efficacy Variable: For the humoral immune response in terms of HI antibodies against A/California/7/2009 (H1N1)v-like antigen, the following parameters were calculated with 97.5% Confidence Intervals (CIs), in all subjects <ul style="list-style-type: none"> Geometric mean titres (GMTs) and seropositivity rates of H1N1 HI antibody titres (Day 0, Day 21 and Day 42) SCR* at Day 21 and Day 42 SPR** at Day 21 and Day 42 GMFR*** at Day 21 and Day 42 *SCR is defined as the percentage of vaccinees that have either a pre-vaccination titre $< 1:10$ and a post-vaccination titre $\geq 1:40$ or a pre-vaccination titre $\geq 1:10$ and at least a four-fold increase in post-vaccination titre. **SPR is defined as the percentage of vaccinees with a serum HI titre $\geq 1:40$, that usually is accepted as indicating protection. ***GMFR, also called seroconversion factor (SCF), is defined the fold increase in serum HI GMTs post-vaccination compared to pre-vaccination.
Secondary Outcome/Efficacy Variable(s): <i>Safety</i> <ul style="list-style-type: none"> Occurrence, duration and intensity of each solicited local symptom (any and grade 3) within 7 days (Day 0 – Day 6) after each vaccination. Occurrence, duration, intensity and relation to vaccination of each solicited general symptom (any, grade 3 and related) within 7 days (Day 0 – Day 6) after each vaccination. Occurrence, intensity and relationship to vaccination of unsolicited adverse events (AEs) within 21 days after the first vaccination and within 63 days after the second vaccination (Day 0 to Day 20 and Day 21 to Day 84#),

according to the Medical Dictionary for Regulatory Activities (MedDRA) classification.

- Occurrence and relationship to vaccination of adverse events of special interest (AESIs) and serious adverse events (SAEs) during the entire study period (up to Day 182) #.

Immunogenicity

For the humoral immune response in terms of HI antibodies against A/California/7/2009 (H1N1)v-like antigen the following parameters were calculated with 95% CIs, in all subjects:

- GMTs and seropositivity rates at Days 0, 21, 42 and 182#
- SCR at Days 21, 42 and 182#
- SPR at Days 0, 21, 42 and 182#
- GMFR (SCF) at Days 21, 42 and 182#

For the humoral immune response in terms of neutralizing antibodies against A/California/7/2009 (H1N1)v-like antigen the following parameters were calculated with 95% CIs, in all subjects: §

- GMTs and seropositivity rates at Days 0, 21, 42 and 182
- SCR at Days 21, 42 and 182

At the time of writing this summary, data were available up to Day 42 only. This summary will be updated when additional results become available.

§ Not available at the time of writing this summary.

Statistical Methods:

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

- The Total Vaccinated cohort included all vaccinated subjects.
- 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), who received the 2 vaccine doses and for whom assay results for antibodies against vaccine antigen were available.

Analysis of immunogenicity:

The analysis was done on the ATP cohort for immunogenicity.

The analysis of immunogenicity was done as a descriptive analysis of the humoral immune response in adults 20-64 years of age. The cohort for evaluation of the CHMP (subjects from 20 to 60 years of age) and that one for CBER regulatory acceptance criteria (subjects from 20 to 64 years of age) were the same as the maximum age of the enrolled subjects was 59 years.

For the humoral immune response in terms of H1N1 HI antibodies the following parameters were computed with 97.5% CIs for primary variables and with 95% CIs and by age strata (between 20 and 40 years and between 41 and 64 years) for secondary variables:

- Seropositivity rates and GMTs of H1N1 HI antibody titres at Day 0, Day 21 and Day 42.
- SCR at Day 21 and Day 42.
- SPR at Day 0, Day 21 and Day 42.
- SCF at Day 21 and Day 42.

Analysis of safety:

The incidence of solicited local and general symptoms occurring during the 7 days after each vaccination dose was tabulated with exact 95% CI. The same calculations were performed for symptoms of any intensity and those with intensity of Grade 3, as well as for solicited general symptoms with relationship to vaccination. All solicited local symptoms were assessed as causally related.

The percentage of subjects with at least one report of an unsolicited AEs classified by MedDRA preferred terms up to 21 days after each dose of vaccine was tabulated with exact 95% CI for the vaccine group. The same tabulation was performed for Grade 3 unsolicited AEs and for unsolicited AEs that were assessed by the investigator as possibly related to vaccination.

SAEs and AESIs were collected and summarized through the follow-up period (Day 0-Day 42).

Study Population: Healthy Japanese male and female adults 20 to 64 years of age at time of the first vaccination, inclusive, were enrolled in the study. If the subject was female and of childbearing potential, she had to be abstinent or to have used contraceptive precautions for 30 days prior to vaccination; she has to have a negative pregnancy test at study entry and had to agree to continue contraceptive precautions for 2 months after completion of the vaccination series. Written informed consent was obtained from the subject prior to study entry.

Number of Subjects:	Flu Group	
	20-40 years	41-64 years
Planned, N	50	50
Randomised, N (Total Vaccinated cohort)	50	50
Completed up to Day 21, n (%)	50 (100)	50 (100)

Completed up to Day 42, n (%)				50 (100)				50 (100)			
Total Number Subjects Withdrawn, n (%)				0 (0.0)				0 (0.0)			
Withdrawn due to Adverse Events n (%)				0 (0.0)				0 (0.0)			
Withdrawn due to Lack of Efficacy n (%)				Not applicable				Not applicable			
Withdrawn for other reasons n (%)				0 (0.0)				0 (0.0)			
Demographics				Flu Group							
				20-40 years				41-64 years			
N (Total Vaccinated cohort)				50				50			
Females: Males				64:36							
Mean Age, years (SD)				39.3 (11.65)							
Asian - Japanese heritage, n (%)				100 (100)							
Primary Efficacy Results: Seropositivity rates and GMTs for HI antibodies against Flu A/CAL/7/09.HA1 (ATP cohort for immunogenicity, aged 20-64 years)											
				≥ 1:10				GMT			
				97.5% CI				97.5% CI			
Antibody against	Group	Timing	N	n	%	LL	UL	value	LL	UL	
Flu A/CAL/7/09.HA1	Flu	PRE	100	43	43.0	31.9	54.7	8.8	7.3	10.5	
		PI(D21)	100	100	100	95.7	100	230.3	177.7	298.4	
		PII(D42)	100	100	100	95.7	100	485.0	420.3	559.7	
<p>GMT = geometric mean antibody titre calculated on all subjects N = number of subjects with available results n/% = number/percentage of subjects with titre within the specified range 97.5% CI = 97.5% confidence interval; LL = Lower Limit, UL = Upper Limit PRE= Pre-vaccination, Day 0 PI(D21)= Post-dose 1, Day 21 PII(D42)= Post-dose 2, Day 42</p>											
Primary Efficacy Results: SCR for HI antibodies against Flu A/CAL/7/09.HA (ATP cohort for immunogenicity, aged 20-64 years)											
				SCR							
				97.5% CI							
Antibody against	Group	Timing	N	n	%	LL	UL				
Flu A/CAL/7/09.HA1	Flu	PI(D21)	100	94	94.0	86.4	98.1				
		PII(D42)	100	100	100	95.7	100				
<p>Seroconversion defined as: For initially seronegative subjects, antibody titre ≥ 1:40 after vaccination For initially seropositive subjects, antibody titre after vaccination ≥ 4 fold the pre-vaccination antibody titre N = Number of subjects with pre- and post-vaccination results available n/% = Number/percentage of seroconverted subjects 97.5% CI = 97.5% confidence interval, LL = Lower Limit, UL = Upper Limit PI(D21)= Post-dose 1, Day 21 PII(D42)= Post-dose 2, Day 42</p>											
Primary Efficacy Results: SPR for HI antibodies against Flu A/CAL/7/09.HA1 (ATP cohort for immunogenicity, aged 20-64 years)											
				SPR							
				97.5% CI							
Antibody against	Group	Timing	N	n	%	LL	UL				
Flu A/CAL/7/09.HA1	Flu	PRE	100	6	6.0	1.9	13.6				
		PI(D21)	100	95	95.0	87.7	98.6				
		PII(D42)	100	100	100	95.7	100				
<p>N = Number of subjects with available results n/% = Number/percentage of seroprotected subjects (HI titre ≥ 1:40) 97.5% CI = 97.5% confidence interval, LL = Lower Limit, UL = Upper Limit PRE= Pre-vaccination, Day 0 PI(D21)= Post-dose 1, Day 21</p>											

PII(D42)= Post-dose 2, Day 42											
Primary Efficacy Results: SCF for HI antibody titre (ATP cohort for immunogenicity, aged 20-64 years)											
										SCF	
										97.5% CI	
Vaccine strain	Group	Timing	N	Value	LL	UL					
Flu A/CAL/7/09.HA1 Ab (1/DIL)	Flu	PI(D21)	100	26.3	20.6	33.5					
		PII(D42)	100	55.4	45.6	67.2					
<p>N = Number of subjects with pre- and post-vaccination results available SCF = Seroconversion Factor or geometric mean ratio (mean[log10(POST/PRE)]) 97.5% CI = 97.5% confidence interval, LL = Lower Limit, UL = Upper Limit PI(D21)= Post-dose 1, Day 21 PII(D42)= Post-dose 2, Day 42</p>											
Secondary Outcome Variable(s): Seropositivity rates and GMTs for HI antibodies against Flu A/CAL/7/09.HA1 by age strata (ATP cohort for immunogenicity)											
					≥ 1:10			GMT			
					95% CI			95% CI			
Antibody against	Group	Sub-group	Timing	N	n	%	LL	UL	value	LL	UL
Flu A/CAL/7/09.HA1	Flu	20-40y	PRE	50	22	44.0	30.0	58.7	8.9	7.1	11.1
			PI(D21)	50	50	100	92.9	100	258.3	191.3	348.7
			PII(D42)	50	50	100	92.9	100	505.6	427.9	597.6
		41-64y	PRE	50	21	42.0	28.2	56.8	8.6	6.8	10.9
			PI(D21)	50	50	100	92.9	100	205.3	145.4	290.0
			PII(D42)	50	50	100	92.9	100	465.3	384.5	563.0
<p>20-40y = Subjects aged between 20 years and 40 years 41-64y = Subjects aged between 20 years and 64 years GMT = geometric mean antibody titre calculated on all subjects N = number of subjects with available results n/% = number/percentage of subjects with titre within the specified range 95% CI = 95% confidence interval; LL = Lower Limit, UL = Upper Limit PRE= Pre-vaccination, Day 0 PI(D21)= Post-dose 1, Day 21 PII(D42)= Post-dose 2, Day 42</p>											
Secondary Outcome Variable(s): SCR for HI antibodies against Flu A/CAL/7/09.HA1 by age strata (ATP cohort for immunogenicity)											
										SCR	
										95% CI	
Antibody against	Group	Sub-group	Timing	N	n	%	LL	UL			
Flu A/CAL/7/09.HA1	Flu	20-40y	PI(D21)	50	50	100	92.9	100			
			PII(D42)	50	50	100	92.9	100			
		41-64y	PI(D21)	50	44	88.0	75.7	95.5			
			PII(D42)	50	50	100	92.9	100			
<p>20-40y = Subjects aged between 20 years and 40 years 41-64y = Subjects aged between 20 years and 64 years Seroconversion defined as: For initially seronegative subjects, antibody titre ≥ 1:40 after vaccination For initially seropositive subjects, antibody titre after vaccination ≥ 4 fold the pre-vaccination antibody titre 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 PI(D21)= Post-dose 1, Day 21 PII(D42)= Post-dose 2, Day 42</p>											
Secondary Outcome Variable(s): SPR for HI antibodies against Flu A/CAL/7/09.HA1 by age strata (ATP cohort for immunogenicity)											
										SPR	

							95% CI	
Antibody against	Group	Sub-group	Timing	N	n	%	LL	UL
Flu A/CAL/7/09.HA1	Flu	20-40y	PRE	50	3	6.0	1.3	16.5
			PI(D21)	50	50	100	92.9	100
			PII(D42)	50	50	100	92.9	100
		41-64y	PRE	50	3	6.0	1.3	16.5
			PI(D21)	50	45	90.0	78.2	96.7
			PII(D42)	50	50	100	92.9	100
20-40y = Subjects aged between 20 years and 40 years 41-64y = Subjects aged between 20 years and 64 years N = Number of subjects with available results n/% = Number/percentage of seroprotected subjects (HI titre ≥ 1:40) 95% CI = 95% confidence interval, LL = Lower Limit, UL = Upper Limit PRE= Pre-vaccination, Day 0 PI(D21)= Post-dose 1, Day 21 PII(D42)= Post-dose 2, Day 42								
Secondary Outcome Variable(s): SCF for HI antibodies by age strata (ATP cohort for immunogenicity)								
					SCF			
					95% CI			
Vaccine strain	Group	Sub-group	Timing	N	Value	LL	UL	
Flu A/CAL/7/09.HA1 Ab (1/DIL)	Flu	20-40y	PI(D21)	50	29.1	21.8	38.9	
			PII(D42)	50	57.0	44.3	73.2	
		41-64y	PI(D21)	50	23.8	17.4	32.6	
			PII(D42)	50	53.9	42.6	68.1	
20-40y = Subjects aged between 20 years and 40 years 41-64y = Subjects aged between 20 years and 64 years N = Number of subjects with pre- and post-vaccination results available SCF = Seroconversion Factor or geometric mean ratio (mean[log10(POST/PRE)]) 95% CI = 95% confidence interval, LL = Lower Limit, UL = Upper Limit PI(D21)= Post-dose 1, Day 21 PII(D42)= Post-dose 2, Day 42								
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)								
					Flu Group			
					95 % CI			
Symptom		Intensity	N	n	%	LL	UL	
Dose 1								
Pain	Any		100	98	98.0	93.0	99.8	
	Grade 3		100	3	3.0	0.6	8.5	
Redness	Any		100	7	7.0	2.9	13.9	
	> 100 mm		100	1	1.0	0.0	5.4	
Swelling	All		100	17	17.0	10.2	25.8	
	> 100 mm		100	2	2.0	0.2	7.0	
Dose 2								
Pain	Any		100	93	93.0	86.1	97.1	
	Grade 3		100	2	2.0	0.2	7.0	
Redness	Any		100	8	8.0	3.5	15.2	
	> 100 mm		100	0	0.0	0.0	3.6	
Swelling	Any		100	17	17.0	10.2	25.8	
	> 100 mm		100	1	1.0	0.0	5.4	
Across doses								
Pain	Any		100	99	99.0	94.6	100	
	Grade 3		100	5	5.0	1.6	11.3	
Redness	Any		100	13	13.0	7.1	21.2	
	> 100 mm		100	1	1.0	0.0	5.4	

Swelling	Any	100	24	24.0	16.0	33.6
	> 100 mm	100	2	2.0	0.2	7.0
<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 local symptom regardless of intensity grade Grade 3 pain= Significant pain at rest; prevented normal activities as assessed by inability to attend/do work or school</p>						
Secondary Outcome Variable(s): Number of days with local symptoms during the solicited post-vaccination period (Total Vaccinated cohort)						
Solicited symptom	Dose	Group	N	Mean	Median	
Pain	Dose 1	Flu	98	3.9	4.0	
	Dose 2	Flu	93	3.7	3.0	
	Overall/dose	Flu	191	3.8	4.0	
Redness	Dose 1	Flu	7	3.6	3.0	
	Dose 2	Flu	8	3.1	3.0	
	Overall/dose	Flu	15	3.3	3.0	
Swelling	Dose 1	Flu	17	3.5	3.0	
	Dose 2	Flu	17	3.7	3.0	
	Overall/dose	Flu	34	3.6	3.0	
N = number of doses with the symptom						
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 (Total Vaccinated cohort)						
			Flu Group			
			95 % CI			
Symptom	Intensity/ Relationship	N	n	%	LL	UL
Dose 1						
Fatigue	Any	100	46	46.0	36.0	56.3
	Grade 3	100	2	2.0	0.2	7.0
	Related	100	45	45.0	35.0	55.3
Headache	Any	100	35	35.0	25.7	45.2
	Grade 3	100	1	1.0	0.0	5.4
	Related	100	34	34.0	24.8	44.2
Joint pain at other location	Any	100	14	14.0	7.9	22.4
	Grade 3	100	0	0.0	0.0	3.6
	Related	100	14	14.0	7.9	22.4
Muscle aches	Any	100	44	44.0	34.1	54.3
	Grade 3	100	1	1.0	0.0	5.4
	Related	100	44	44.0	34.1	54.3
Shivering	Any	100	19	19.0	11.8	28.1
	Grade 3	100	0	0.0	0.0	3.6
	Related	100	19	19.0	11.8	28.1
Sweating	Any	100	7	7.0	2.9	13.9
	Grade 3	100	0	0.0	0.0	3.6
	Related	100	7	7.0	2.9	13.9
Temperature/(Axillary)	≥ 37.5°C	100	2	2.0	0.2	7.0
	≥ 39.0°C	100	0	0.0	0.0	3.6
	Related	100	2	2.0	0.2	7.0
Dose 2						
Fatigue	Any	100	54	54.0	43.7	64.0
	Grade 3	100	3	3.0	0.6	8.5
	Related	100	54	54.0	43.7	64.0
Headache	Any	100	39	39.0	29.4	49.3
	Grade 3	100	2	2.0	0.2	7.0
	Related	100	37	37.0	27.6	47.2

Joint pain at other location	Any	100	30	30.0	21.2	40.0
	Grade 3	100	1	1.0	0.0	5.4
	Related	100	30	30.0	21.2	40.0
Muscle aches	Any	100	51	51.0	40.8	61.1
	Grade 3	100	0	0.0	0.0	3.6
	Related	100	51	51.0	40.8	61.1
Shivering	Any	100	29	29.0	20.4	38.9
	Grade 3	100	4	4.0	1.1	9.9
	Related	100	29	29.0	20.4	38.9
Sweating	Any	100	9	9.0	4.2	16.4
	Grade 3	100	0	0.0	0.0	3.6
	Related	100	9	9.0	4.2	16.4
Temperature/(Axillary)	≥ 37.5°C	100	7	7.0	2.9	13.9
	≥ 39.0°C	100	1	1.0	0.0	5.4
	Related	100	6	6.0	2.2	12.6

Across doses

Fatigue	Any	100	69	69.0	59.0	77.9
	Grade 3	100	5	5.0	1.6	11.3
	Related	100	68	68.0	57.9	77.0
Headache	Any	100	51	51.0	40.8	61.1
	Grade 3	100	3	3.0	0.6	8.5
	Related	100	49	49.0	38.9	59.2
Joint pain at other location	Any	100	33	33.0	23.9	43.1
	Grade 3	100	1	1.0	0.0	5.4
	Related	100	33	33.0	23.9	43.1
Muscle aches	Any	100	59	59.0	48.7	68.7
	Grade 3	100	1	1.0	0.0	5.4
	Related	100	59	59.0	48.7	68.7
Shivering	Any	100	37	37.0	27.6	47.2
	Grade 3	100	4	4.0	1.1	9.9
	Related	100	37	37.0	27.6	47.2
Sweating	Any	100	13	13.0	7.1	21.2
	Grade 3	100	0	0.0	0.0	3.6
	Related	100	13	13.0	7.1	21.2
Temperature/(Axillary)	≥ 37.5°C	100	7	7.0	2.9	13.9
	≥ 39.0°C	100	1	1.0	0.0	5.4
	Related	100	6	6.0	2.2	12.6

N= number of subjects with the 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 symptom regardless of intensity grade or relationship to vaccination

Grade 3= general symptom that prevented normal everyday activities as assessed by inability to attend/do work or school, or required intervention of a physician/healthcare provider

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

Secondary Outcome Variable(s): Number of days with general symptoms during the solicited post-vaccination period (Total Vaccinated cohort)

Solicited symptom	Dose	Group	N	Mean	Median
Fatigue	Dose 1	Flu	46	2.2	2.0
	Dose 2	Flu	54	2.2	2.0
	Overall/dose	Flu	100	2.2	2.0
Headache	Dose 1	Flu	35	1.8	1.0
	Dose 2	Flu	39	2.0	1.0
	Overall/dose	Flu	74	1.9	1.0
Joint pain at other location	Dose 1	Flu	14	1.9	2.0

	Dose 2	Flu	30	2.0	2.0
	Overall/dose	Flu	44	2.0	2.0
Muscle aches	Dose 1	Flu	44	3.0	3.0
	Dose 2	Flu	51	3.1	3.0
	Overall/dose	Flu	95	3.0	3.0
Sweating	Dose 1	Flu	7	2.0	1.0
	Dose 2	Flu	9	1.3	1.0
	Overall/dose	Flu	16	1.6	1.0
Shivering	Dose 1	Flu	19	1.4	1.0
	Dose 2	Flu	29	1.4	1.0
	Overall/dose	Flu	48	1.4	1.0
Temperature	Dose 1	Flu	2	1.0	1.0
	Dose 2	Flu	7	1.1	1.0
	Overall/dose	Flu	9	1.1	1.0
N = number of doses with the symptom					
Secondary Outcome Variable(s): Number (%) of subjects with adverse events of specific interest up to Day 42 (Total Vaccinated cohort)					
Most frequent AESIs -			Flu Group N = 100		
Subjects with any AESI(s), n (%)			0 (0.0)		
Subjects with related AESI(s), n (%)			0 (0.0)		
Related= event assessed by the investigator as causally related to the study vaccination					
Safety results: Number (%) of subjects with unsolicited adverse events within the 42-day (Days 0-41) post-vaccination period (Total Vaccinated cohort)					
Most frequent adverse events - On-Therapy (occurring within day 0-20 following vaccination)			Flu Group N = 100		
Subjects with any AE(s), n (%)			35 (35.0)		
Subjects with grade 3 AE(s), n (%)			0 (0.0)		
Subjects with related AE(s), n (%)			18 (18.0)		
Diarrhoea			4 (4.0)		
Headache			3 (3.0)		
Injection site haemorrhage			3 (3.0)		
Nasopharyngitis			3 (3.0)		
Nausea			3 (3.0)		
Oropharyngeal pain			3 (3.0)		
Pruritus			3 (3.0)		
Pyrexia			3 (3.0)		
Abdominal pain			2 (2.0)		
Decreased appetite			2 (2.0)		
Dizziness			2 (2.0)		
Rash			2 (2.0)		
Rhinorrhoea			2 (2.0)		
Stomatitis			2 (2.0)		
Tinnitus			2 (2.0)		
Upper respiratory tract infection			2 (2.0)		
Grade 3= event that prevented normal activities					
Related= event assessed by the investigator as causally related to the study vaccination					
Counting rule: more than 30 subjects per treatment group and ≤ 3 groups: display the most frequent 10 events					
Safety results: Number (%) of subjects with serious adverse events up to Day 42 (Total Vaccinated cohort)					
Serious adverse event, n (%) [n considered by the investigator to be related to study medication]					
All SAEs			Flu Group N= 100		
Subjects with any SAE(s), n (%) [n assessed by the investigator as related]			0 (0.0) [0]		
Fatal SAEs			Flu Group		

	N= 100
Subjects with fatal SAE(s), n (%) [n assessed by the investigator as related]	0 (0.0) [0]

Conclusion:

At Day 21 following the first dose of Flu vaccine, all subjects had HI antibodies against A/California/7/2009 (H1N1)v-like $\geq 1:10$, with a GMT of 230.3. At the same time point, SCR was 94.0%, SPR was 95.0% and SCF was of 26.3.

At Day 42 following the second dose of Flu vaccine, all subjects still have HI antibodies against A/California/7/2009 (H1N1)v-like $\geq 1:10$, with a GMT of 485.0. At the same time point, SCR and SPR were 100% and SCF was of 55.4.

During the 42-day follow-up period after the second dose of Flu vaccine, 35 (35.0%) subjects reported at least one unsolicited adverse event. No SAEs were reported up to Day 42.

Publications: None

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