The study listed may include approved and non-approved uses, formulations or treatment regimens. The results reported in any single study may not reflect the overall results obtained on studies of a product. Before prescribing any product mentioned in this Register, healthcare professionals should consult prescribing information for the product approved in their country.

Study No.: 108251 (H5N1-010); 108252 (H5N1-021 EXT 010 D180); 111275 (H5N1-010 EXT:MTH12); 111276 (H5N1-010 EXT:MTH24)

Title: A phase II, randomised, open study to evaluate the immunogenicity and safety of a single or double-dose of the pandemic influenza candidate vaccine given following a two-administration schedule (21 days apart) in adults over 60 years of age.

Rationale: The present study was designed to evaluate the immunogenicity and safety of a singleor double dose of 2 formulations of pandemic influenza (H5N1) vaccine identified in study H5N1-007 (106750), adjuvanted or not, for healthy adults over 60 years of age. Further, the persistence of H5N1 influenza antibodies was also evaluated up to 2 years after vaccination. Subjects who had not been vaccinated with an influenza vaccine for the 2006-2007 season received *Fluarix*™ at least 3 weeks before administration of the first dose(s) of the H5N1 vaccine.
H5N1 vaccine: GlaxoSmithKline (GSK) Biologicals' pandemic monovalent influenza vaccine.
Fluarix™ (Flu): GSK Biologicals' seasonal influenza vaccine

Phase: II

Study Period:
108251 (H5N1-010): 17 November 2006 to 27 October 2007
108252 (H5N1-021 EXT 010 D180): 14 June 2007 to 05 March 2008
111275 (H5N1-010 EXT:MTH12): 06 March 2008 to 12 September 2008
111276 (H5N1-010 EXT:MTH24): 09 March 2009 to 14 September 2009

Study Design: Multi-centre, randomised (3:1:3:1), open study with 4 parallel groups

Centres:
108251 and 108252: 12 study centres in 2 countries- 7 in Belgium and 5 in Italy.
111275 and 111276: 7 centres in Belgium.

Indication: Immunisation against influenza A virus with pandemic potential in subjects over 60 years of age.

Treatment: The study groups were as follows:

- Sd/Adj Group: received a single dose of the adjuvanted H5N1 vaccine.
- Sd/NoAdj Group: received a single dose of the non-adjuvanted H5N1 vaccine.
- Dd/Adj Group: received a double dose of the adjuvanted H5N1 vaccine.
- Dd/NoAdj Group: received a double dose of the non-adjuvanted H5N1 vaccine.

Subjects not previously vaccinated with an influenza vaccine for the 2006-2007 season were administered Flu vaccine intramuscularly at least 3 weeks before administration of the first dose(s) of the H5N1 vaccine.
At days 0 and 21, all subjects were administered 1 or 2 doses of H5N1 vaccine intramuscularly, in the deltoid region of the non-dominant arm for the single dose, in each arm for the double dose.

Objectives:

- To evaluate the immunogenicity of the H5N1 vaccine administered as a single or double dose in terms of humoral immune response 21 days after the first and second vaccination (for anti-haemagglutinin [anti-HA] antibody response) and 21 days after the second vaccination (for neutralising antibody response).
- To assess the persistence of antibodies 180 days, one year and two years after the first vaccination with the H5N1 vaccine.

Primary Outcome/Efficacy Variable:
Immunogenicity
For the humoral immune response in terms of H5N1 Haemagglutination-inhibition (HI) antibodies, the following parameters (with 95% confidence intervals [CIs]) were calculated for each group:

- Geometric mean titres (GMTs) of H5N1 antibody titres at Days 0, 21, 42 and 180 for all subjects and in addition, Month 12 and Month 24 for subjects in Belgium.
- Seroconversion rates*§ (SCR) at Days 21, 42 and 180 for all subjects and in addition, Month 12 and Month 24 for subjects in Belgium.
- Seroconversion factors** (SCF) at Days 21, 42 and 180 for all subjects and in addition, Month 12 and Month 24 for subjects in Belgium.
- Seroprotection rates*** (SPR) at Days 0, 21, 42 and 180 for all subjects and in addition, Month 12 and Month 24 for subjects in Belgium.

In addition, humoral immune response in terms of neutralising antibodies was evaluated in a subset of subjects in the adjuvanted groups using the following parameters (with 95% CIs):

- GMTs of H5N1 antibody titres at Days 0, 42 and 180 and in addition, Month 12 and Month 24 for subjects in Belgium.
- SCR*§ at Days 42 and 180 and in addition, Month 12 and Month 24 for subjects in Belgium.

* SCR for anti-HA antibody response was defined as the percentage of vaccinees who had either a pre-vaccination titre < 1:10 and a post-vaccination titre ≥ 1:40 or a pre-vaccination titre ≥ 1:10 and at least a 4-fold increase in post-vaccination titre.
**SCF was defined as the fold increase in serum anti-HA antibody GMTs post-vaccination compared to Day 0.
***SPR was defined as the percentage of vaccinees with a serum anti-HA antibody titre ≥ 1:40 that is usually accepted as indicating protection.
§ SCR for neutralising antibody response was defined as the percentage of vaccinees with a minimum 4-fold increase in neutralising antibody titre at post-vaccination.

Secondary Outcome/Efficacy Variables:

Safety

- Percentage, intensity and relationship to vaccination of solicited local and general signs and symptoms during a 7-day follow-up period (Day 0-6) after each dose of the H5N1 vaccine and overall.
    - Percentage, intensity and relationship to vaccination of unsolicited local and general signs and symptoms during the 21 days following the first vaccination with the H5N1 vaccine (Day of first vaccination and 20 subsequent days)) and during the 30 days following the second vaccination (Day of second vaccination and 29 subsequent days).
- Occurrence of serious adverse events (SAEs) during the entire study period.
- Occurrence of adverse events of specific interest (AESIs) during the entire study (for subjects in Belgium)*.
- Number and percentage of subjects with normal or abnormal values at each scheduled time point (Day 0, Day 2, Day 21, Day 23), for biochemical assessments and for haematological analysis.

* No AESIs were reported during the entire study period.

Immunogenicity

For the cell-mediated immunity (CMI) response evaluation:

The following parameters (with 95% CIs) were calculated at Days 0, 21, 42 and 180 for all subjects and in addition, Month 12 and Month 24 for subjects in Belgium:

- Frequency of influenza-specific Cluster of Differentiation (CD) 4/CD8 T-cells per 10^6 in tests producing at least two different cytokines (CD40 ligand [CD40L], interleukin-2 [IL-2], tumour necrosis factor-alpha [TNF-α], interferon-gamma [IFN-γ]).
- Frequency of influenza-specific CD4/CD8 T-cells per 10^6 in tests producing at least CD40L and another signal molecule (IL-2, IFN-γ, TNF-α).
- Frequency of influenza-specific CD4/CD8 T-cells per 10^6 in tests producing at least IL-2 and another signal molecule (CD40L, IFN-γ, TNF-α).
- Frequency of influenza-specific CD4/CD8 T-cells per 10^6 in tests producing at least TNF-α and another signal molecule (IL-2, IFN-γ, CD40L).
- Frequency of influenza-specific CD4/CD8 T-cells per 10^6 in tests producing at least IFN-γ and another signal molecule (CD40L, IL-2, TNF-α).

Statistical Methods:

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

- The Total Vaccinated Cohort included all vaccinated subjects for whom data were available.
- 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 immunogenicity data were available. This included all subjects for whom assay results for antibodies against at least one study vaccine antigen component after vaccination were available.
- The ATP cohort for persistence included all evaluable subjects who met all eligibility criteria, who complied with the protocol procedures during the entire study period and with the intervals defined in the protocol at Day 180, at Month 12 and at Month 24, who did not meet the elimination criteria during the study, for whom data concerning persistence outcome variable measures were available. This included all subjects for whom assay results for antibodies against at least one study vaccine antigen component at Day 180, at Month 12 and at Month 24 were available.

Analysis of immunogenicity:

The analysis was performed on the ATP cohort for immunogenicity and the ATP cohort for persistence.

Inferential analysis:

For the humoral immune response in terms of both H5N1 HI antibodies and neutralising antibodies:
The 95% CIs of anti-H5N1 GMT ratios (double dose group GMT divided by single dose group GMT) 21 days after each vaccination with H5N1 vaccine, were computed. The asymptotic standardised 95% CI for the difference (double dose group minus single dose group) in SCRs was computed.

Descriptive analysis:
For the humoral immune response in terms of H5N1 HI antibodies, the GMTs of H5N1 HI antibody titres and SPR at Days 0, 21, 42 and 180, for all subjects and at months 12 & 24 for subjects in Belgium, SCR and SCF at Days 21, 42 and 180, for all subjects and at months 12 & 24, for subjects in Belgium with their 95% CIs were calculated.
For the humoral immune response in terms of neutralising antibodies, the GMTs of H5N1 HI antibody titres at Days 0, 42 180 and at months 12 & 24, for subjects in Belgium, SCR at days 42 and 180 and at months 12 & 24, for subjects in Belgium were evaluated in a subset of subjects in the adjuvanted groups with 95% CI. Antibody titres below the cut-off of the assay were given an arbitrary value of half the cut-off for the purpose of GMT calculation. The frequency of influenza-specific CD4/CD8 T lymphocytes cells was summarised (descriptive statistics) at Days 0, 21, 42 and 180, for all subjects and AT months 12 & 24 for subjects in Belgium.

Analysis of safety
The analysis was based on the Total Vaccinated Cohort.
The percentage of subjects reporting each individual solicited local and general symptom during the 7-day (Day 0-6) solicited follow-up period was tabulated with exact 95% CI. The same tabulation was performed for grade 3 symptoms and for general symptoms assessed by the investigator as related to the study vaccination.
The number and proportion of subjects with normal or abnormal values for each haematology and biochemistry parameter was tabulated for each study group at each scheduled time point.
The proportion of subjects with at least one report of unsolicited AE classified by the Medical Dictionary for Regulatory Activities (MedDRA) preferred terms and reported up to 21 days after the first vaccination with H5N1 vaccine and 30 days after the second vaccination was tabulated. The same tabulation was performed for grade 3 AEs and for AEs with a relationship to vaccination. The occurrence of SAEs during the study period was tabulated according to MedDRA preferred terms.

Study Population: Male or female subjects aged 61 years and above at the time of first vaccination, who were healthy or with well controlled underlying disease, were enrolled in the study. Written informed consent was obtained from the subjects prior to study entry.

Primary Study (108251)

Number of Subjects:	**Dd/NoAdj Group**	**Sd/NoAdj Group**	**Dd/Adj Group**	**Sd/Adj Group**
Planned, N	60	60	180	180
Randomised, N (Total Vaccinated Cohort)	52	61	159	165
Completed, n (%)	48 (92.3)	56 (91.8)	153 (96.2)	158 (95.8)
Total Number Subjects Withdrawn, n (%)	4 (7.7)	5 (8.2)	6 (3.8)	7 (4.2)
Withdrawn due to Adverse Events n (%)	0 (0.0)	1 (1.6)	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 (%)	4 (7.7)	4 (6.6)	6 (3.8)	7 (4.2)
Demographics	**Dd/NoAdj Group**	**Sd/NoAdj Group**	**Dd/Adj Group**	**Sd/Adj Group**
N,(Total Vaccinated Cohort)	52	61	159	165
Females: Males	23:29	28:33	77:82	72:93
Mean Age, years (SD)	70.8 (7.35)	69.9 (6.38)	69.7 (6.51)	69.7 (6.33)
White-Caucasian/European heritage, n (%)	50 (96.2)	60 (98.4)	151 (95.0)	163 (98.8)

Day 180 (108252)

Number of subjects:	**Dd/NoAdj Group**	**Sd/NoAdj Group**	**Dd/Adj Group**	**Sd/Adj Group**
Planned, N	51	58	158	164
Randomised, N (Total Vaccinated Cohort)	51	58	158	164
Completed, n (%)	51 (100)	55 (94.8)	153 (96.8)	162 (98.8)
Total Number Subjects Withdrawn, n (%)	0(0.0)	3 (5.2)	5 (3.2)	2 (1.2)
Withdrawn due to Adverse Events, n (%)	0(0.0)	3 (5.2)	2 (1.3)	0(0.0)
Withdrawn due to Lack of Efficacy, n (%)	Not applicable	Not applicable	Not applicable	Not applicable
Withdrawn for other reasons, n (%)	0(0.0)	0(0.0)	3 (1.9)	2 (1.2)

Demographics	Dd/NoAdj Group	Sd/NoAdj Group	Dd/Adj Group	Sd/Adj Group
N (Total Vaccinated Cohort)	51	58	158	164
Females: Males	22:29	26:32	74:84	72:92
Mean Age, years (SD)	70.6 (7.33)	69.8 (6.34)	69.6 (6.54)	69.7 (6.37)
Missing race, n (%)	51 (100)	58 (100)	158 (100)	164 (100)
Month 12 (111275)				
Number of subjects:	**Dd/NoAdj Group**	**Sd/NoAdj Group**	**Dd/Adj Group**	**Sd/Adj Group**
Planned, N	42	48	125	130
Randomised, N (Total Vaccinated Cohort)	42	48	125	130
Completed, n (%)	42 (100)	48 (100)	125 (100)	130 (100)
Total Number Subjects Withdrawn, n (%)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
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 (%)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Demographics	**Dd/NoAdj Group**	**Sd/NoAdj Group**	**Dd/Adj Group**	**Sd/Adj Group**
N (Total Vaccinated Cohort)	42	48	125	130
Females:Males	18:24	24:24	63:62	58:72
Mean Age, years (SD)	70.9 (7.38)	69.4 (5.95)	69.5 (6.43)	69.4 (6.67)
White-Caucasian /European heritage, n (%)	40 (95.2)	47 (97.9)	118 (94.4)	128 (98.5)
Month 24 (111276)				
Number of subjects:	**Dd/NoAdj Group**	**Sd/NoAdj Group**	**Dd/Adj Group**	**Sd/Adj Group**
Planned, N	36	45	117	122
Randomised, N (Total Vaccinated Cohort)	36	45	117	122
Completed, n (%)	36 (100)	45 (100)	117 (100)	122 (100)
Total Number Subjects Withdrawn, n (%)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
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 (%)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Demographics	**Dd/NoAdj Group**	**Sd/NoAdj Group**	**Dd/Adj Group**	**Sd/Adj Group**
N (Total Vaccinated Cohort)	36	45	117	122
Females:Males	14:22	21:24	62:55	54:68
Mean Age, years (SD)	69.1 (6.68)	69.2 (5.92)	69.3 (6.48)	69.5 (6.76)
White-Caucasian/European heritage, n (%)	34 (94.4)	44 (97.8)	110 (94.0)	120 (98.4)

Primary Outcome/Efficacy Variable: GMT ratios for Sd/Adj, Sd/NoAdj, Dd/Adj, and Dd/NoAdj Groups at Day 42 against A/Vietnam/1194/2004 and A/Indonesia/5/2005 vaccine strains (ATP cohort for Immunogenicity)

Group description	N	GMT	Group description	N	GMT	GMT ratio				P-value
						Ratio order	Value	95% CI		
								LL	UL	
For H5N1 HI Antibodies against A/Vietnam/1194/2004										
Dd/Adj	145	237.3	**Dd/NoAdj**	44	25.3	Dd/Adj/Dd/NoAdj	9.38	5.93	14.83	<0.0001
Sd/Adj	152	126.8	**Sd/NoAdj**	54	22.7	Sd/Adj/Sd/NoAdj	5.58	3.48	8.95	<0.0001
Dd/Adj	145	237.3	**Sd/Adj**	152	126.8	Dd/Adj/Sd/Adj	1.87	1.36	2.59	0.0002
Dd/NoAdj	44	25.3	**Sd/NoAdj**	54	22.7	Dd/NoAdj/SdNoAdj	1.11	0.61	2.04	0.7235
For H5N1 HI Antibodies against A/Indonesia/5/2005										
Dd/Adj	145	24.4	**Dd/NoAdj**	44	6.3	Dd/Adj/Dd/NoAdj	3.89	2.64	5.73	<0.0001
Sd/Adj	152	13.7	**Sd/NoAdj**	54	6.1	Sd/Adj/Sd/NoAdj	2.22	1.60	3.10	<0.0001
Dd/Adj	145	24.4	**Sd/Adj**	152	13.7	Dd/Adj/Sd/Adj	1.79	1.36	2.35	<0.0001
Dd/NoAdj	44	6.3	**Sd/NoAdj**	54	6.1	Dd/NoAdj/Sd/NoAdj	1.02	0.78	1.33	0.8661

N = number of subjects with available results

95 % CI = 95 % confidence interval; LL and UL = lower and upper limits of the CI
P-value = 2-sided Fisher Exact Test

Primary Outcome/Efficacy Variable: Difference in terms of seroconversion rate between adjuvanted and non-adjuvanted vaccine groups (ATP cohort for Immunogenicity)

Group 1	N	%	Group 2	N	%	Difference in seroconversion rate (Group 2 minus Group 1)				P-value
						Difference	%	95 % CI		
								LL	UL	
HI Antibody against: A/Vietnam/1194/2004										
Dd/NoAdj	44	22.7	**Dd/Adj**	145	88.3	Dd/Adj - Dd/NoAdj	65.55	50.30	76.76	<0.001
Sd/NoAdj	54	22.2	**Sd/Adj**	152	72.4	Sd/Adj - Sd/NoAdj	50.15	35.59	61.73	<0.001
Sd/Adj	152	72.4	**Dd/Adj**	145	88.3	Dd/Adj - Sd/Adj	15.91	7.00	24.79	<0.001
Sd/NoAdj	54	22.2	**Dd/NoAdj**	44	22.7	Dd/NoAdj - Sd/NoAdj	0.51	-15.90	17.66	1.000
HI Antibody against: A/Indonesia/5/2005										
Dd/NoAdj	44	4.5	**Dd/Adj**	145	40.0	Dd/Adj - Dd/NoAdj	35.45	23.10	44.74	<0.001
Sd/NoAdj	54	3.7	**Sd/Adj**	152	23.0	Sd/Adj - Sd/NoAdj	19.32	9.16	27.47	<0.001
Sd/Adj	152	23.0	**Dd/Adj**	145	40.0	Dd/Adj - Sd/Adj	16.97	6.46	27.23	0.002
Sd/NoAdj	54	3.7	**Dd/NoAdj**	44	4.5	Dd/NoAdj - Sd/NoAdj	0.84	-8.67	11.88	1.000

N = number of subjects with available results
% = percentage of subjects who seroconverted
95% CI = 95% Standardized asymptotic confidence interval; LL = lower limit, UL = upper limit
P-value = 2-sided Fisher Exact Test

Primary Outcome/Efficacy Variable: Seropositivity rates and GMTs of H5N1 HI antibodies against the vaccine strain A/Vietnam/1194/2004 (ATP cohort for immunogenicity)

Group	Timing	N	≥ 1:10				GMT		
			n	%	95% CI		value	95% CI	
					LL	UL		LL	UL
Dd/NoAdj	PRE	44	16	36.4	22.4	52.2	8.8	6.6	11.8
	PI(D21)	44	26	59.1	43.2	73.7	20.8	13.0	33.3
	PII(D42)	44	32	72.7	57.2	85.0	25.3	16.0	40.1
Sd/NoAdj	PRE	54	21	38.9	25.9	53.1	9.7	7.3	13.0
	PI(D21)	54	32	59.3	45.0	72.4	16.8	11.7	24.0
	PII(D42)	54	36	66.7	52.5	78.9	22.7	15.1	34.1
Dd/Adj	PRE	145	52	35.9	28.1	44.2	10.2	8.4	12.5
	PI(D21)	145	130	89.7	83.5	94.1	69.4	52.1	92.3
	PII(D42)	145	142	97.9	94.1	99.6	237.3	191.9	293.6
Sd/Adj	PRE	152	62	40.8	32.9	49.0	11.3	9.2	13.9
	PI(D21)	152	122	80.3	73.0	86.3	50.0	38.1	65.6
	PII(D42)	152	142	93.4	88.2	96.8	126.8	99.4	161.7

GMT = Geometric mean antibody titre
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 on Day 0
PI (D21) = Post-vaccination on Day 21
PII (D42) = Post-vaccination 2 on Day 42

Primary Outcome/Efficacy Variable: Seropositivity rates and GMTs of H5N1 HI antibodies against the A/Indonesia/5/2005 strain (ATP cohort for immunogenicity)

Group	Timing	N	≥ 1:10				GMT		
			n	%	95% CI		value	95% CI	
					LL	UL		LL	UL
Dd/NoAdj	PRE	44	0	0.0	0.0	8.0	5.0	5.0	5.0
	PI(D21)	44	5	11.4	3.8	24.6	5.6	5.0	6.3
	PII(D42)	44	8	18.2	8.2	32.7	6.3	5.2	7.6
Sd/NoAdj	PRE	54	2	3.7	0.5	12.7	5.2	4.9	5.5

	PI(D21)	54	2	3.7	0.5	12.7	5.3	4.8	5.9
	PII(D42)	54	7	13.0	5.4	24.9	6.1	5.1	7.4
Dd/Adj	PRE	145	4	2.8	0.8	6.9	5.1	5.0	5.2
	PI(D21)	145	48	33.1	25.5	41.4	8.6	7.3	10.1
	PII(D42)	145	108	74.5	66.6	81.4	24.4	19.9	30.0
Sd/Adj	PRE	152	2	1.3	0.2	4.7	5.1	5.0	5.1
	PI(D21)	152	36	23.7	17.2	31.3	6.9	6.2	7.7
	PII(D42)	152	83	54.6	46.3	62.7	13.7	11.3	16.4

GMT = Geometric mean antibody titre
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 on Day 0
PI (D21) = Post-vaccination on Day 1
PII (D42) = Post-vaccination 2 on Day 42

Primary Outcome/Efficacy Variable: Seropositivity rates and GMTs of H5N1 HI antibodies against A/Vietnam/1194/2004 and A/Indonesia/05/2005 strains at Day 0 and Day 180 (ATP cohort for persistence at Day 180)

Antibodies against	**Group**	**Timing**	**N**	≥ 1:10				**GMT**		
				n	**%**	**95% CI**		**value**	**95% CI**	
						LL	**UL**		**LL**	**UL**
A/Vietnam/1194/2004	Dd/NoAdj	PRE	42	14	33.3	19.6	49.5	7.8	6.3	9.7
		PII(D180)	44	22	50.0	34.6	65.4	13.1	8.9	19.2
	Sd/NoAdj	PRE	52	21	40.4	27.0	54.9	10.0	7.4	13.5
		PII(D180)	50	26	52.0	37.4	66.3	16.3	11.0	24.3
	Dd/Adj	PRE	135	48	35.6	27.5	44.2	10.0	8.2	12.3
		PII(D180)	131	113	86.3	79.2	91.6	53.5	41.9	68.4
	Sd/Adj	PRE	142	58	40.8	32.7	49.4	11.6	9.4	14.3
		PII(D180)	140	107	76.4	68.5	83.2	38.5	30.0	49.5
A/Indonesia/5/2005	Dd/NoAdj	PRE	42	0	0.0	0.0	8.4	5.0	5.0	5.0
		PII(D180)	44	1	2.3	0.1	12.0	5.2	4.8	5.5
	Sd/NoAdj	PRE	52	2	3.8	0.5	13.2	5.2	4.9	5.5
		PII(D180)	50	3	6.0	1.3	16.5	5.5	4.8	6.4
	Dd/Adj	PRE	135	3	2.2	0.5	6.4	5.1	5.0	5.2
		PII(D180)	131	54	41.2	32.7	50.2	8.6	7.5	9.9
	Sd/Adj	PRE	142	3	2.1	0.4	6.0	5.1	5.0	5.2
		PII(D180)	140	30	21.4	14.9	29.2	6.6	6.0	7.3

GMT = Geometric mean antibody titre
N = Number of subjects with available results
n/% = number/percentage of seropositive subjects (HI titre ≥ 1:10)
95% CI = 95% confidence interval, LL = Lower Limit, UL = Upper Limit
PRE = Pre-vaccination on Day 0
PII(D180) = Post-vaccination 2 on Day 180

Primary Outcome/Efficacy Variable: Seropositivity rates and GMTs of H5N1 HI antibody titres A/Vietnam/1194/2004 and against A/Indonesia/05/2005 strains at Month 12 (ATP cohort for persistence at Month 12)

Antibodies against	**Group**	**Timing**	**N**	**≥ 1:10**				**GMT**		
				n	**%**	**95% CI**		**value**	**95% CI**	
						LL	**UL**		**LL**	**UL**
A/Vietnam/1194/2004	Dd/NoAdj	PRE	34	12	35.3	19.7	53.5	7.9	6.2	10.1
		PII(M12)	35	15	42.9	26.3	60.6	11.4	7.7	16.7
	Sd/NoAdj	PRE	43	16	37.2	23.0	53.3	9.7	6.9	13.5
		PII(M12)	45	23	51.1	35.8	66.3	13.3	9.3	19.0
	Dd/Adj	PRE	105	39	37.1	27.9	47.1	10.9	8.5	14.0
		PII(M12)	106	81	76.4	67.2	84.1	26.5	20.3	34.6
	Sd/Adj	PRE	112	43	38.4	29.4	48.1	11.6	9.0	15.0

		PII(M12)	112	67	59.8	50.1	69.0	21.4	16.4	28.0
A/Indonesia/5/2005	Dd/NoAdj	PRE	34	0	0.0	0.0	10.3	5.0	5.0	5.0
		PII(M12)	35	7	20.0	8.4	36.9	6.9	5.4	8.9
	Sd/NoAdj	PRE	43	1	2.3	0.1	12.3	5.1	4.9	5.2
		PII(M12)	45	9	20.0	9.6	34.6	6.6	5.5	7.9
	Dd/Adj	PRE	105	3	2.9	0.6	8.1	5.1	5.0	5.3
		PII(M12)	106	61	57.5	47.6	67.1	13.1	10.9	15.8
	Sd/Adj	PRE	112	3	2.7	0.6	7.6	5.1	5.0	5.3
		PII(M12)	112	43	38.4	29.4	48.1	9.8	8.2	11.7

GMT = Geometric mean antibody titre
N = Number of subjects with available results
n/% = number/percentage of seropositive subjects (HI titre $\geq$ 1:10)
95% CI = 95% confidence interval, LL = Lower Limit, UL = Upper Limit
PRE = Pre-vaccination on Day 0
PII(M12) = Post-vaccination 2 at Month 12

Primary Outcome/Efficacy Variable: Seropositivity rates and GMTs of H5N1 HI antibody titres against A/Vietnam/1194/2004 and A/Indonesia/05/2005 strains at Month 24 (ATP cohort for persistence at Month 24)

Antibodies against	**Group**	**Timing**	**N**	$\geq$ 1:10				**GMT**		
				n	**%**	**95% CI**		**value**	**95% CI**	
						LL	**UL**		**LL**	**UL**
A/Vietnam/1194/2004	Dd/NoAdj	PRE	22	6	27.3	10.7	50.2	6.8	5.4	8.7
		PII(M12)	23	9	39.1	19.7	61.5	10.0	6.5	15.5
		PII(M24)	24	11	45.8	25.6	67.2	9.8	6.7	14.4
	Sd/NoAdj	PRE	36	12	33.3	18.6	51.0	9.3	6.3	13.6
		PII(M12)	37	18	48.6	31.9	65.6	13.6	8.9	20.8
		PII(M24)	37	20	54.1	36.9	70.5	12.3	8.9	16.9
	Dd/Adj	PRE	81	27	33.3	23.2	44.7	9.7	7.4	12.5
		PII(M12)	81	63	77.8	67.2	86.3	25.7	19.3	34.3
		PII(M24)	81	57	70.4	59.2	80.0	18.4	14.2	23.8
	Sd/Adj	PRE	86	34	39.5	29.2	50.7	11.5	8.7	15.1
		PII(M12)	86	54	62.8	51.7	73.0	22.2	16.5	29.9
		PII(M24)	86	54	62.8	51.7	73.0	17.6	13.7	22.5
A/Indonesia/5/2005	Dd/NoAdj	PRE	22	0	0.0	0.0	15.4	5.0	5.0	5.0
		PII(M12)	23	6	26.1	10.2	48.4	8.0	5.5	11.5
		PII(M24)	24	0	0.0	0.0	14.2	5.0	5.0	5.0
	Sd/NoAdj	PRE	36	1	2.8	0.1	14.5	5.1	4.9	5.3
		PII(M12)	37	7	18.9	8.0	35.2	6.4	5.3	7.6
		PII(M24)	37	4	10.8	3.0	25.4	5.6	4.9	6.4
	Dd/Adj	PRE	81	2	2.5	0.3	8.6	5.1	5.0	5.3
		PII(M12)	81	51	63.0	51.5	73.4	14.4	11.6	17.9
		PII(M24)	81	23	28.4	18.9	39.5	7.3	6.2	8.6
	Sd/Adj	PRE	86	2	2.3	0.3	8.1	5.1	5.0	5.2
		PII(M12)	86	34	39.5	29.2	50.7	10.2	8.2	12.6
		PII(M24)	86	23	26.7	17.8	37.4	7.0	6.1	8.1

GMT = Geometric mean antibody titre
N = Number of subjects with available results
n/% = number/percentage of seropositive subjects (HI titre ≥ 1:10)
95% CI = 95% confidence interval, LL = Lower Limit, UL = Upper Limit
PRE = Pre-vaccination on Day 0
PII(M12)= Post-vaccination 2 at Month 12
PII(M24)= Post-vaccination 2 at Month 24

Primary Outcome/Efficacy Variable: SCR for H5N1 HI antibodies against A/Vietnam /1194/2004 and A/Indonesia/5/2005 strains at each post-vaccination at Day 21 and Day 42 (ATP cohort for immunogenicity)

Antibodies against	**Group**	**Timing**	**N**	**SCR**

				n	%	95% CI	
						LL	UL
A/Vietnam/1194/2004	Dd/NoAdj	PI(D21)	44	8	18.2	8.2	32.7
		PII(D42)	44	10	22.7	11.5	37.8
	Sd/NoAdj	PI(D21)	54	8	14.8	6.6	27.1
		PII(D42)	54	12	22.2	12.0	35.6
	Dd/Adj	PI(D21)	145	76	52.4	44.0	60.8
		PII(D42)	145	128	88.3	81.9	93.0
	Sd/Adj	PI(D21)	152	69	45.4	37.3	53.7
		PII(D42)	152	110	72.4	64.5	79.3
A/Indonesia/5/2005	Dd/NoAdj	PI(D21)	44	1	2.3	0.1	12.0
		PII(D42)	44	2	4.5	0.6	15.5
	Sd/NoAdj	PI(D21)	54	1	1.9	0.0	9.9
		PII(D42)	54	2	3.7	0.5	12.7
	Dd/Adj	PI(D21)	145	13	9.0	4.9	14.8
		PII(D42)	145	58	40.0	32.0	48.5
	Sd/Adj	PI(D21)	152	5	3.3	1.1	7.5
		PII(D42)	152	35	23.0	16.6	30.5

N = number of subjects with available results
PI(D21) = Post vaccination on Day 21
PII(D42) =Post vaccination 2 on Day 42
n (%) =number (percentage) of subjects with either a pre-vaccination titre <1:10 and post-vaccination titre ≥1:40 or a pre-vaccination titre ≥1:10 and a minimum 4-fold increase in pot-vaccination titre
95% confidence interval, LL= Lower Limit, UL= Upper Limit

Primary Outcome/Efficacy Variable: SCR for H5N1 HI antibodies against A/Vietnam /1194/2004 and A/Indonesia/5/2005 strains at post-vaccination Day 180 (ATP cohort for persistence at Day 180)

Antibodies against	**Group**	**Timing**	**N**	**SCR**			
				n	**%**	**95% CI**	
						LL	**UL**
A/Vietnam/1194/2004	Dd/NoAdj	PII(D180)	42	6	14.3	5.4	28.5
	Sd/NoAdj	PII(D180)	48	6	12.5	4.7	25.2
	Dd/Adj	PII(D180)	130	70	53.8	44.9	62.6
	Sd/Adj	PII(D180)	140	52	37.1	29.1	45.7
A/Indonesia/5/2005	Dd/NoAdj	PII(D180)	42	0	0.0	0.0	8.4
	Sd/NoAdj	PII(D180)	48	1	2.1	0.1	11.1
	Dd/Adj	PII(D180)	130	8	6.2	2.7	11.8
	Sd/Adj	PII(D180)	140	5	3.6	1.2	8.1

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
PII(D180) = Post-vaccination 2 on Day 180

Primary Outcome/Efficacy Variable: SCR for H5N1 HI antibody titres against A/Indonesia/05/2005 and A/Vietnam/1194/2004 strains at Month 12 (ATP cohort for persistence at Month 12)

Antibodies against	**Group**	**Timing**	**N**	**SCR**

				n	%	95% CI	
						LL	UL
A/Vietnam/1194/2004	Dd/NoAdj	PII(M12)	34	4	11.8	3.3	27.5
	Sd/NoAdj	PII(M12)	43	6	14.0	5.3	27.9
	Dd/Adj	PII(M12)	105	24	22.9	15.2	32.1
	Sd/Adj	PII(M12)	112	24	21.4	14.2	30.2
A/Indonesia/5/2005	Dd/NoAdj	PII(M12)	34	3	8.8	1.9	23.7
	Sd/NoAdj	PII(M12)	43	2	4.7	0.6	15.8
	Dd/Adj	PII(M12)	105	22	21.0	13.6	30.0
	Sd/Adj	PII(M12)	112	17	15.2	9.1	23.2

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
PII(M12) = Post-vaccination 2 at Month 12

Primary Outcome/Efficacy Variable: SCR for H5N1 HI antibody titres against A/Vietnam/1194/2004 and A/Indonesia/05/2005 strains at Month 24 (ATP cohort for persistence at Month 24)

Antibodies against	**Group**	**Timing**	**N**	**SCR**			
				n	**%**	**95% CI**	
						LL	**UL**
A/Vietnam/1194/2004	Dd/NoAdj	PII(M12)	22	2	9.1	1.1	29.2
		PII(M24)	22	2	9.1	1.1	29.2
	Sd/NoAdj	PII(M12)	36	6	16.7	6.4	32.8
		PII(M24)	36	2	5.6	0.7	18.7
	Dd/Adj	PII(M12)	81	22	27.2	17.9	38.2
		PII(M24)	81	9	11.1	5.2	20.0
	Sd/Adj	PII(M12)	86	21	24.4	15.8	34.9
		PII(M24)	86	8	9.3	4.1	17.5
A/Indonesia/5/2005	Dd/NoAdj	PII(M12)	22	3	13.6	2.9	34.9
		PII(M24)	22	0	0.0	0.0	15.4
	Sd/NoAdj	PII(M12)	36	1	2.8	0.1	14.5
		PII(M24)	36	1	2.8	0.1	14.5
	Dd/Adj	PII(M12)	81	20	24.7	15.8	35.5
		PII(M24)	81	4	4.9	1.4	12.2
	Sd/Adj	PII(M12)	86	14	16.3	9.2	25.8
		PII(M24)	86	4	4.7	1.3	11.5

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
PRE = Pre-vaccination on Day 0
PII(M12)= Post-vaccination 2 at Month 12
PII(M24)= Post-vaccination 2 at Month 24

Primary Outcome/Efficacy Variable: SCF for H5N1 HI antibodies against A/Vietnam/1194/2004 and A/Indonesia/5/2005 strain (ATP cohort for immunogenicity)

Antibodies against	**Group**	**Timing**	**N**	**SCF**		
				Value	**95% CI**	
					LL	**UL**
A/Vietnam/1194/2004	Dd/NoAdj	PI(D21)	44	2.4	1.7	3.4
		PII(D42)	44	2.9	2.0	4.1
	Sd/NoAdj	PI(D21)	54	1.7	1.3	2.3

		PII(D42)	54	2.3	1.6	3.3
	Dd/Adj	PI(D21)	145	6.8	5.3	8.6
		PII(D42)	145	23.2	18.5	29.0
	Sd/Adj	PI(D21)	152	4.4	3.5	5.5
		PII(D42)	152	11.2	8.9	14.1
A/Indonesia/5/2005	Dd/NoAdj	PI(D21)	44	1.1	1.0	1.3
		PII(D42)	44	1.3	1.0	1.5
	Sd/NoAdj	PI(D21)	54	1.0	0.9	1.1
		PII(D42)	54	1.2	1.0	1.4
	Dd/Adj	PI(D21)	145	1.7	1.4	2.0
		PII(D42)	145	4.8	3.9	5.9
	Sd/Adj	PI(D21)	152	1.4	1.2	1.5
		PII(D42)	152	2.7	2.2	3.2

N = number of subjects with available results
n (%) = number (percentage) of subjects with titre within the specified range
PRE =Pre-vaccination
PI(D21) = Post vaccination on Day 21
PII(D42) = Post vaccination 2 on Day 42
95% confidence interval, LL= Lower Limit, UL= Upper Limit

Primary Outcome/Efficacy Variable: SCF for H5N1 HI antibodies against A/Vietnam/1194/2004 and A/Indonesia/5/2005 strains at post-vaccination Day 180 (ATP cohort for persistence at Day 180)

Antibodies against	**Group**	**Timing**	**N**	**SCF**		
				Value	**95% CI**	
					LL	**UL**
A/Vietnam/1194/2004	Dd/NoAdj	PII(D180)	42	1.8	1.3	2.4
	Sd/NoAdj	PII(D180)	48	1.6	1.2	2.2
	Dd/Adj	PII(D180)	130	5.4	4.4	6.7
	Sd/Adj	PII(D180)	140	3.3	2.7	4.0
A/Indonesia/5/2005	Dd/NoAdj	PII(D180)	42	1.0	1.0	1.1
	Sd/NoAdj	PII(D180)	48	1.1	0.9	1.3
	Dd/Adj	PII(D180)	130	1.7	1.5	1.9
	Sd/Adj	PII(D180)	140	1.3	1.2	1.4

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
PII(D180) = Post-vaccination 2 on Day 180

Primary Outcome/Efficacy Variable: SCF for H5N1 HI antibody titres against A/Indonesia/05/2005 and A/Vietnam/1194/2004 strains at Month 12 (ATP cohort for persistence at Month 12)

Antibodies against	**Group**	**Timing**	**N**	**SCF**		
				Value	**95% CI**	
					LL	**UL**
A/Vietnam/1194/2004	Dd/NoAdj	PII(M12)	34	1.5	1.1	2.1
	Sd/NoAdj	PII(M12)	43	1.3	1.0	1.7
	Dd/Adj	PII(M12)	105	2.5	2.0	3.0
	Sd/Adj	PII(M12)	112	1.8	1.5	2.2
A/Indonesia/5/2005	Dd/NoAdj	PII(M12)	34	1.4	1.1	1.8
	Sd/NoAdj	PII(M12)	43	1.3	1.1	1.6
	Dd/Adj	PII(M12)	105	2.6	2.2	3.1
	Sd/Adj	PII(M12)	112	1.9	1.6	2.3

N = Number of subjects with pre- and post-vaccination results available
SCF = Seroconversion Factor or geometric mean ratio (mean[$\log_{10}$(POST/PRE)])
95% CI = 95% confidence interval, LL = Lower Limit, UL = Upper Limit
PII(M12) = Post-vaccination 2 at Month 12

Primary Outcome/Efficacy Variable: SCF for H5N1 HI antibody titres against A/Vietnam /1194/2004 and A/Indonesia/05/2005 strains at Month 24 (ATP cohort for persistence at Month 24)

Antibodies against	Group	Timing	N	SCF		
				Value	95% CI	
					LL	UL
A/Vietnam/1194/2004	Dd/NoAdj	PII(M12)	22	1.5	1.0	2.2
		PII(M24)	22	1.4	1.0	2.1
	Sd/NoAdj	PII(M12)	36	1.4	1.0	2.0
		PII(M24)	36	1.3	0.9	1.7
	Dd/Adj	PII(M12)	81	2.7	2.1	3.3
		PII(M24)	81	1.9	1.6	2.3
	Sd/Adj	PII(M12)	86	1.9	1.5	2.4
		PII(M24)	86	1.5	1.3	1.8
A/Indonesia/5/2005	Dd/NoAdj	PII(M12)	22	1.6	1.1	2.4
		PII(M24)	22	1.0	1.0	1.0
	Sd/NoAdj	PII(M12)	36	1.3	1.1	1.5
		PII(M24)	36	1.1	1.0	1.3
	Dd/Adj	PII(M12)	81	2.8	2.3	3.5
		PII(M24)	81	1.4	1.2	1.7
	Sd/Adj	PII(M12)	86	2.0	1.6	2.5
		PII(M24)	86	1.4	1.2	1.6

N = Number of subjects with pre- and post-vaccination results available
SCF = Seroconversion Factor or geometric mean ratio (mean[$\log_{10}$(POST/PRE)])
95% CI = 95% confidence interval, LL = Lower Limit, UL = Upper Limit
PII(M12)= Post-vaccination 2 at Month 12
PII(M24)= Post-vaccination 2 at Month 24

Primary Outcome/Efficacy Variable: SPR for H5N1 HI antibodies against A/Vietnam/1194/2004 and A/Indonesia/5/2005 strain (ATP cohort for immunogenicity)

Antibodies against	Group	Timing	N	SPR			
				n	%	95% CI	
						LL	UL
A/Vietnam/1194/2004	Dd/NoAdj	PRE	44	2	4.5	0.6	15.5
		PI(D21)	44	15	34.1	20.5	49.9
		PII(D42)	44	17	38.6	24.4	54.5
	Sd/NoAdj	PRE	54	7	13.0	5.4	24.9
		PI(D21)	54	15	27.8	16.5	41.6
		PII(D42)	54	19	35.2	22.7	49.4
	Dd/Adj	PRE	145	23	15.9	10.3	22.8
		PI(D21)	145	90	62.1	53.6	70.0
		PII(D42)	145	139	95.9	91.2	98.5
	Sd/Adj	PRE	152	28	18.4	12.6	25.5
		PI(D21)	152	93	61.2	53.0	69.0
		PII(D42)	152	127	83.6	76.7	89.1
A/Indonesia/5/2005	Dd/NoAdj	PRE	44	0	0.0	0.0	8.0
		PI(D21)	44	1	2.3	0.1	12.0
		PII(D42)	44	2	4.5	0.6	15.5
	Sd/NoAdj	PRE	54	0	0.0	0.0	6.6
		PI(D21)	54	1	1.9	0.0	9.9
		PII(D42)	54	2	3.7	0.5	12.7
	Dd/Adj	PRE	145	0	0.0	0.0	2.5
		PI(D21)	145	13	9.0	4.9	14.8
		PII(D42)	145	59	40.7	32.6	49.2
	Sd/Adj	PRE	152	0	0.0	0.0	2.4
		PI(D21)	152	5	3.3	1.1	7.5
		PII(D42)	152	35	23.0	16.6	30.5

N = number of subjects with available results

n (%) = number (percentage) of subjects with titre within the specified range
PRE =Pre-vaccination on Day 0.
PI(D21) = Post vaccination on Day 21
PII(D42) = Post vaccination 2 on Day 42
95% CI = 95% confidence interval, LL= Lower Limit, UL= Upper Limit

Primary Outcome/Efficacy Variable: SPR for H5N1 HI antibodies against A/Vietnam/1194/2004 and A/Indonesia/5/2005 strains at Day 0 and Day 180 (ATP cohort for persistence at Day 180)

Antibodies against	Group	Timing	N	SPR			
				n	%	95% CI	
						LL	UL
A/Vietnam/1194/2004	Dd/NoAdj	PRE	42	1	2.4	0.1	12.6
		PII(D180)	44	9	20.5	9.8	35.3
	Sd/NoAdj	PRE	52	7	13.5	5.6	25.8
		PII(D180)	50	13	26.0	14.6	40.3
	Dd/Adj	PRE	135	21	15.6	9.9	22.8
		PII(D180)	131	91	69.5	60.8	77.2
	Sd/Adj	PRE	142	29	20.4	14.1	28.0
		PII(D180)	140	74	52.9	44.2	61.3
A/Indonesia/5/2005	Dd/NoAdj	PRE	42	0	0.0	0.0	8.4
		PII(D180)	44	0	0.0	0.0	8.0
	Sd/NoAdj	PRE	52	0	0.0	0.0	6.8
		PII(D180)	50	1	2.0	0.1	10.6
	Dd/Adj	PRE	135	0	0.0	0.0	2.7
		PII(D180)	131	8	6.1	2.7	11.7
	Sd/Adj	PRE	142	0	0.0	0.0	2.6
		PII(D180)	140	5	3.6	1.2	8.1

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 on Day 0
PII(D180) = Post-vaccination 2 on Day 180

Primary Outcome/Efficacy Variable: SPR for H5N1 HI antibody titres against A/Indonesia/05/2005 and A/Vietnam/1194/2004 strains at Month 12 (ATP cohort for persistence at Month 12)

Antibodies against	Group	Timing	N	SPR			
				n	%	95% CI	
						LL	UL
A/Vietnam/1194/2004	Dd/NoAdj	PRE	34	1	2.9	0.1	15.3
		PII(M12)	35	7	20.0	8.4	36.9
	Sd/NoAdj	PRE	43	5	11.6	3.9	25.1
		PII(M12)	45	11	24.4	12.9	39.5
	Dd/Adj	PRE	105	19	18.1	11.3	26.8
		PII(M12)	106	45	42.5	32.9	52.4
	Sd/Adj	PRE	112	22	19.6	12.7	28.2
		PII(M12)	112	49	43.8	34.4	53.4
A/Indonesia/5/2005	Dd/NoAdj	PRE	34	0	0.0	0.0	10.3
		PII(M12)	35	3	8.6	1.8	23.1
	Sd/NoAdj	PRE	43	0	0.0	0.0	8.2
		PII(M12)	45	2	4.4	0.5	15.1
	Dd/Adj	PRE	105	0	0.0	0.0	3.5
		PII(M12)	106	22	20.8	13.5	29.7
	Sd/Adj	PRE	112	0	0.0	0.0	3.2
		PII(M12)	112	17	15.2	9.1	23.2

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 on Day 0
PII(M12) = Post-vaccination 2 at Month 12

Primary Outcome/Efficacy Variable: SPR for H5N1 HI antibody titres against A/Indonesia/05/2005 and A/Vietnam/1194/2004 strains at Month 24 (ATP cohort for persistence at Month 24)

Antibodies against	Group	Timing	N	SPR			
				n	%	95% CI	
						LL	UL
A/Indonesia/5/2005	Dd/NoAdj	PRE	22	0	0.0	0.0	15.4
		PII(M12)	23	3	13.0	2.8	33.6
		PII(M24)	24	0	0.0	0.0	14.2
	Sd/NoAdj	PRE	36	0	0.0	0.0	9.7
		PII(M12)	37	1	2.7	0.1	14.2
		PII(M24)	37	1	2.7	0.1	14.2
	Dd/Adj	PRE	81	0	0.0	0.0	4.5
		PII(M12)	81	20	24.7	15.8	35.5
		PII(M24)	81	5	6.2	2.0	13.8
	Sd/Adj	PRE	86	0	0.0	0.0	4.2
		PII(M12)	86	14	16.3	9.2	25.8
		PII(M24)	86	4	4.7	1.3	11.5
A/Vietnam/1194/2004	Dd/NoAdj	PRE	22	0	0.0	0.0	15.4
		PII(M12)	23	4	17.4	5.0	38.8
		PII(M24)	24	2	8.3	1.0	27.0
	Sd/NoAdj	PRE	36	4	11.1	3.1	26.1
		PII(M12)	37	10	27.0	13.8	44.1
		PII(M24)	37	6	16.2	6.2	32.0
	Dd/Adj	PRE	81	11	13.6	7.0	23.0
		PII(M12)	81	36	44.4	33.4	55.9
		PII(M24)	81	25	30.9	21.1	42.1
	Sd/Adj	PRE	86	16	18.6	11.0	28.4
		PII(M12)	86	39	45.3	34.6	56.5
		PII(M24)	86	32	37.2	27.0	48.3

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 on Day 0
PII(M12)= Post-vaccination 2 at Month 12
PII(M24)= Post-vaccination 2 at Month 24

Primary Outcome/Efficacy Variable: Seropositivity rates and GMTs of neutralising antibody titres against A/Indonesia/5/2005 strain at Days 0 and 42 – for a subset of subjects (ATP cohort for immunogenicity

Group	Timing	N	≥ 1:28				GMT		
			n	%	95% CI		value	95% CI	
					LL	UL		LL	UL
Dd/Adj	PRE	82	48	58.5	47.1	69.3	39.7	32.0	49.3
	PII(D42)	82	82	100	95.6	100	169.6	144.7	198.9
Sd/Adj	PRE	87	57	65.5	54.6	75.4	44.2	36.0	54.1
	PII(D42)	87	82	94.3	87.1	98.1	107.5	88.9	130.0

N = Number of subjects with available results
n (%) = number (percentage) of seropositive subjects (neutralising titre ≥ 1:28)
95% CI = 95% confidence interval, LL = Lower Limit, UL = Upper Limit
PRE = Pre-vaccination on Day 0
PII(D42) = Post-vaccination 2 on Day 42

Primary Outcome/Efficacy Variable: Seropositivity rates and GMTs of neutralising antibody titres against A/Vietnam/1194/2005 strain at Days 0 and 42 – for a subset of subjects (ATP cohort for immunogenicity

Group	Timing	N	≥ 1:28			GMT	
			n	%	95% CI	value	95% CI

					LL	UL		LL	UL
Dd/Adj	PRE	82	77	93.9	86.3	98.0	112.5	90.7	139.5
	PII(D42)	82	82	100	95.6	100	595.8	487.7	727.8
Sd/Adj	PRE	87	81	93.1	85.6	97.4	121.1	94.6	154.9
	PII(D42)	87	87	100	95.8	100	447.3	359.3	557.0

N = Number of subjects with available results
n (%) = number (percentage) of seropositive subjects (neutralising titre ≥ 1:28)
95% CI = 95% confidence interval, LL = Lower Limit, UL = Upper Limit
PRE = Pre-vaccination on Day 0
PII(D42) = Post-vaccination 2 on Day 42

Primary Outcome/Efficacy Variable: Seropositivity rates and GMTs of neutralising antibody titres against A/Vietnam/05/2005 and A/Indonesia/5/2005 strains at Day 180 –for a subset of subjects (ATP cohort for persistence at Day 180)

Antibodies against	**Group**	**Timing**	**N**	**≥ 1:28**				**GMT**		
				n	**%**	**95% CI**		**value**	**95% CI**	
						LL	**UL**		**LL**	**UL**
A/Vietnam/1194/2004	Dd/Adj	PRE	76	72	94.7	87.1	98.5	113.2	91.1	140.5
		PII(D180)	73	73	100	95.1	100	260.9	207.7	327.8
	Sd/Adj	PRE	77	73	94.8	87.2	98.6	131.3	101.0	170.7
		PII(D180)	76	76	100	95.3	100	218.2	172.4	276.2
A/Indonesia/5/2005	Dd/Adj	PRE	76	42	55.3	43.4	66.7	37.6	30.0	47.2
		PII(D180)	73	72	98.6	92.6	100	134.5	113.4	159.7
	Sd/Adj	PRE	77	49	63.6	51.9	74.3	43.2	34.6	53.9
		PII(D180)	76	72	94.7	87.1	98.5	97.8	82.0	116.5

N = Number of subjects with available results
n/% = number/percentage of seropositive subjects (neutralising titre ≥ 1:28)
95% CI = 95% confidence interval, LL = Lower Limit, UL = Upper Limit
PRE = Pre-vaccination on Day 0
PII(D180) = Post-vaccination 2 on Day 180

Primary Outcome/Efficacy Variable: Seropositivity rates and GMTs of neutralising antibody titres against A/Vietnam/1194/2004 and A/Indonesia/05/2005 strains at Month 12 – for a subset of subjects (ATP cohort for persistence at Month 12)

Antibodies against	**Group**	**Timing**	**N**	**≥ 1:28**				**GMT**		
				n	**%**	**95% CI**		**value**	**95% CI**	
						LL	**UL**		**LL**	**UL**
A/Vietnam/1194/2004	Dd/Adj	PRE	71	67	94.4	86.2	98.4	108.5	86.6	135.9
		PII(M12)	71	71	100	94.9	100	268.8	211.4	341.8
	Sd/Adj	PRE	69	65	94.2	85.8	98.4	134.0	101.1	177.7
		PII(M12)	69	69	100	94.8	100	274.7	213.4	353.5
A/Indonesia/5/2005	Dd/Adj	PRE	71	38	53.5	41.3	65.5	36.2	28.6	45.7
		PII(M12)	71	65	91.5	82.5	96.8	119.8	94.0	152.7
	Sd/Adj	PRE	69	45	65.2	52.8	76.3	46.9	37.0	59.5
		PII(M12)	69	58	84.1	73.3	91.8	82.5	63.0	107.9

GMT = Geometric Mean antibody Titre
N = Number of subjects with available results
n/% = number/percentage of seropositive subjects (neutralising titre ≥ 1:28)
95% CI = 95% confidence interval, LL = Lower Limit, UL = Upper Limit
PRE = Pre-vaccination on Day 0
PII(M12) = Post-vaccination 2 at Month 12

Primary Outcome/Efficacy Variable: Seropositivity rates and GMTs of neutralising antibody titres against A/Vietnam/1194/2004 and A/Indonesia/05/2005 strains at Month 24 – for a subset of subjects (ATP cohort for persistence at Month 24)

Antibody	**Group**	**Timing**	**N**	**≥1:28**				**GMT**		
				n	**%**	**95% CI**		**value**	**95% CI**	
						LL	**UL**		**LL**	**UL**

A/Vietnam/1194/2004	Dd/Adj	PRE	54	52	96.3	87.3	99.5	115.6	90.0	148.4
		PII(M12)	54	54	100	93.4	100	272.0	210.0	352.3
		PII(M24)	54	54	100	93.4	100	382.8	317.4	461.6
	Sd/Adj	PRE	51	47	92.2	81.1	97.8	131.8	95.4	182.1
		PII(M12)	51	51	100	93.0	100	274.8	203.6	370.9
		PII(M24)	49	49	100	92.7	100	391.0	295.5	517.5
A/Indonesia/5/2005	Dd/Adj	PRE	54	29	53.7	39.6	67.4	36.6	27.8	48.1
		PII(M12)	54	52	96.3	87.3	99.5	137.7	107.9	175.6
		PII(M24)	54	52	96.3	87.3	99.5	84.9	67.0	107.6
	Sd/Adj	PRE	51	36	70.6	56.2	82.5	50.4	38.6	65.8
		PII(M12)	51	44	86.3	73.7	94.3	87.6	64.1	119.9
		PII(M24)	49	44	89.8	77.8	96.6	75.4	57.2	99.4

GMT = Geometric Mean antibody Titre
N = Number of subjects with available results
n/% = number/percentage of seropositive subjects (neutralising titre ≥ 1:28)
95% CI = 95% confidence interval, LL = Lower Limit, UL = Upper Limit
PRE = Pre-vaccination on Day 0
PII(M12)= Post-vaccination 2 at Month 12
PII(M24)= Post-vaccination 2 at Month 24

Primary Outcome/Efficacy Variable: SCR for neutralising antibody response against A/Vitenam/1194/2004 strain at Day 42 – for a subset of subjects(ATP cohort for immunogenicity)

Group	**Timing**	**N**	**SCR**			
			n	**%**	**95% CI**	
					LL	**UL**
Dd/Adj	PII(D42)	82	46	56.1	44.7	67.0
Sd/Adj	PII(D42)	87	39	44.8	34.1	55.9

SCR defined as:
For initially seronegative subjects, antibody titre ≥ 1:56 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
PII(D42) = Post-vaccination 2 on Day 42

Primary Outcome/Efficacy Variable: SCR for neutralising antibody response against A/Indonesia/5/2005 strain at Day 42 – for a subset of subjects(ATP cohort for immunogenicity)

Group	**Timing**	**N**	**SCR**			
			n	**%**	**95% CI**	
					LL	**UL**
Dd/Adj	PII(D42)	82	40	48.8	37.6	60.1
Sd/Adj	PII(D42)	87	25	28.7	19.5	39.4

SCR defined as:
For initially seronegative subjects, antibody titre ≥ 1:56 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
PII(D42) = Post-vaccination 2 on Day 42

Primary Outcome/Efficacy Variable: SCR for neutralising antibody response against A/Vitenam/1194/2004 and A/Indonesia/5/2005 strain at Day 180 - for a subset of subjects (ATP cohort for persistence at Day 180)

Antibodies against	**Group**	**Timing**	**N**	**SCR**			
				n	**%**	**95% CI**	
						LL	**UL**
A/Vietnam/1194/2004	Dd/Adj	PII(D180)	73	21	28.8	18.8	40.6
	Sd/Adj	PII(D180)	76	16	21.1	12.5	31.9
A/Indonesia/5/2005	Dd/Adj	PII(D180)	73	32	43.8	32.2	55.9

	Sd/Adj	PII(D180)	76	20	26.3	16.9	37.7

Seroconversion defined as:
For initially seronegative subjects, antibody titre >= 1:56 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
PII(D180) = Post-vaccination on Day 180

Primary Outcome/Efficacy Variable: SCRs for neutralising antibody titres against A/Vietnam/1194/2004 and A/Indonesia/05/2005 strains at Month 12 – for a subset of subjects (ATP cohort for persistence at Month 12)

Antibodies against	Group	Timing	N	SCR			
				n	%	95% CI	
						LL	UL
A/Vietnam/1194/2004	Dd/Adj	PII(M12)	71	21	29.6	19.3	41.6
	Sd/Adj	PII(M12)	69	18	26.1	16.3	38.1
A/Indonesia/5/2005	Dd/Adj	PII(M12)	71	28	39.4	28.0	51.7
	Sd/Adj	PII(M12)	69	13	18.8	10.4	30.1

Seroconversion defined as:
For initially seronegative subjects, antibody titre $\geq$ 1:56 after vaccination
For initially seropositive subjects, antibody titre after vaccination $\geq$ 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
PII(M12) = Post-vaccination 2 at Month 12

Primary Outcome/Efficacy Variable: SCRs for neutralising antibody titres against A/Vietnam/1194/2004 and A/Indonesia/05/2005 strains at Month 24 – for a subset of subjects (ATP cohort for persistence at Month 24)

Antibodies against	Group	Timing	N	SCR			
				n	%	95% CI	
						LL	UL
A/Vietnam/1194/2004	Dd/Adj	PII(M12)	54	15	27.8	16.5	41.6
		PII(M24)	54	22	40.7	27.6	55.0
	Sd/Adj	PII(M12)	51	14	27.5	15.9	41.7
		PII(M24)	49	18	36.7	23.4	51.7
A/Indonesia/5/2005	Dd/Adj	PII(M12)	54	24	44.4	30.9	58.6
		PII(M24)	54	16	29.6	18.0	43.6
	Sd/Adj	PII(M12)	51	8	15.7	7.0	28.6
		PII(MO24)	49	6	12.2	4.6	24.8

Seroconversion defined as:
For initially seronegative subjects, antibody titre ≥ 1:56 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
PII(M12)= Post-vaccination 2 at Month 12
PII(M24)= Post-vaccination 2 at Month 24

Secondary Outcome/Efficacy Variables: Descriptive Statistics on the frequency cytokine-positive CD4 T-cells on Days 0, 21 and 42 (per 10^6)for CD4.CD40L, CD4.all doubles (T-cells producing at least 2 cytokines), CD4.IL-2, CD4.TNFα, CD4.INFγ stimulated by H5N1 A/Vietnam/1194/2004 strain (ATP cohort for immunogenicity)

Test description	Group	Timing	N	GM	Mean	SD
CD4 All doubles	Dd/NoAdj	PRE	40	545.37	785.98	820.30
		PI(D21)	34	1284.19	1620.26	1058.55
		PII(D42)	30	1316.80	1596.33	1060.97
	Sd/NoAdj	PRE	44	494.27	662.07	518.93
		PI(D21)	42	943.54	1252.02	1034.54
		PII(D42)	43	920.90	1208.16	745.36

	Dd/Adj	PRE	122	495.77	670.50	606.84
		PI(D21)	110	1793.92	2315.24	1867.92
		PII(D42)	118	3049.03	4171.24	4208.17
	Sd/Adj	PRE	129	393.71	620.14	590.66
		PI(D21)	112	1407.29	1845.30	1354.44
		PII(D42)	120	2260.19	3034.88	2242.14
CD4-CD40L	Dd/NoAdj	PRE	40	540.73	761.80	771.32
		PI(D21)	34	1230.48	1547.94	989.52
		PII(D42)	30	1254.99	1510.43	974.20
	Sd/NoAdj	PRE	44	461.29	644.09	513.70
		PI(D21)	42	944.17	1226.12	1015.89
		PII(D42)	43	944.59	1172.72	728.39
	Dd/Adj	PRE	122	485.71	655.20	594.88
		PI(D21)	110	1731.58	2247.71	1828.74
		PII(D42)	118	2971.34	4056.64	4076.52
	Sd/Adj	PRE	129	388.69	604.88	571.91
		PI(D21)	112	1374.26	1782.67	1304.02
		PII(D42)	120	2198.66	2943.00	2165.46
CD4-IL-2	Dd/NoAdj	PRE	40	510.47	710.15	700.70
		PI(D21)	34	1178.95	1490.62	1001.08
		PII(D42)	30	1242.26	1485.70	976.18
	Sd/NoAdj	PRE	44	448.43	610.68	500.03
		PI(D21)	42	868.24	1149.02	967.47
		PII(D42)	43	854.90	1127.19	727.62
	Dd/Adj	PRE	122	461.23	609.22	552.91
		PI(D21)	110	1651.88	2146.25	1776.72
		PII(D42)	118	2762.65	3778.94	3720.42
	Sd/Adj	PRE	129	376.03	571.24	545.75
		PI(D21)	112	1318.03	1716.82	1250.79
		PII(D42)	120	2086.84	2813.43	2086.66
CD4-INFγ	Dd/NoAdj	PRE	40	371.67	595.68	695.33
		PI(D21)	34	852.75	1137.03	823.22
		PII(D42)	30	828.99	1044.83	732.58
	Sd/NoAdj	PRE	44	322.17	460.80	349.01
		PI(D21)	42	579.45	876.48	828.17
		PII(D42)	43	671.86	821.67	552.02
	Dd/Adj	PRE	122	343.35	505.50	549.24
		PI(D21)	110	997.15	1291.85	1023.96
		PII(D42)	118	1535.37	2293.17	2864.48
	Sd/Adj	PRE	129	270.99	459.03	500.13
		PI(D21)	112	685.44	1026.93	884.75
		PII(D42)	120	1123.16	1626.48	1356.18
CD4-TNFα	Dd/NoAdj	PRE	40	382.79	563.75	641.28
		PI(D21)	34	910.69	1203.59	861.04
		PII(D42)	30	918.50	1161.33	822.20
	Sd/NoAdj	PRE	44	369.54	496.30	427.12
		PI(D21)	42	708.15	980.36	915.15
		PII(D42)	43	701.35	896.12	691.26
	Dd/Adj	PRE	122	358.27	518.70	538.07
		PI(D21)	110	1207.95	1641.36	1527.86
		PII(D42)	118	2170.46	3100.96	3380.48
	Sd/Adj	PRE	129	310.91	464.85	486.27
		PI(D21)	112	932.64	1239.38	974.72
		PII(D42)	120	1595.64	2227.27	1798.95

All doubles: T-cells producing at least 2 cytokines
CD4-CD40L: CD4 T-cells producing at least CD40L and another cytokine
CD4-IL-2: CD4 T-cells producing at least IL2 and another cytokine
CD4-INFγ: CD4 T-cells producing at least INF gamma and another cytokine
CD4-TNFα: CD4 T-cells producing at least TNF alpha and another cytokine
N = number of subjects with available results
GM= Geometric Mean
SD = Standard Deviation
PRE = pre-vaccination on Day 0
PI(D21) = post-vaccination on Day 21
PII(D42) = post-vaccination 2 on Day 42.

Secondary Outcome/Efficacy Variables: Descriptive Statistics on the frequency cytokine-positive CD4 T-cells on Days 0 and 180 (per million T-cells) for CD4.CD40L, CD4.ALL DOUBLES (T-cells producing at least two cytokines), CD4.IL-2, CD4.TNF-alpha, CD4.INF-gamma stimulated by H5N1 A/Vietnam/1194/2004 strain (ATP cohort for persistence at Day 180)

Test description	Group	Timing	N	GM	Mean	SD
CD4 ALL DOUBLES	Dd/NoAdj	PRE	38	562.24	819.95	839.36
		PII(D180)	41	850.48	1067.80	764.04
	Sd/NoAdj	PRE	43	479.49	656.58	530.93
		PII(D180)	47	760.03	914.34	637.84
	Dd/Adj	PRE	114	478.17	642.69	580.86
		PII(D180)	122	1515.07	1985.20	1982.71
	Sd/Adj	PRE	120	386.36	626.66	609.62
		PII(D180)	132	1247.34	1521.60	1000.47
CD4-CD40L	Dd/NoAdj	PRE	38	558.51	794.71	788.74
		PII(D180)	41	808.25	998.39	678.83
	Sd/NoAdj	PRE	43	447.49	638.58	525.39
		PII(D180)	47	729.72	867.40	583.83
	Dd/Adj	PRE	114	468.50	627.99	570.09
		PII(D180)	122	1455.68	1886.15	1789.27
	Sd/Adj	PRE	120	382.75	611.22	588.69
		PII(D180)	132	1188.86	1449.26	939.31
CD4-IL-2	Dd/NoAdj	PRE	38	528.84	741.82	717.09
		PII(D180)	41	774.93	991.66	742.90
	Sd/NoAdj	PRE	43	440.16	609.42	509.36
		PII(D180)	47	704.32	849.51	596.04
	Dd/Adj	PRE	114	441.56	582.12	538.27
		PII(D180)	122	1433.08	1887.17	1921.82
	Sd/Adj	PRE	120	369.09	577.90	563.25
		PII(D180)	132	1172.16	1434.47	957.55
CD4-INF-γ	Dd/NoAdj	PRE	38	391.29	630.97	709.44
		PII(D180)	41	558.99	740.15	654.35
	Sd/NoAdj	PRE	43	310.36	454.81	356.67
		PII(D180)	47	461.80	613.26	494.66
	Dd/Adj	PRE	114	325.98	476.00	531.62
		PII(D180)	122	763.06	1078.66	1243.60
	Sd/Adj	PRE	120	264.43	461.18	514.57
		PII(D180)	132	654.11	850.89	661.08
CD4-TNF-α	Dd/NoAdj	PRE	38	401.45	594.21	654.27
		PII(D180)	41	636.00	846.07	713.19
	Sd/NoAdj	PRE	43	361.49	493.74	432.99
		PII(D180)	47	585.70	729.47	578.22
	Dd/Adj	PRE	114	342.26	496.33	530.44
		PII(D180)	122	1143.69	1525.03	1444.11
	Sd/Adj	PRE	120	310.14	472.11	498.36
		PII(D180)	132	937.82	1182.06	839.91

All doubles: T-cells producing at least 2 cytokines
CD4-CD40L: CD4 T-cells producing at least CD40L and another cytokine
CD4-IL-2: CD4 T-cells producing at least IL2 and another cytokine
CD4-INFγ: CD4 T-cells producing at least INF gamma and another cytokine
CD4-TNFα: CD4 T-cells producing at least TNF alpha and another cytokine
N = number of subjects with available results
GM= Geometric Mean
SD = Standard Deviation
PRE= pre-vaccination on Day 0
PII(D180) = post-vaccination 2 on Day 180

Secondary Outcome/Efficacy Variables: Descriptive Statistics on the frequency cytokine-positive CD4 T-cells on Day 0 and at Month 12 (per 10^6)for CD4.CD40L, CD4.all doubles (T-cells producing at least 2 cytokines), CD4.IL-2, CD4.TNFα, CD4.INFγ stimulated by H5N1 A/Vietnam/1194/2004 strain (ATP Cohort for persistence Month 12)

Test description	Group	Timing	N	GM	Mean	SD
CD4 ALL DOUBLES	Dd/NoAdj	PRE	32	504.22	716.19	704.70
		PII(M12)	30	869.43	1038.70	632.50
	Sd/NoAdj	PRE	36	493.67	629.31	429.45
		PII(M12)	41	693.48	839.76	668.33
	Dd/Adj	PRE	89	476.14	619.53	414.17
		PII(M12)	91	1170.36	1480.40	1021.43
	Sd/Adj	PRE	96	367.90	610.44	640.49
		PII(M12)	90	898.52	1270.86	1050.39
CD4-CD40L	Dd/NoAdj	PRE	32	500.90	692.19	653.90
		PII(M12)	30	850.80	1012.23	612.75
	Sd/NoAdj	PRE	36	477.38	614.22	415.35
		PII(M12)	41	675.52	817.88	655.85
	Dd/Adj	PRE	89	463.00	606.72	411.14
		PII(M12)	91	1146.47	1453.32	1002.22
	Sd/Adj	PRE	96	364.80	595.16	620.28
		PII(M12)	90	934.35	1252.94	1020.83
CD4-IL-2	Dd/NoAdj	PRE	32	476.15	644.63	577.84
		PII(M12)	30	798.58	964.57	598.14
	Sd/NoAdj	PRE	36	461.80	586.89	407.97
		PII(M12)	41	628.12	771.49	623.44
	Dd/Adj	PRE	89	453.83	562.74	380.64
		PII(M12)	91	1118.63	1405.66	973.32
	Sd/Adj	PRE	96	355.29	566.08	595.83
		PII(M12)	90	902.69	1217.27	1006.77
CD4-INF-γ	Dd/NoAdj	PRE	32	360.72	558.59	599.43
		PII(M12)	30	542.62	689.30	471.58
	Sd/NoAdj	PRE	36	317.49	444.39	304.04
		PII(M12)	41	442.16	531.20	419.92
	Dd/Adj	PRE	89	321.28	453.17	348.03
		PII(M12)	91	586.60	772.51	577.71
	Sd/Adj	PRE	96	242.71	456.28	553.41
		PII(M12)	90	442.66	703.12	743.99
CD4-TNF-α	Dd/NoAdj	PRE	32	361.03	498.16	437.60
		PII(M12)	30	647.75	793.33	528.32
	Sd/NoAdj	PRE	36	376.86	479.83	364.61
		PII(M12)	41	515.70	634.02	484.61
	Dd/Adj	PRE	89	345.91	478.76	355.38
		PII(M12)	91	884.64	1155.80	847.51

	Sd/Adj	PRE	96	307.62	473.28	536.35
		PII(M12)	90	678.60	993.50	870.28

All doubles: T-cells producing at least 2 cytokines
CD4-CD40L: CD4 T-cells producing at least CD40L and another cytokine
CD4-IL-2: CD4 T-cells producing at least IL2 and another cytokine
CD4-INFγ: CD4 T-cells producing at least INF gamma and another cytokine
CD4-TNFα: CD4 T-cells producing at least TNF alpha and another cytokine
N = number of subjects with available results
GM = Geometric Mean
SD = Standard Deviation
PRE = Pre-vaccination on Day 0
PII(M12) = Post-vaccination 2 at Month 12

Secondary Outcome/Efficacy Variables: Descriptive Statistics on the frequency cytokine-positive CD4 T-cells at Month 24 (per 10^6)for CD4.CD40L, CD4.all doubles (T-cells producing at least 2 cytokines), CD4.IL-2, CD4.TNFα, CD4.INFγ stimulated by H5N1 A/Vietnam/1194/2004 strain (ATP Cohort for persistence Month 24)

Test description	Group	Timing	N	GM	Mean	SD
CD4 ALL DOUBLES	Dd/NoAdj	PII(M24)	22	832.74	1072.59	908.25
	Sd/NoAdj	PII(M24)	34	569.84	847.97	1058.95
	Dd/Adj	PII(M24)	72	1126.86	1483.86	1375.31
	Sd/Adj	PII(M24)	73	779.93	1052.59	771.46
CD4-CD40L	Dd/NoAdj	PII(M24)	22	740.77	945.86	820.93
	Sd/NoAdj	PII(M24)	34	454.56	800.85	1060.83
	Dd/Adj	PII(M24)	72	1041.16	1399.31	1356.01
	Sd/Adj	PII(M24)	73	710.53	1002.15	712.25
CD4-IL-2	Dd/NoAdj	PII(M24)	22	783.88	1007.91	868.28
	Sd/NoAdj	PII(M24)	34	509.21	790.44	1039.78
	Dd/Adj	PII(M24)	72	1043.95	1400.18	1333.41
	Sd/Adj	PII(M24)	73	769.56	1009.84	718.28
CD4-INF-γ	Dd/NoAdj	PII(M24)	22	563.18	834.23	849.25
	Sd/NoAdj	PII(M24)	34	391.45	636.56	923.81
	Dd/Adj	PII(M24)	72	651.02	932.38	947.13
	Sd/Adj	PII(M24)	73	455.05	675.34	608.16
CD4-TNF-α	Dd/NoAdj	PII(M24)	22	598.88	838.82	860.46
	Sd/NoAdj	PII(M24)	34	374.53	651.24	962.01
	Dd/Adj	PII(M24)	72	806.94	1096.81	1012.40
	Sd/Adj	PII(M24)	73	500.82	734.85	555.63

All doubles: T-cells producing at least 2 cytokines
CD4-CD40L: CD4 T-cells producing at least CD40L and another cytokine
CD4-IL-2: CD4 T-cells producing at least IL2 and another cytokine
CD4-INFγ: CD4 T-cells producing at least INF gamma and another cytokine
CD4-TNFα: CD4 T-cells producing at least TNF alpha and another cytokine
N = number of subjects with available results
GM= Geometric Mean
SD = Standard Deviation
PII(M24) = Post-vaccination 2 at Month 24

Secondary Outcome/Efficacy Variables: Descriptive Statistics on the frequency cytokine-positive CD8 T-cells (per 10^6) on Days 0, 21 and 42 for CD8.all doubles (T-cells producing at least 2 cytokines), CD8.CD40L, CD8.IL-2, CD8.TNFα, CD8.INFγ stimulated by H5N1 A/Vietnam/1194/2004 strain (ATP cohort for immunogenicity)

Test description	Group	Timing	N	GM	Mean	SD
CD8All doubles	Dd/NoAdj	PRE	40	94.74	789.93	1903.91
		PI(D21)	34	115.83	723.32	1790.72
		PII(D42)	29	141.31	962.69	2816.12
	Sd/NoAdj	PRE	44	52.25	255.34	497.68
		PI(D21)	41	80.16	375.29	643.85
		PII(D42)	43	63.45	261.63	462.64

	Dd/Adj	PRE	121	71.93	352.07	626.44
		PI(D21)	109	77.70	312.37	661.43
		PII(D42)	118	79.56	370.58	765.47
	Sd/Adj	PRE	129	83.30	299.57	407.94
		PI(D21)	111	70.23	297.30	391.63
		PII(D42)	120	77.73	296.52	499.25
CD8-CD40L	Dd/NoAdj	PRE	40	4.30	85.45	322.83
		PI(D21)	34	4.86	47.29	162.75
		PII(D42)	29	3.41	65.00	253.17
	Sd/NoAdj	PRE	44	2.94	17.52	34.07
		PI(D21)	41	3.45	18.49	30.93
		PII(D42)	43	3.51	14.88	24.09
	Dd/Adj	PRE	121	3.58	20.88	48.88
		PI(D21)	109	5.61	24.78	34.07
		PII(D42)	118	5.23	30.97	51.86
	Sd/Adj	PRE	129	3.37	24.04	52.35
		PI(D21)	111	3.90	26.86	52.29
		PII(D42)	120	5.32	34.11	100.78
CD8-IL-2	Dd/NoAdj	PRE	40	56.29	579.38	1426.27
		PI(D21)	34	77.59	491.97	1217.04
		PII(D42)	29	97.06	671.69	1832.58
	Sd/NoAdj	PRE	44	43.45	187.82	334.22
		PI(D21)	41	57.71	270.02	422.85
		PII(D42)	43	40.01	177.35	296.52
	Dd/Adj	PRE	121	59.70	218.11	340.60
		PI(D21)	109	45.97	200.17	342.71
		PII(D42)	118	50.37	228.35	413.85
	Sd/Adj	PRE	129	53.90	190.62	241.03
		PI(D21)	111	45.48	197.19	251.49
		PII(D42)	120	42.77	181.76	261.13
CD8-INFγ	Dd/NoAdj	PRE	40	98.30	760.55	1888.61
		PI(D21)	34	95.39	687.47	1777.86
		PII(D42)	29	119.73	948.97	2845.99
	Sd/NoAdj	PRE	44	44.71	234.82	489.55
		PI(D21)	41	62.56	345.07	629.74
		PII(D42)	43	64.19	253.02	434.70
	Dd/Adj	PRE	121	80.54	339.86	618.55
		PI(D21)	109	55.07	290.79	661.84
		PII(D42)	118	63.71	353.79	767.88
	Sd/Adj	PRE	129	83.14	287.51	394.32
		PI(D21)	111	61.44	289.99	390.60
		PII(D42)	120	55.71	280.14	506.29
CD8-TNFα	Dd/NoAdj	PRE	40	82.77	605.90	1532.47
		PI(D21)	34	82.29	575.65	1468.85
		PII(D42)	29	72.24	768.48	2394.50
	Sd/NoAdj	PRE	44	36.83	194.52	414.08
		PI(D21)	41	75.79	323.51	579.85
		PII(D42)	43	40.62	211.56	375.13
	Dd/Adj	PRE	121	45.34	294.21	573.91
		PI(D21)	109	63.94	261.77	609.54
		PII(D42)	118	59.10	315.86	689.32
	Sd/Adj	PRE	129	63.19	239.59	355.75
		PI(D21)	111	55.42	225.67	306.06
		PII(D42)	120	59.51	239.68	434.37

All doubles: T-cells producing at least 2 cytokines
CD8-CD40L: CD8 T-cells producing at least CD40L and another cytokine
CD8-IL-2: CD8 T-cells producing at least IL2 and another cytokine
CD8-INFγ: CD8 T-cells producing at least INF gamma and another cytokine
CD8-TNFα: CD8 T-cells producing at least TNF alpha and another cytokine
N = number of subjects with available results
GM= Geometric Mean
SD = Standard Deviation
PRE = pre-vaccination on Day 0
PI(D21) = post-vaccination on Day 21
PII(D42) = post-vaccination on Day 42.

Secondary Outcome/Efficacy Variables: Descriptive Statistics on the frequency cytokine-positive CD8 T-cells (per 10^6) on Days 0 and 180 for CD8.all doubles (T-cells producing at least 2 cytokines), CD8.CD40L, CD8.IL-2, CD8.TNFα, CD8.INFγ stimulated by H5N1 A/Vietnam/1194/2004 strain (ATP cohort for persistence at Day 180)

Test description	Group	Timing	N	GM	Mean	SD
CD8 ALL DOUBLES	Dd/NoAdj	PRE	38	97.84	824.45	1948.21
		PII(D180)	41	36.77	297.17	685.05
	Sd/NoAdj	PRE	43	48.64	192.09	265.89
		PII(D180)	47	23.66	186.06	370.71
	Dd/Adj	PRE	113	69.86	360.58	644.26
		PII(D180)	121	41.28	282.34	753.94
	Sd/Adj	PRE	120	77.34	275.28	332.50
		PII(D180)	132	32.11	185.05	293.81
CD8-CD40L	Dd/NoAdj	PRE	38	4.64	89.89	330.83
		PII(D180)	41	1.80	9.93	23.59
	Sd/NoAdj	PRE	43	2.92	15.16	26.70
		PII(D180)	47	1.93	11.72	31.43
	Dd/Adj	PRE	113	3.60	22.23	51.42
		PII(D180)	121	2.47	57.69	499.31
	Sd/Adj	PRE	120	3.21	20.57	44.56
		PII(D180)	132	2.04	11.54	26.32
CD8-IL-2	Dd/NoAdj	PRE	38	68.44	608.26	1458.36
		PII(D180)	41	18.95	190.46	465.37
	Sd/NoAdj	PRE	43	41.40	148.70	164.66
		PII(D180)	47	18.86	120.13	269.95
	Dd/Adj	PRE	113	58.85	222.50	349.86
		PII(D180)	121	23.70	200.64	704.78
	Sd/Adj	PRE	120	51.91	177.63	201.96
		PII(D180)	132	18.78	113.14	178.46
CD8-INF-γ	Dd/NoAdj	PRE	38	110.08	797.13	1931.82
		PII(D180)	41	28.29	286.29	688.23
	Sd/NoAdj	PRE	43	40.16	167.07	244.49
		PII(D180)	47	28.27	191.00	365.36
	Dd/Adj	PRE	113	82.46	352.20	635.24
		PII(D180)	121	41.21	257.12	663.40
	Sd/Adj	PRE	120	80.00	264.55	321.00
		PII(D180)	132	26.37	171.13	288.43
CD8-TNF-α	Dd/NoAdj	PRE	38	80.53	628.82	1569.78
		PII(D180)	41	40.55	258.83	588.74
	Sd/NoAdj	PRE	43	36.72	141.09	210.87
		PII(D180)	47	20.94	153.62	289.74
	Dd/Adj	PRE	113	46.58	303.72	590.59
		PII(D180)	121	36.68	212.20	390.84
	Sd/Adj	PRE	120	61.36	222.37	286.67

		PII(D180)	132	22.30	157.54	270.88

All doubles: T-cells producing at least 2 cytokines
CD8-CD40L: CD8 T-cells producing at least CD40L and another cytokine
CD8-IL-2: CD8 T-cells producing at least IL2 and another cytokine
CD8-INFγ: CD8 T-cells producing at least INF gamma and another cytokine
CD8-TNFα: CD8 T-cells producing at least TNF alpha and another cytokine
N = number of subjects with available results
GM= Geometric Mean
SD = Standard Deviation
PRE= pre-vaccination on Day 0
PII(D180) = post-vaccination 2 on Day 180

Secondary Outcome/Efficacy Variables: Descriptive Statistics on the frequency cytokine-positive CD8 T-cells (per 10^6) on Day 0 and at Month 12 for CD8.all doubles (T-cells producing at least 2 cytokines), CD8.CD40L, CD8.IL-2, CD8.TNFα, CD8.INFγ stimulated by H5N1 A/Vietnam/1194/2004 strain (ATP cohort for persistence at Month 12)

Test description	Group	Timing	N	GM	Mean	SD
CD8 ALL DOUBLES	Dd/NoAdj	PRE	32	82.29	687.22	1795.65
		PII(M12)	30	34.21	324.33	838.37
	Sd/NoAdj	PRE	36	59.88	205.53	279.85
		PII(M12)	41	29.42	141.63	283.23
	Dd/Adj	PRE	88	64.77	350.23	653.58
		PII(M12)	91	27.88	167.02	261.68
	Sd/Adj	PRE	96	76.10	259.68	284.24
		PII(M12)	90	34.28	175.46	275.22
CD8-CD40L	Dd/NoAdj	PRE	32	4.33	48.31	178.90
		PII(M12)	30	2.48	14.33	31.11
	Sd/NoAdj	PRE	36	3.27	17.06	28.45
		PII(M12)	41	2.22	10.20	20.24
	Dd/Adj	PRE	88	3.21	18.03	33.42
		PII(M12)	91	2.99	15.43	28.90
	Sd/Adj	PRE	96	2.78	15.96	30.19
		PII(M12)	90	2.08	11.93	28.46
CD8-IL-2	Dd/NoAdj	PRE	32	56.34	506.91	1339.28
		PII(M12)	30	28.85	247.70	598.65
	Sd/NoAdj	PRE	36	48.44	155.58	170.03
		PII(M12)	41	24.72	93.17	153.94
	Dd/Adj	PRE	88	60.23	207.74	307.82
		PII(M12)	91	19.95	108.04	164.36
	Sd/Adj	PRE	96	48.96	175.27	194.43
		PII(M12)	90	18.84	112.71	167.58
CD8-INF-γ	Dd/NoAdj	PRE	32	95.39	661.06	1788.59
		PII(M12)	30	32.99	310.43	829.25
	Sd/NoAdj	PRE	36	48.50	179.06	256.50
		PII(M12)	41	24.45	129.98	285.49
	Dd/Adj	PRE	88	76.94	343.09	649.61
		PII(M12)	91	20.75	151.33	260.19
	Sd/Adj	PRE	96	76.43	250.39	281.06
		PII(M12)	90	29.13	155.96	271.12
CD8-TNF-α	Dd/NoAdj	PRE	32	67.01	503.53	1438.17
		PII(M12)	30	31.35	246.13	595.41
	Sd/NoAdj	PRE	36	45.01	154.81	224.90
		PII(M12)	41	32.59	131.98	230.03
	Dd/Adj	PRE	88	41.97	293.76	597.80
		PII(M12)	91	28.15	154.10	246.49
	Sd/Adj	PRE	96	55.98	206.97	232.89

		PII(M12)	90	35.67	159.66	251.66

All doubles: T-cells producing at least 2 cytokines
CD8-CD40L: CD8 T-cells producing at least CD40L and another cytokine
CD8-IL-2: CD8 T-cells producing at least IL2 and another cytokine
CD8-INFγ: CD8 T-cells producing at least INF gamma and another cytokine
CD8-TNFα: CD8 T-cells producing at least TNF alpha and another cytokine
N = number of subjects with available results
GM = Geometric Mean
SD = Standard Deviation
PRE = Pre-vaccination on Day 0
PII(M12) = Post-vaccination 2 at Month 12

Secondary Outcome/Efficacy Variables: Descriptive Statistics on the frequency cytokine-positive CD8 T-cells (per 10^6) at Month 12 CD8.all doubles (T-cells producing at least 2 cytokines), CD8.CD40L, CD8.IL-2, CD8.TNFα, CD8.INFγ stimulated by H5N1 A/Vietnam/1194/2004 strain (ATP cohort for persistence at Month 24)

Test description	Group	Timing	N	GM	Mean	SD
CD8 ALL DOUBLES	Dd/NoAdj	PII(M24)	22	14.92	143.41	381.27
	Sd/NoAdj	PII(M24)	33	8.06	44.64	60.49
	Dd/Adj	PII(M24)	72	21.67	153.63	258.83
	Sd/Adj	PII(M24)	73	8.05	57.37	94.19
CD8-CD40L	Dd/NoAdj	PII(M24)	22	1.48	6.23	18.20
	Sd/NoAdj	PII(M24)	33	2.65	16.36	33.03
	Dd/Adj	PII(M24)	72	2.58	14.43	32.70
	Sd/Adj	PII(M24)	73	1.94	11.99	29.28
CD8-IL-2	Dd/NoAdj	PII(M24)	22	6.51	97.18	310.91
	Sd/NoAdj	PII(M24)	33	4.16	29.76	69.59
	Dd/Adj	PII(M24)	72	8.16	84.83	181.28
	Sd/Adj	PII(M24)	73	5.04	37.90	65.04
CD8-INF-γ	Dd/NoAdj	PII(M24)	22	12.47	140.82	382.05
	Sd/NoAdj	PII(M24)	33	9.05	50.00	79.82
	Dd/Adj	PII(M24)	72	23.39	153.01	257.70
	Sd/Adj	PII(M24)	73	7.43	55.49	93.13
CD8-TNF-α	Dd/NoAdj	PII(M24)	22	15.30	124.18	325.83
	Sd/NoAdj	PII(M24)	33	4.05	28.06	51.49
	Dd/Adj	PII(M24)	72	17.22	131.89	231.77
	Sd/Adj	PII(M24)	73	4.76	35.49	65.03

All doubles: T-cells producing at least 2 cytokines
CD8-CD40L: CD8 T-cells producing at least CD40L and another cytokine
CD8-IL-2: CD8 T-cells producing at least IL2 and another cytokine
CD8-INFγ: CD8 T-cells producing at least INF gamma and another cytokine
CD8-TNFα: CD8 T-cells producing at least TNF alpha and another cytokine
N = number of subjects with available results
GM= Geometric Mean
SD = Standard Deviation
PII(M24) = Post-vaccination 2 at Month 24

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

Symptom	Intensity	Dd/NoAdj Group					Sd/NoAdj Group				
		N	n	%	95 % CI		N	n	%	95 % CI	
					LL	UL				LL	UL
Dose 1											
Ecchymosis	Any	51	1	2.0	0.0	10.4	61	0	0.0	0.0	5.9
	> 100 mm	51	0	0.0	0.0	7.0	61	0	0.0	0.0	5.9
Induration	Any	51	0	0.0	0.0	7.0	61	0	0.0	0.0	5.9
	> 100 mm	51	0	0.0	0.0	7.0	61	0	0.0	0.0	5.9

Pain	Any	51	2	3.9	0.5	13.5	61	4	6.6	1.8	15.9
	Grade 3	51	0	0.0	0.0	7.0	61	0	0.0	0.0	5.9
Redness	Any	51	1	2.0	0.0	10.4	61	0	0.0	0.0	5.9
	> 100 mm	51	0	0.0	0.0	7.0	61	0	0.0	0.0	5.9
Swelling	Any	51	0	0.0	0.0	7.0	61	0	0.0	0.0	5.9
	> 100 mm	51	0	0.0	0.0	7.0	61	0	0.0	0.0	5.9
Dose 2											
Ecchymosis	Any	49	0	0.0	0.0	7.3	55	0	0.0	0.0	6.5
	> 100 mm	49	0	0.0	0.0	7.3	55	0	0.0	0.0	6.5
Induration	Any	49	0	0.0	0.0	7.3	55	0	0.0	0.0	6.5
	> 100 mm	49	0	0.0	0.0	7.3	55	0	0.0	0.0	6.5
Pain	Any	49	2	4.1	0.5	14.0	55	4	7.3	2.0	17.6
	Grade 3	49	0	0.0	0.0	7.3	55	0	0.0	0.0	6.5
Redness	Any	49	0	0.0	0.0	7.3	55	0	0.0	0.0	6.5
	> 100 mm	49	0	0.0	0.0	7.3	55	0	0.0	0.0	6.5
Swelling	Any	49	0	0.0	0.0	7.3	55	0	0.0	0.0	6.5
	> 100 mm	49	0	0.0	0.0	7.3	55	0	0.0	0.0	6.5
Across doses											
Ecchymosis	Any	51	1	2.0	0.0	10.4	61	0	0.0	0.0	5.9
	> 100 mm	51	0	0.0	0.0	7.0	61	0	0.0	0.0	5.9
Induration	Any	51	0	0.0	0.0	7.0	61	0	0.0	0.0	5.9
	> 100 mm	51	0	0.0	0.0	7.0	61	0	0.0	0.0	5.9
Pain	Any	51	3	5.9	1.2	16.2	61	6	9.8	3.7	20.2
	Grade 3	51	0	0.0	0.0	7.0	61	0	0.0	0.0	5.9
Redness	Any	51	1	2.0	0.0	10.4	61	0	0.0	0.0	5.9
	> 100 mm	51	0	0.0	0.0	7.0	61	0	0.0	0.0	5.9
Swelling	Any	51	0	0.0	0.0	7.0	61	0	0.0	0.0	5.9
	> 100 mm	51	0	0.0	0.0	7.0	61	0	0.0	0.0	5.9
		Dd/Adj Group					**Sd/Adj Group**				
		N	**n**	**%**	**95 % CI**		**N**	**n**	**%**	**95 % CI**	
					LL	**UL**				**LL**	**UL**
Dose 1											
Ecchymosis	Any	159	5	3.1	1.0	7.2	164	1	0.6	0.0	3.4
	> 100 mm	159	0	0.0	0.0	2.3	164	0	0.0	0.0	2.2
Induration	Any	159	6	3.8	1.4	8.0	164	7	4.3	1.7	8.6
	> 100 mm	159	0	0.0	0.0	2.3	164	0	0.0	0.0	2.2
Pain	Any	159	63	39.6	32.0	47.7	164	56	34.1	26.9	41.9
	Grade 3	159	0	0.0	0.0	2.3	164	0	0.0	0.0	2.2
Redness	Any	159	19	11.9	7.4	18.0	164	9	5.5	2.5	10.2
	> 100 mm	159	1	0.6	0.0	3.5	164	0	0.0	0.0	2.2
Swelling	Any	159	8	5.0	2.2	9.7	164	9	5.5	2.5	10.2
	> 100 mm	154	0	0.0	0.0	2.3	164	0	0.0	0.0	2.2
Dose 2											
Ecchymosis	Any	154	0	0.0	0.0	2.4	161	0	0.0	0.0	2.3
	> 100 mm	154	0	0.0	0.0	2.4	161	0	0.0	0.0	2.3
Induration	Any	154	11	7.1	3.6	12.4	161	4	2.5	0.7	6.2
	> 100 mm	154	0	0.0	0.0	2.4	161	0	0.0	0.0	2.3
Pain	Any	154	57	37.0	29.4	45.2	161	50	31.1	24.0	38.8
	Grade 3	154	2	1.3	0.2	4.6	161	0	0.0	0.0	2.3
Redness	Any	154	20	13.0	8.1	19.3	161	12	7.5	3.9	12.7
	> 100 mm	154	0	0.0	0.0	2.4	161	0	0.0	0.0	2.3
Swelling	Any	154	10	6.5	3.2	11.6	161	14	8.7	4.8	14.2
	> 100 mm	313	0	0.0	0.0	2.4	161	0	0.0	0.0	2.3
Across doses											

Ecchymosis	Any	159	5	3.1	1.0	7.2	164	1	0.6	0.0	3.4
	> 100 mm	159	0	0.0	0.0	2.3	164	0	0.0	0.0	2.2
Induration	Any	159	15	9.4	5.4	15.1	164	10	6.1	3.0	10.9
	> 100 mm	159	0	0.0	0.0	2.3	164	0	0.0	0.0	2.2
Pain	Any	159	75	47.2	39.2	55.2	164	69	42.1	34.4	50.0
	Grade 3	159	2	1.3	0.2	4.5	164	0	0.0	0.0	2.2
Redness	Any	159	30	18.9	13.1	25.8	164	19	11.6	7.1	17.5
	> 100 mm	159	1	0.6	0.0	3.5	164	0	0.0	0.0	2.2
Swelling	Any	159	15	9.4	5.4	15.1	164	19	11.6	7.1	17.5
	> 100 mm	159	0	0.0	0.0	2.3	164	0	0.0	0.0	2.2

Any = occurrence of any solicited local symptom regardless of their intensity grade
Grade 3 pain = pain that prevented normal activity
N= number of subjects with at least one documented dose
n (%) = number (percentage) of subjects reporting at least once the symptom

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

Symptom	**Intensity/ Relationship**	**Dd/NoAdj Group**					**Sd/NoAdj Group**				
		N	**n**	**%**	**95 % CI**		**N**	**n**	**%**	**95 % CI**	
					LL	**UL**				**LL**	**UL**
Dose 1											
Arthralgia	Any	51	1	2.0	0.0	10.4	61	4	6.6	1.8	15.9
	Grade 3	51	0	0.0	0.0	7.0	61	0	0.0	0.0	5.9
	Related	51	0	0.0	0.0	7.0	61	1	1.6	0.0	8.8
Fatigue	Any	51	4	7.8	2.2	18.9	61	6	9.8	3.7	20.2
	Grade 3	51	0	0.0	0.0	7.0	61	2	3.3	0.4	11.3
	Related	51	0	0.0	0.0	7.0	61	1	1.6	0.0	8.8
Fever/ (Axillary) (°C)	>37.5	51	0	0.0	0.0	7.0	61	1	1.6	0.0	8.8
	>39.0	51	0	0.0	0.0	7.0	61	1	1.6	0.0	8.8
	Related	51	0	0.0	0.0	7.0	61	1	1.6	0.0	8.8
Headache	Any	51	1	2.0	0.0	10.4	61	6	9.8	3.7	20.2
	Grade 3	51	0	0.0	0.0	7.0	61	1	1.6	0.0	8.8
	Related	51	0	0.0	0.0	7.0	61	3	4.9	1.0	13.7
Myalgia	Any	51	2	3.9	0.5	13.5	61	4	6.6	1.8	15.9
	Grade 3	51	0	0.0	0.0	7.0	61	0	0.0	0.0	5.9
	Related	51	0	0.0	0.0	7.0	61	1	1.6	0.0	8.8
Shivering	Any	51	1	2.0	0.0	10.4	61	2	3.3	0.4	11.3
	Grade 3	51	0	0.0	0.0	7.0	61	0	0.0	0.0	5.9
	Related	51	0	0.0	0.0	7.0	61	2	3.3	0.4	11.3
Sweating	Any	51	2	3.9	0.5	13.5	61	5	8.2	2.7	18.1
	Grade 3	51	0	0.0	0.0	7.0	61	0	0.0	0.0	5.9
	Related	51	0	0.0	0.0	7.0	61	1	1.6	0.0	8.8
Dose 2											
Arthralgia	Any	49	1	2.0	0.1	10.9	54	2	3.7	0.5	12.7
	Grade 3	49	0	0.0	0.0	7.3	54	0	0.0	0.0	6.6
	Related	49	0	0.0	0.0	7.3	54	0	0.0	0.0	6.6
Fatigue	Any	49	3	6.1	1.3	16.9	54	3	5.6	1.2	15.4
	Grade 3	49	0	0.0	0.0	7.3	54	0	0.0	0.0	6.6
	Related	49	0	0.0	0.0	7.3	54	0	0.0	0.0	6.6
Fever/ (Axillary) (°C)	>37.5	49	0	0.0	0.0	7.3	54	0	0.0	0.0	6.6
	>39.0	49	0	0.0	0.0	7.3	54	0	0.0	0.0	6.6
	Related	49	0	0.0	0.0	7.3	54	0	0.0	0.0	6.6
Headache	Any	49	1	2.0	0.1	10.9	54	2	3.7	0.5	12.7
	Grade 3	49	0	0.0	0.0	7.3	54	0	0.0	0.0	6.6

	Related	49	0	0.0	0.0	7.3	54	0	0.0	0.0	6.6
Myalgia	Any	49	2	4.1	0.5	14.0	54	2	3.7	0.5	12.7
	Grade 3	49	1	2.0	0.1	10.9	54	0	0.0	0.0	6.6
	Related	49	0	0.0	0.0	7.3	54	0	0.0	0.0	6.6
Shivering	Any	49	1	2.0	0.1	10.9	54	1	1.9	0.0	9.9
	Grade 3	49	0	0.0	0.0	7.3	54	0	0.0	0.0	6.6
	Related	49	0	0.0	0.0	7.3	54	0	0.0	0.0	6.6
Sweating	Any	49	1	2.0	0.1	10.9	54	4	7.4	2.1	17.9
	Grade 3	49	0	0.0	0.0	7.3	54	0	0.0	0.0	6.6
	Related	49	0	0.0	0.0	7.3	54	0	0.0	0.0	6.6
Across doses											
Arthralgia	Any	51	1	2.0	0.0	10.4	61	5	8.2	2.7	18.1
	Grade 3	51	0	0.0	0.0	7.0	61	0	0.0	0.0	5.9
	Related	51	0	0.0	0.0	7.0	61	1	1.6	0.0	8.8
Fatigue	Any	51	6	11.8	4.4	23.9	61	7	11.5	4.7	22.2
	Grade 3	51	0	0.0	0.0	7.0	61	2	3.3	0.4	11.3
	Related	51	0	0.0	0.0	7.0	61	1	1.6	0.0	8.8
Fever/ (Axillary) (°C)	>37.5	51	0	0.0	0.0	7.0	61	1	1.6	0.0	8.8
	>39.0	51	0	0.0	0.0	7.0	61	1	1.6	0.0	8.8
	Related	51	0	0.0	0.0	7.0	61	1	1.6	0.0	8.8
Headache	Any	51	2	3.9	0.5	13.5	61	6	9.8	3.7	20.2
	Grade 3	51	0	0.0	0.0	7.0	61	1	1.6	0.0	8.8
	Related	51	0	0.0	0.0	7.0	61	3	4.9	1.0	13.7
Myalgia	Any	51	3	5.9	1.2	16.2	61	5	8.2	2.7	18.1
	Grade 3	51	1	2.0	0.0	10.4	61	0	0.0	0.0	5.9
	Related	51	0	0.0	0.0	7.0	61	1	1.6	0.0	8.8
Shivering	Any	51	2	3.9	0.5	13.5	61	3	4.9	1.0	13.7
	Grade 3	51	0	0.0	0.0	7.0	61	0	0.0	0.0	5.9
	Related	51	0	0.0	0.0	7.0	61	2	3.3	0.4	11.3
Sweating	Any	51	2	3.9	0.5	13.5	61	8	13.1	5.8	24.2
	Grade 3	51	0	0.0	0.0	7.0	61	0	0.0	0.0	5.9
	Related	51	0	0.0	0.0	7.0	61	1	1.6	0.0	8.8
Symptom	**Intensity/ Relationship**	**Dd/Adj Group**					**Sd/Adj Group**				
		N	**n**	**%**	**95 % CI**		**N**	**n**	**%**	**95 % CI**	
					LL	**UL**				**LL**	**UL**
Dose 1											
Arthralgia	Any	159	7	4.4	1.8	8.9	164	5	3.0	1.0	7.0
	Grade 3	159	2	1.3	0.2	4.5	164	0	0.0	0.0	2.2
	Related	159	1	0.6	0.0	3.5	164	0	0.0	0.0	2.2
Fatigue	Any	159	26	16.4	11.0	23.0	164	16	9.8	5.7	15.4
	Grade 3	159	2	1.3	0.2	4.5	164	1	0.6	0.0	3.4
	Related	159	4	2.5	0.7	6.3	164	1	0.6	0.0	3.4
Fever/ (Axillary) (°C)	>37.5	159	2	1.3	0.2	4.5	164	0	0.0	0.0	2.2
	>39.0	159	1	0.6	0.0	3.5	164	0	0.0	0.0	2.2
	Related	159	0	0.0	0.0	2.3	164	0	0.0	0.0	2.2
Headache	Any	159	18	11.3	6.8	17.3	164	15	9.1	5.2	14.6
	Grade 3	159	0	0.0	0.0	2.3	164	0	0.0	0.0	2.2
	Related	159	4	2.5	0.7	6.3	164	0	0.0	0.0	2.2
Myalgia	Any	159	23	14.5	9.4	20.9	164	13	7.9	4.3	13.2
	Grade 3	159	3	1.9	0.4	5.4	164	0	0.0	0.0	2.2
	Related	159	3	1.9	0.4	5.4	164	0	0.0	0.0	2.2
Shivering	Any	159	3	1.9	0.4	5.4	164	0	0.0	0.0	2.2
	Grade 3	159	1	0.6	0.0	3.5	164	0	0.0	0.0	2.2

	Related	159	1	0.6	0.0	3.5	164	0	0.0	0.0	2.2
Sweating	Any	159	11	6.9	3.5	12.0	164	8	4.9	2.1	9.4
	Grade 3	159	1	0.6	0.0	3.5	164	0	0.0	0.0	2.2
	Related	159	0	0.0	0.0	2.3	164	0	0.0	0.0	2.2
Dose 2											
Arthralgia	Any	154	9	5.8	2.7	10.8	161	10	6.2	3.0	11.1
	Grade 3	154	0	0.0	0.0	2.4	161	1	0.6	0.0	3.4
	Related	154	2	1.3	0.2	4.6	161	0	0.0	0.0	2.3
Fatigue	Any	154	28	18.2	12.4	25.2	161	26	16.1	10.8	22.8
	Grade 3	154	4	2.6	0.7	6.5	161	1	0.6	0.0	3.4
	Related	154	5	3.2	1.1	7.4	161	0	0.0	0.0	2.3
Fever/ (Axillary) (°C)	>37.5	154	3	1.9	0.4	5.6	161	2	1.2	0.2	4.4
	>39.0	154	0	0.0	0.0	2.4	161	1	0.6	0.0	3.4
	Related	154	1	0.6	0.0	3.6	161	0	0.0	0.0	2.3
Headache	Any	154	27	17.5	11.9	24.5	161	20	12.4	7.8	18.5
	Grade 3	154	1	0.6	0.0	3.6	161	0	0.0	0.0	2.3
	Related	154	4	2.6	0.7	6.5	161	2	1.2	0.2	4.4
Myalgia	Any	154	13	8.4	4.6	14.0	161	15	9.3	5.3	14.9
	Grade 3	154	1	0.6	0.0	3.6	161	1	0.6	0.0	3.4
	Related	154	2	1.3	0.2	4.6	161	2	1.2	0.2	4.4
Shivering	Any	154	7	4.5	1.8	9.1	161	2	1.2	0.2	4.4
	Grade 3	154	0	0.0	0.0	2.4	161	1	0.6	0.0	3.4
	Related	154	2	1.3	0.2	4.6	161	0	0.0	0.0	2.3
Sweating	Any	154	12	7.8	4.1	13.2	161	12	7.5	3.9	12.7
	Grade 3	154	0	0.0	0.0	2.4	161	0	0.0	0.0	2.3
	Related	154	1	0.6	0.0	3.6	161	0	0.0	0.0	2.3
Across doses											
Arthralgia	Any	159	13	8.2	4.4	13.6	164	13	7.9	4.3	13.2
	Grade 3	159	2	1.3	0.2	4.5	164	1	0.6	0.0	3.4
	Related	159	2	1.3	0.2	4.5	164	0	0.0	0.0	2.2
Fatigue	Any	159	39	24.5	18.1	32.0	164	32	19.5	13.7	26.4
	Grade 3	159	6	3.8	1.4	8.0	164	2	1.2	0.1	4.3
	Related	159	8	5.0	2.2	9.7	164	1	0.6	0.0	3.4
Fever/ (Axillary) (°C)	>37.5	159	5	3.1	1.0	7.2	164	2	1.2	0.1	4.3
	>39.0	159	1	0.6	0.0	3.5	164	1	0.6	0.0	3.4
	Related	159	1	0.6	0.0	3.5	164	0	0.0	0.0	2.2
Headache	Any	159	34	21.4	15.3	28.6	164	27	16.5	11.1	23.0
	Grade 3	159	1	0.6	0.0	3.5	164	0	0.0	0.0	2.2
	Related	159	6	3.8	1.4	8.0	164	2	1.2	0.1	4.3
Myalgia	Any	159	28	17.6	12.0	24.4	164	24	14.6	9.6	21.0
	Grade 3	159	4	2.5	0.7	6.3	164	1	0.6	0.0	3.4
	Related	159	4	2.5	0.7	6.3	164	2	1.2	0.1	4.3
Shivering	Any	159	9	5.7	2.6	10.5	164	2	1.2	0.1	4.3
	Grade 3	159	1	0.6	0.0	3.5	164	1	0.6	0.0	3.4
	Related	159	2	1.3	0.2	4.5	164	0	0.0	0.0	2.2
Sweating	Any	159	19	11.9	7.4	18.0	164	16	9.8	5.7	15.4
	Grade 3	159	1	0.6	0.0	3.5	164	0	0.0	0.0	2.2
	Related	159	1	0.6	0.0	3.5	164	0	0.0	0.0	2.2

Any: occurrence of any solicited general symptom regardless of their intensity grade or relationship to vaccination
Grade 3 arthralgia, fatigue, headache, myalgia, shivering, sweating: symptom that prevented normal activity
Related = assessed by the investigator as related to the vaccination
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

Secondary Outcome/Efficacy Variables: Haematological and biochemical levels with respect to normal ranges (Total Vaccinated cohort)															
Laboratory parameter	**Timing**	**Dd/Adj Group**							**Sd/NoAdj Group**						
			Below		**Within**		**Above**			**Below**		**Within**		**Above**	
		N	**n**	**%**	**n**	**%**	**n**	**%**	**N**	**n**	**%**	**n**	**%**	**n**	**%**
Alanine Aminotransferase	PRE	159	1	0.63	152	95.60	6	3.77	61	0	0.00	58	95.08	3	4.92
	PI(Day 2)	158	1	0.63	151	95.57	6	3.80	61	0	0.00	59	96.72	2	3.28
	PI(Day 21)	156	1	0.64	144	92.31	11	7.05	57	0	0.00	54	94.74	3	5.26
	PII(Day 23)	155	1	0.65	146	94.19	8	5.16	57	0	0.00	55	96.49	2	3.51
Aspartate Aminotransferase	PRE	159	0	0.00	150	94.34	9	5.66	61	0	0.00	57	93.44	4	6.56
	PI(Day 2)	158	0	0.00	152	96.20	6	3.80	61	0	0.00	59	96.72	2	3.28
	PI(Day 21)	156	0	0.00	146	93.59	10	6.41	57	0	0.00	51	89.47	6	10.53
	PII(Day 23)	155	0	0.00	149	96.13	6	3.87	57	0	0.00	54	94.74	3	5.26
Basophils	PRE	159	0	0.00	159	100.0	0	0.00	61	0	0.00	61	100.0	0	0.00
	PI(Day 2)	158	0	0.00	158	100.0	0	0.00	61	0	0.00	61	100.0	0	0.00
	PI(Day 21)	155	0	0.00	155	100.0	0	0.00	57	0	0.00	57	100.0	0	0.00
	PII(Day 23)	155	0	0.00	155	100.0	0	0.00	57	0	0.00	57	100.0	0	0.00
Creatinine Phosphokinase	PRE	158	0	0.00	136	86.08	22	13.92	60	0	0.00	45	75.00	15	25.00
	PI(Day 2)	158	1	0.63	141	89.24	16	10.13	61	0	0.00	49	80.33	12	19.67
	PI(Day 21)	156	0	0.00	130	83.33	26	16.67	57	0	0.00	45	78.95	12	21.05
	PII(Day 23)	155	0	0.00	136	87.74	19	12.26	57	0	0.00	49	85.96	8	14.04
Creatinine	PRE	159	0	0.00	148	93.08	11	6.92	61	1	1.64	54	88.52	6	9.84
	PI(Day 2)	158	1	0.63	146	92.41	11	6.96	61	0	0.00	55	90.16	6	9.84
	PI(Day 21)	156	1	0.64	142	91.03	13	8.33	57	0	0.00	51	89.47	6	10.53
	PII(Day 23)	155	1	0.65	139	89.68	15	9.68	57	0	0.00	49	85.96	8	14.04
Eosinophils	PRE	159	5	3.14	153	96.23	1	0.63	61	3	4.92	58	95.08	0	0.00
	PI(Day 2)	158	5	3.16	152	96.20	1	0.63	61	3	4.92	58	95.08	0	0.00
	PI(Day 21)	155	4	2.58	150	96.77	1	0.65	57	0	0.00	57	100.0	0	0.00
	PII(Day 23)	155	4	2.58	149	96.13	2	1.29	57	0	0.00	57	100.0	0	0.00
Haemoglobin	PRE	159	14	8.81	130	81.76	15	9.43	61	3	4.92	50	81.97	8	13.11
	PI(Day 2)	158	16	10.13	135	85.44	7	4.43	61	6	9.84	53	86.89	2	3.28
	PI(Day 21)	155	15	9.68	130	83.87	10	6.45	57	2	3.51	53	92.98	2	3.51
	PII(Day 23)	155	17	10.97	133	85.81	5	3.23	57	3	5.26	54	94.74	0	0.00
Lactate Dehydrogenase	PRE	156	2	1.28	136	87.18	18	11.54	61	2	3.28	51	83.61	8	13.11
	PI(Day 2)	158	2	1.27	144	91.14	12	7.59	61	1	1.64	56	91.80	4	6.56
	PI(Day 21)	156	1	0.64	142	91.03	13	8.33	57	1	1.75	44	77.19	12	21.05
	PII(Day 23)	155	2	1.29	141	90.97	12	7.74	57	1	1.75	54	94.74	2	3.51
Lymphocytes	PRE	159	137	86.16	22	13.84	0	0.00	61	53	86.89	8	13.11	0	0.00
	PI(Day 2)	158	136	86.08	22	13.92	0	0.00	61	53	86.89	8	13.11	0	0.00
	PI(Day 21)	155	135	87.10	20	12.90	0	0.00	57	52	91.23	5	8.77	0	0.00
	PII(Day 23)	155	135	87.10	20	12.90	0	0.00	57	52	91.23	5	8.77	0	0.00
Monocytes	PRE	159	136	85.53	23	14.47	0	0.00	61	52	85.25	9	14.75	0	0.00
	PI(Day 2)	158	134	84.81	24	15.19	0	0.00	61	53	86.89	8	13.11	0	0.00
	PI(Day 21)	155	134	86.45	21	13.55	0	0.00	57	52	91.23	5	8.77	0	0.00
	PII(Day 23)	155	134	86.45	17	10.97	4	2.58	57	52	91.23	5	8.77	0	0.00
Neutrophils	PRE	158	141	89.24	17	10.76	0	0.00	61	55	90.16	5	8.20	1	1.64
	PI(Day 2)	158	141	89.24	17	10.76	0	0.00	61	55	90.16	6	9.84	0	0.00
	PI(Day 21)	155	138	89.03	15	9.68	2	1.29	57	52	91.23	4	7.02	1	1.75
	PII(Day 23)	155	138	89.03	17	10.97	0	0.00	57	52	91.23	4	7.02	1	1.75
Platelets	PRE	159	3	1.89	148	93.08	8	5.03	61	4	6.56	51	83.61	6	9.84
	PI(Day 2)	158	4	2.53	147	93.04	7	4.43	61	2	3.28	51	83.61	8	13.11
	PI(Day 21)	155	4	2.58	145	93.55	6	3.87	57	6	10.53	49	85.96	2	3.51
	PII(Day 23)	155	2	1.29	147	94.84	6	3.87	57	3	5.26	52	91.23	2	3.51
Red Blood Cell	PRE	159	21	13.21	125	78.62	13	8.18	61	5	8.20	54	88.52	2	3.28

count	PI(Day 2)	158	20	12.66	133	84.18	5	3.16	61	8	13.11	52	85.25	1	1.64
	PI(Day 21)	155	20	12.90	127	81.94	8	5.16	57	6	10.53	47	82.46	4	7.02
	PII(Day 23)	155	19	12.26	134	86.45	2	1.29	57	8	14.04	47	82.46	2	3.51
Urea	PRE	159	4	2.52	101	63.52	54	33.96	61	0	0.00	36	59.02	25	40.98
	PI(Day 2)	158	4	2.53	114	72.15	40	25.32	61	0	0.00	38	62.30	23	37.70
	PI(Day 21)	156	3	1.92	100	64.10	53	33.97	57	0	0.00	30	52.63	27	47.37
	PII(Day 23)	155	2	1.29	106	68.39	47	30.32	57	0	0.00	36	63.16	21	36.84
White Blood Cell count	PRE	159	3	1.89	155	97.48	1	0.63	61	2	3.28	56	91.80	3	4.92
	PI(Day 2)	158	4	2.53	152	96.20	2	1.27	61	2	3.28	56	91.80	3	4.92
	PI(Day 21)	155	3	1.94	149	96.13	3	1.94	57	2	3.51	53	92.98	2	3.51
	PII(Day 23)	155	7	4.52	148	95.48	0	0.00	57	4	7.02	49	85.96	4	7.02
Laboratory parameter	**Timing**	**Sd/Adj Group**							**Dd/NoAdj Group**						
			Below		**Within**		**Above**			**Below**		**Within**		**Above**	
		N	**n**	**%**	**n**	**%**	**n**	**%**	**N**	**n**	**%**	**n**	**%**	**n**	**%**
Alanine Aminotransferase	PRE	165	0	0.00	152	92.12	13	7.88	52	0	0.00	47	90.38	5	9.62
	PI(Day 2)	165	0	0.00	152	92.12	13	7.88	52	0	0.00	48	92.31	4	7.69
	PI(Day 21)	163	0	0.00	153	93.87	10	6.13	52	0	0.00	48	92.31	4	7.69
	PII(Day 23)	163	0	0.00	152	93.25	11	6.75	52	0	0.00	49	94.23	3	5.77
Aspartate Aminotransferase	PRE	165	0	0.00	154	93.33	11	6.67	52	0	0.00	48	92.31	4	7.69
	PI(Day 2)	165	0	0.00	154	93.33	11	6.67	52	0	0.00	49	94.23	3	5.77
	PI(Day 21)	163	0	0.00	154	94.48	9	5.52	52	0	0.00	47	90.38	5	9.62
	PII(Day 23)	163	0	0.00	153	93.87	10	6.13	52	0	0.00	47	90.38	5	9.62
Basophils	PRE	163	0	0.00	163	100.0	0	0.00	52	0	0.00	52	100.0	0	0.00
	PI(Day 2)	165	0	0.00	164	99.39	1	0.61	52	0	0.00	52	100.0	0	0.00
	PI(Day 21)	163	0	0.00	163	100.0	0	0.00	52	0	0.00	52	100.0	0	0.00
	PII(Day 23)	163	0	0.00	163	100.0	0	0.00	51	0	0.00	51	100.0	0	0.00
Creatinine Phosphokinase	PRE	165	0	0.00	149	90.30	16	9.70	52	0	0.00	47	90.38	5	9.62
	PI(Day 2)	165	0	0.00	150	90.91	15	9.09	52	0	0.00	44	84.62	8	15.38
	PI(Day 21)	163	1	0.61	140	85.89	22	13.50	52	0	0.00	45	86.54	7	13.46
	PII(Day 23)	163	0	0.00	146	89.57	17	10.43	52	0	0.00	44	84.62	8	15.38
Creatinine	PRE	165	0	0.00	144	87.27	21	12.73	52	0	0.00	43	82.69	9	17.31
	PI(Day 2)	165	1	0.61	144	87.27	20	12.12	51	0	0.00	42	82.35	9	17.65
	PI(Day 21)	163	0	0.00	134	82.21	29	17.79	52	0	0.00	42	80.77	10	19.23
	PII(Day 23)	163	1	0.61	142	87.12	20	12.27	52	0	0.00	45	86.54	7	13.46
Eosinophils	PRE	163	4	2.45	159	97.55	0	0.00	52	2	3.85	50	96.15	0	0.00
	PI(Day 2)	165	4	2.42	161	97.58	0	0.00	52	3	5.77	49	94.23	0	0.00
	PI(Day 21)	163	4	2.45	158	96.93	1	0.61	52	2	3.85	50	96.15	0	0.00
	PII(Day 23)	163	4	2.45	159	97.55	0	0.00	51	2	3.92	49	96.08	0	0.00
Haemoglobin	PRE	163	11	6.75	137	84.05	15	9.20	52	3	5.77	43	82.69	6	11.54
	PI(Day 2)	165	21	12.73	139	84.24	5	3.03	52	3	5.77	47	90.38	2	3.85
	PI(Day 21)	163	13	7.98	144	88.34	6	3.68	52	4	7.69	44	84.62	4	7.69
	PII(Day 23)	163	20	12.27	139	85.28	4	2.45	52	5	9.62	44	84.62	3	5.77
Lactate Dehydrogenase	PRE	164	1	0.61	147	89.63	16	9.76	52	0	0.00	49	94.23	3	5.77
	PI(Day 2)	165	2	1.21	148	89.70	15	9.09	52	0	0.00	45	86.54	7	13.46
	PI(Day 21)	162	0	0.00	151	93.21	11	6.79	52	0	0.00	48	92.31	4	7.69
	PII(Day 23)	163	4	2.45	147	90.18	12	7.36	52	0	0.00	50	96.15	2	3.85
Lymphocytes	PRE	163	145	88.96	18	11.04	0	0.00	52	45	86.54	7	13.46	0	0.00
	PI(Day 2)	165	148	89.70	17	10.30	0	0.00	52	46	88.46	6	11.54	0	0.00
	PI(Day 21)	163	144	88.34	19	11.66	0	0.00	52	45	86.54	7	13.46	0	0.00
	PII(Day 23)	163	145	88.96	17	10.43	1	0.61	51	44	86.27	7	13.73	0	0.00
Monocytes	PRE	163	143	87.73	20	12.27	0	0.00	52	45	86.54	7	13.46	0	0.00
	PI(Day 2)	165	143	86.67	21	12.73	1	0.61	52	45	86.54	7	13.46	0	0.00
	PI(Day 21)	163	140	85.89	23	14.11	0	0.00	52	45	86.54	7	13.46	0	0.00
	PII(Day 23)	163	141	86.50	19	11.66	3	1.84	51	44	86.27	7	13.73	0	0.00

Neutrophils	PRE	163	148	90.80	13	7.98	2	1.23	52	47	90.38	5	9.62	0	0.00
	PI(Day 2)	165	149	90.30	13	7.88	3	1.82	52	47	90.38	4	7.69	1	1.92
	PI(Day 21)	163	147	90.18	14	8.59	2	1.23	52	47	90.38	4	7.69	1	1.92
	PII(Day 23)	163	148	90.80	14	8.59	1	0.61	51	46	90.20	5	9.80	0	0.00
Platelets	PRE	163	4	2.45	145	88.96	14	8.59	52	2	3.85	46	88.46	4	7.69
	PI(Day 2)	165	2	1.21	152	92.12	11	6.67	52	2	3.85	45	86.54	5	9.62
	PI(Day 21)	163	3	1.84	147	90.18	13	7.98	52	1	1.92	46	88.46	5	9.62
	PII(Day 23)	163	2	1.23	150	92.02	11	6.75	52	0	0.00	48	92.31	4	7.69
Red Blood Cell count	PRE	163	21	12.88	132	80.98	10	6.13	52	5	9.62	42	80.77	5	9.62
	PI(Day 2)	165	25	15.15	134	81.21	6	3.64	52	7	13.46	43	82.69	2	3.85
	PI(Day 21)	163	24	14.72	133	81.60	6	3.68	52	7	13.46	42	80.77	3	5.77
	PII(Day 23)	163	33	20.25	127	77.91	3	1.84	52	8	15.38	43	82.69	1	1.92
Urea	PRE	165	0	0.00	90	54.55	75	45.45	52	0	0.00	34	65.38	18	34.62
	PI(Day 2)	164	1	0.61	96	58.54	67	40.85	52	0	0.00	32	61.54	20	38.46
	PI(Day 21)	163	0	0.00	91	55.83	72	44.17	52	0	0.00	32	61.54	20	38.46
	PII(Day 23)	163	0	0.00	105	64.42	58	35.58	52	0	0.00	36	69.23	16	30.77
White Blood Cell count	PRE	163	5	3.07	152	93.25	6	3.68	52	3	5.77	45	86.54	4	7.69
	PI(Day 2)	165	4	2.42	152	92.12	9	5.45	52	3	5.77	47	90.38	2	3.85
	PI(Day 21)	163	4	2.45	150	92.02	9	5.52	52	3	5.77	49	94.23	0	0.00
	PII(Day 23)	163	6	3.68	145	88.96	12	7.36	52	3	5.77	47	90.38	2	3.85

N = number of subjects with available results
n/%= number/percentage of subjects in the specified category
PRE = Pre-vaccination on Day 0
PI (Day 2) = Post-vaccination on Day 2
PI (Day 21) = Post-vaccination on Day 21
PII (Day 23) = Post-vaccination 2 at Day 23

Safety results: Number (%) of subjects with unsolicited adverse events (Total vaccinated cohort)

Most frequent adverse events - On-Therapy (occurring within Day 0- 20 after first vaccination and within Day 0-29 after second vaccination)	**Dd/NoAdj Group N=52**	**Sd/NoAdj Group N=61**	**Dd/Adj Group N=159**	**Sd/Adj Group N=165**
Subjects with any AE(s), n (%)	8 (15.4)	16 (26.2)	28 (17.6)	36 (21.8)
Subjects with Grade 3 AE(s), n (%)	1 (1.9)	2 (3.3)	3 (1.9)	5 (3.0)
Subjects with related AE(s), n (%)	1 (1.9)	2 (3.3)	10 (6.3)	9 (5.5)
Diarrhea	1 (1.9)		1 (0.6)	3 (1.8)
Nausea	-	-	3 (1.9)	2 (1.2)
Vertigo	-	2 (3.3)	1 (0.6)	2 (1.2)
Tracheitis	1 (1.9)	-	-	4 (2.4)
Erythema	-	1 (1.6)	1 (0.6)	2 (1.2)
Gastroenteritis	-	2 (3.3)	1 (0.6)	-
Injection site pruritus	-	-	4 (2.5)	-
Nasopharyngitis	1 (1.9)	1 (1.6)	-	2 (1.2)
Rhinitis	-	1 (1.6)	1 (0.6)	2 (1.2)
Cough	-	-	1 (0.6)	2 (1.2)
Bronchitis	1 (1.9)	1 (1.6)	-	-
Neck pain	-	-	2 (1.3)	-
Pain in extremity	-	-	-	3 (1.8)
Pharyngitis	-	-	2 (1.3)	-
Abdominal pain upper	-	-	-	2 (1.2)
Arthralgia	-	-	-	2 (1.2)
Dyspnoea	-	1 (1.6)	1 (0.6)	-
Influenza like illness	-	1 (1.6)	1 (0.6)	-
Rhinorrhoea	1 (1.9)	-	1 (0.6)	-
Back pain	-	-	1 (0.6)	-

Gout	1 (1.9)	-	-	-
Sciatica	-	1 (1.6)	-	-
Toothache	-	-	1 (0.6)	-
Gastrointestinal pain	1 (1.9)	-	-	-
Cheilitis	-	-	1 (0.6)	-
Chest pain	1 (1.9)	-	-	-
Congestive cardiomyopathy	-	-	1 (0.6)	-
Coronary artery disease	-	-	1 (0.6)	-
Cystitis	1 (1.9)	-	-	-
Diverticulitis	1 (1.9)	-	-	-
Drug hypersensitivity	-	-	1 (0.6)	-
Fall	-	1 (1.6)	-	-
Fatigue	-	-	1 (0.6)	-
Foot fracture	-	1 (1.6)	-	-
Genital infection fungal	1 (1.9)	-	-	-
Influenza	-	-	1 (0.6)	-
Injection site rash	-	-	1 (0.6)	-
Labyrinthitis	-	1 (1.6)	-	-
Lymphadenopathy	-	-	1 (0.6)	-
Muscle spasms	-	-	1 (0.6)	-
Oedema peripheral	1 (1.9)	-	-	-
Oral fungal infection	-	1 (1.6)	-	-
Otitis media	-	-	1 (0.6)	-
Osteoarthritis	-	-	1 (0.6)	-
Paraesthesia	-	-	1 (0.6)	-
Paraesthesia oral	-	-	1 (0.6)	-
Pneumonia	-	1 (1.6)	-	-
Respiratory disorder	-	1 (1.6)	-	-
Rhinitis allergic	-	-	1 (0.6)	-
Scleroderma	-	-	1 (0.6)	-
Sensory disturbance	-	-	1 (0.6)	-
Sinusitis	-	-	1 (0.6)	-
Synovial cyst	-	1 (1.6)	-	-
Tachycardia	-	-	1 (0.6)	-
Tendonitis	1 (1.9)	-	-	-
Tinnitus	-	-	1 (0.6)	-
Tooth abscess	-	-	1 (0.6)	-
Urinary incontinence	-	1 (1.6)	-	-
Grade 3 = event that prevented normal, everyday activities Related = event assessed by the investigator as causally related to the study vaccination -: Adverse event absent				
Safety results: Number (%) of subjects with SAEs between Day 0 and Day 51 (Total vaccinated cohort)				
Serious adverse event, n (%) [n considered by the investigator to be related to study medication]				
All SAEs	**Dd/NoAdj Group N=52**	**Sd/NoAdj Group N=61**	**Dd/Adj Group N=159**	**Sd/Adj Group N=165**
Subjects with any SAE(s), n (%) [n assessed by the investigator as related]	1 (1.9) [0]	1 (1.6) [0]	1 (0.6) [0]	1 (0.6) [0]
Coronary artery disease	0 (0.0) [0]	0 (0.0) [0]	1 (0.6) [0]	0 (0.0) [0]
Diverticulitis	1 (1.9) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]
Gastroenteritis	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	1 (0.6) [0]
Pneumonia	0 (0.0) [0]	1 (1.6) [0]	0 (0.0) [0]	0 (0.0) [0]
Fatal SAEs	**Dd/NoAdj Group**	**Sd/NoAdj Group**	**Dd/Adj Group**	**Sd/Adj Group**

	N=52	N=61	N=159	N=165
Subjects with fatal SAE(s), n (%) [n assessed by the investigator as related]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]
Safety results: Number (%) of subjects with SAEs between Day 52 and Day 180 (Total vaccinated cohort)				
Serious adverse event, n (%) [n considered by the investigator to be related to study medication]				
All SAEs	**Dd/NoAdj Group N = 51**	**Sd/NoAdj Group N = 58**	**Dd/Adj Group N = 158**	**Sd/Adj Group N = 164**
Subjects with any SAE(s), n (%) [n assessed by the investigator as related]	0 (0.0) [0]	3 (5.2) [0]	5 (3.2) [0]	5 (3.0) [0]
Cardiac failure congestive	0 (0.0) [0]	1 (1.7) [0]	1 (0.6) [0]	0 (0.0) [0]
Adenocarcinoma pancreas	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	1 (0.6) [0]
Atrial fibrillation	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	1 (0.6) [0]
Cardiac failure acute	0 (0.0) [0]	0 (0.0) [0]	1 (0.6) [0]	0 (0.0) [0]
Cerebral hemorrhage	0 (0.0) [0]	0 (0.0) [0]	1 (0.6) [0]	0 (0.0) [0]
Cerebral ischaemia	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	1 (0.6) [0]
Cerebrovascular accident	0 (0.0) [0]	0 (0.0) [0]	1 (0.6) [0]	0 (0.0) [0]
Femoral neck fracture	0 (0.0) [0]	0 (0.0) [0]	1 (0.6) [0]	0 (0.0) [0]
Renal cell carcinoma stage unspecified	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	1 (0.6) [0]
Sciatica	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	1 (0.6) [0]
Transient ischaemic attack	0 (0.0) [0]	1 (1.7) [0]	0 (0.0) [0]	0 (0.0) [0]
Ventricular fibrillation	0 (0.0) [0]	1 (1.7) [0]	0 (0.0) [0]	0 (0.0) [0]
Fatal SAEs	**Dd/NoAdj Group N = 51**	**Sd/NoAdj Group N = 58**	**Dd/Adj Group N = 158**	**Sd/Adj Group N = 164**
Subjects with fatal SAE(s), n (%) [n assessed by the investigator as related]	0 (0.0) [0]	2 (3.4) [0]	3 (1.9) [0]	0 (0.0) [0]
Cardiac failure congestive	0 (0.0) [0]	1 (1.7) [0]	1 (0.6) [0]	0 (0.0) [0]
Cerebral hemorrhage	0 (0.0) [0]	0 (0.0) [0]	1 (0.6) [0]	0 (0.0) [0]
Cerebrovascular accident	0 (0.0) [0]	0 (0.0) [0]	1 (0.6) [0]	0 (0.0) [0]
Ventricular fibrillation	0 (0.0) [0]	1 (1.7) [0]	0 (0.0) [0]	0 (0.0) [0]
Safety results: Number (%) of subjects with serious adverse events between Month 6 and Month 12 (Total vaccinated cohort at Month 12)				
Serious adverse event, n (%) [n considered by the investigator to be related to study medication]				
All SAEs	**Dd/NoAdj N = 42**	**Sd/NoAdj N = 48**	**Dd/Adj N = 125**	**Sd/Adj N = 130**
Subjects with any SAE(s), n (%) [n assessed by the investigator as related]	2 (4.8) [1]	0 (0.0) [0]	3 (2.4) [0]	4 (3.1) [0]
Cerebrovascular accident	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	2 (1.5) [0]
Pneumonia	0 (0.0) [0]	0 (0.0) [0]	1 (0.8) [0]	1 (0.8) [0]
Lobar pneumonia	1 (2.4) [1]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]
Lower limb fracture	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	1 (0.8) [0]
Lung neoplasm malignant	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	1 (0.8) [0]
Phlebitis	0 (0.0) [0]	0 (0.0) [0]	1 (0.8) [0]	0 (0.0) [0]
Prostate cancer	1 (2.4) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]
Prostate cancer metastatic	0 (0.0) [0]	0 (0.0) [0]	1 (0.8) [0]	0 (0.0) [0]
Schizophrenia	0 (0.0) [0]	0 (0.0) [0]	1 (0.8) [0]	0 (0.0) [0]
Fatal SAEs	**Dd/NoAdj N = 42**	**Sd/NoAdj N = 48**	**Dd/Adj N = 125**	**Sd/Adj N = 130**
Subjects with fatal SAE(s), n (%) [n assessed by the investigator as related]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]
Safety results: Number (%) of subjects with serious adverse events between Month 12 and Month 24 (Total vaccinated cohort at Month 24)				
Serious adverse event, n (%) [n considered by the investigator to be related to study medication]				
All SAEs	**Dd/NoAdj**	**Sd/NoAdj**	**Dd/Adj**	**Sd/Adj**

	N = 36	N = 45	N = 117	N = 122
Subjects with any SAE(s), n (%) [n assessed by the investigator as related]	2 (5.6) [0]	7 (15.6) [0]	7 (6.0) [0]	9 (7.4) [0]
Aortic aneurysm	0 (0.0) [0]	1 (2.2) [0]	1 (0.9) [0]	0 (0.0) [0]
Pneumonia	0 (0.0) [0]	1 (2.2) [0]	0 (0.0) [0]	1 (0.8) [0]
Acute myocardial infarction	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	1 (0.8) [0]
Angioedema	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	1 (0.8) [0]
Aortic valve incompetence	0 (0.0) [0]	1 (2.2) [0]	0 (0.0) [0]	0 (0.0) [0]
Arterial insufficiency	0 (0.0) [0]	1 (2.2) [0]	0 (0.0) [0]	0 (0.0) [0]
Benign prostatic hyperplasia	0 (0.0) [0]	0 (0.0) [0]	1 (0.9) [0]	0 (0.0) [0]
Biliary colic	0 (0.0) [0]	0 (0.0) [0]	1 (0.9) [0]	0 (0.0) [0]
Bradycardia	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	1 (0.8) [0]
Breast cancer	0 (0.0) [0]	1 (2.2) [0]	0 (0.0) [0]	0 (0.0) [0]
Bronchospasm	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	1 (0.8) [0]
Cardiac failure acute	0 (0.0) [0]	1 (2.2) [0]	0 (0.0) [0]	0 (0.0) [0]
Cardiac failure congestive	0 (0.0) [0]	0 (0.0) [0]	1 (0.9) [0]	0 (0.0) [0]
Cerebrovascular accident	0 (0.0) [0]	0 (0.0) [0]	1 (0.9) [0]	0 (0.0) [0]
Cholelithiasis	0 (0.0) [0]	1 (2.2) [0]	0 (0.0) [0]	0 (0.0) [0]
Extrasystoles	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	1 (0.8) [0]
Hip fracture	1 (2.8) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]
Inguinal hernia	0 (0.0) [0]	1 (2.2) [0]	0 (0.0) [0]	0 (0.0) [0]
Intentional overdose	0 (0.0) [0]	1 (2.2) [0]	0 (0.0) [0]	0 (0.0) [0]
Intestinal obstruction	1 (2.8) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]
Polyneuropathy	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	1 (0.8) [0]
Prostate cancer	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	1 (0.8) [0]
Pulmonary embolism	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	1 (0.8) [0]
Rectal cancer	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	1 (0.8) [0]
Renal cell carcinoma	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	1 (0.8) [0]
Renal failure	0 (0.0) [0]	0 (0.0) [0]	1 (0.9) [0]	0 (0.0) [0]
Venous insufficiency	0 (0.0) [0]	0 (0.0) [0]	1 (0.9) [0]	0 (0.0) [0]
Fatal SAEs	**Dd/NoAdj N = 36**	**Sd/NoAdj N = 45**	**Dd/Adj N = 117**	**Sd/Adj N = 122**
Subjects with fatal sae(s), n (%) [n related]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]

Conclusion: At least 4.5% of subjects had putatively seroprotective H5N1 HI antibody titers against the A/Vietnam/1194/2004 strain across all the groups. In the Sd/NoAdj Group, the Dd/NoAdj Group, the Sd/Adj Group, and the Dd/Adj Group: 27.8%, 34.1%, 61.2%, & 62.1% of the subjects, respectively had H5N1 HI antibody titres $\geq$ 1:40 against the A/Vietnam/1194/2004 strain at Day 21; 35.2%, 38.6%, 83.6%, and 95.9%, respectively at Day 42; 26.0%, 20.5%, 52.9% and 69.5%, respectively at Day 180; 24.4%, 20.0%, 43.8% and 42.5%, respectively at month 12 and 16.2%, 8.3%, 37.2% and 30.9%, respectively at month 24.

In the Sd/NoAdj Group, the Dd/NoAdj Group, the Sd/Adj Group, and the Dd/Adj Group: 1.9%, 2.3%, 3.3%, and 9.0% of the subjects, respectively had H5N1 HI antibody titres $\geq$ 1:40 against A/Indonesia/5/2005 strain at Day 21, 3.7%, 4.5%, 23.0, and 40.7% respectively at Day 42; 2.0%, 0.0%, 3.6% & 6.1% respectively at Day 180; 4.4%, 8.6%, 15.2% and 20.8%, respectively at month 12 and 2.7%, 0%, 4.7% and 6.2%, respectively at month 24.

At least one unsolicited AE was reported during the follow-up period after vaccination (21 days after first vaccination and 30 days following second vaccination) by 8 (15.4%), 16 (26.2%), 28 (17.6%) and 36 (21.8%) subjects in the Dd/NoAdj, Sd/NoAdj, Dd/Adj, and Sd/Adj Group, respectively.

From Day 0 up to Day 51, 1 SAE was reported in each group. No fatal SAEs were reported.

Between Day 52 and Day 180, SAEs were reported for 3 (5.2%), 5 (3.2%) and 5 (3.0%) subjects in the Sd/NoAdj, Dd/Adj, and Sd/Adj groups, respectively; 4 SAEs were fatal (2 in the Sd/NoAdj Group and 3 in the Dd/Adj Group).

Between Month 6 and Month 12, SAEs were reported for 2 (4.8%), 3 (2.4%) and 4 (3.1%) subjects in the Dd/NoAdj, Dd/Adj and Sd/Adj, respectively. No fatal SAEs were reported.

Between Month 12 and Month 24, SAEs were reported for 2 (5.6%), 7 (16.6%), 7 (6.0%) and 9 (7.4%) for the Dd/NoAdj. Sd/NoAdj, Dd/Adj and Sd/Adj groups respectively. No fatal SAEs were reported.

All the SAEs reported during the whole study were assessed by the investigators as not related to the study vaccination.

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