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.: 107192 & 107214 (FLU-LD-002 & FLU-LD-006 EXT-002 (D180))

Title: A phase IIb, controlled, randomised, multicenter, observer blinded study to demonstrate the lot-to-lot consistency of three consecutive production lots of low dose of influenza vaccine adjuvanted with AS03, and to evaluate the safety of low dose of influenza vaccine adjuvanted with AS03 compared to *Fluarix*™ (GlaxoSmithKline Biologicals) administered intramuscularly in elderly ≥ 60 years.*Fluarix*™ (Flu): GlaxoSmithKline (GSK) Biologicals' inactivated influenza split vaccine.
FluLD: GSK Biologicals' low dose adjuvanted influenza vaccine

Rationale: The aim of this study was to assess the lot-to-lot consistency of 3 consecutive production lots of FluLD vaccine and to evaluate the safety of FluLD vaccine compared to Flu vaccine administered intramuscularly in elderly aged 60 years old and above.

Phase: IIb

Study Period:
Primary study - 107192 (FLU-LD-002): 27 April 2006 to 06 July 2006
Extension study Day 180 - 107214 (FLU-LD-006 EXT-002 D180): 04 October 2006 to 18 December 2006

Study Design: Multi-centre, observer-blind, randomized (3:3:3:2), controlled study with 4 parallel groups.

Centres: 46 centres: 1 in Estonia, 9 in France, 14 in Germany, 8 in Greece, 4 in Norway, 3 in the Russian Federation and 7 in the United Kingdom.

Indication: Immunization against influenza in male and female subjects aged 60 years and older.

Treatment: The study groups were as follows:

- Lot 1 Group: subjects received FluLD Lot 1;
- Lot 2 Group: subjects received FluLD Lot 2;
- Lot 3 Group: subjects received FluLD Lot 3;
- Flu Group: subjects received Flu vaccine.

All vaccines were administered as a single dose by intramuscular injection into the deltoid region of the non-dominant arm.
For data analyses, the 3 lots groups were pooled into Pooled Lots Group.

Objectives:

- To demonstrate the lot-to-lot consistency of 3 lots of FluLD influenza vaccine in terms of immunogenicity, 21 days after vaccination.
- To assess the safety in elderly subjects ≥ 60 years old vaccinated with FluLD vaccine and Flu vaccine, during the entire study period.

Primary Outcome/Efficacy Variable:
Immunogenicity

- At Days 0 and 21: serum haemagglutination-inhibition (HI) antibody titre, against each of the 3 vaccine influenza virus strains, in a subset of subjects in the FluLD vaccine groups.

Safety

- Occurrence of rare events, defined as adverse events (AEs) with an occurrence rate of 0.1 %, during the entire study period in the low dose adjuvanted (AS03) influenza vaccine groups.*
- Occurrence, intensity and relationship to vaccination of solicited local and general signs and symptoms during a 7-day follow-up period (i.e. day of vaccination and 6 subsequent days) after vaccination in each group.
- Occurrence, intensity and relationship to vaccination of unsolicited AEs during a 30-day follow-up period (i.e. day of vaccination and 29 subsequent days) after vaccination in each group.
- Occurrence and relationship to vaccination of serious adverse events (SAEs) during the entire study period in each group.
- Occurrence of new onset chronic diseases (NOCDs) during the entire study period in each group.
- Occurrence of medically significant conditions prompting emergency room visits or physician visits that were not related to common diseases or routine visits, during the entire study period in each group.

*All rare events were not collected for the entire study period. Only rare NOCDs, unsolicited AES and SAEs are presented in the corresponding tables for the requested period.

Secondary Outcome/Efficacy Variable(s):

- At Days 0 and 21: serum HI antibody titre against each of the 3 vaccine influenza virus strains, in a subset of subjects in the low dose adjuvanted (AS03) influenza vaccine groups and in the Flu Group.

Statistical Methods:

The analyses were performed on the Total Vaccinated cohort, the Total cohort for extension phase and the According-to-Protocol (ATP) cohort for immunogenicity.

- The Total Vaccinated cohort included all vaccinated subjects.
- The Total cohort for extension phase included all subjects who received the study vaccine during the vaccination phase of the study and came back for the visit at Day 180.
- The ATP cohort for immunogenicity included all evaluable subjects (i.e., those meeting all eligibility criteria, complying with the procedures and intervals defined in the protocol, with no elimination criteria during the study) for whom data concerning immunogenicity measures were available. This included subjects for whom assay results were available for antibodies against at least one study vaccine antigen component after vaccination.

Analysis of immunogenicity

The analysis of immunogenicity was performed on the ATP cohort for immunogenicity.

Inferential analyses

- Lot-to-lot consistency was verified if the two-sided 90% confidence interval (CI) for the geometric mean titre (GMT) ratio between each pair among the 3 lots was within [0.67;1.50] in terms of anti-H1N1(A/New Caledonia), anti-H3N2 (A/New York) and anti-B (B/Malaysia) antibody titres (9 comparisons; 3 per strain). If all 9 CIs were within the pre-defined clinical limits of [0.67; 1.50], it was concluded that the 3 lots were consistent.

Descriptive analyses

For each vaccine group and each vaccine strain, the following parameters were tabulated:

- GMT with 95% CI at Days 0 and 21,
- Seroconversion rate* with exact 95% CI at Day 21,
- Seroprotection rate** with exact 95% CI at Days 0 and 21,
- Seroconversion factor*** with 95% CI at Day 21.

* The seroconversion rate was defined as the proportion of subjects with a pre-vaccination serum HI titre <1:10 and a post-vaccination serum HI titre $\geq$ 1:40, or a pre-vaccination serum HI titre $\geq$ 1:10 and a fold increase (post/pre) $\geq$ 4.

** The seroprotection rate was defined as the proportion of subjects with a serum HI titre $\geq$ 1:40.

*** The seroconversion factor was defined as the fold increase in serum HI GMT on Day 21 compared to Day 0.

Analysis of safety

The analysis of safety was performed on the Total Vaccinated cohort and the Total cohort for extension phase.

For each vaccine group, the percentage of subjects reporting each individual solicited local and general symptom during the 7-day (Days 0-6) solicited follow-up period was tabulated with exact 95% CI. The same tabulations were done for Grade 3 symptoms and for general solicited symptoms assessed by the investigators as causally related with the study vaccination.

The percentage of subjects with at least one report of an unsolicited AE up to 30 days (Days 0-29) after vaccination was tabulated according to the Medical Dictionary for Regulatory Activities (MedDRA) preferred terms. The same tabulations were performed for grade 3 AEs and for AEs with a relationship to vaccination. The percentage of subjects reporting the occurrence of NOCDs classified by the MedDRA preferred terms was tabulated up to Day 180. The same tabulation was done for medically significant conditions prompting emergency room visits or physician visits that were not related to common diseases or routine visits. Occurrence of SAEs up to 30 days after vaccination and from Day 30 to Day 180 was tabulated according to MedDRA preferred terms.

Study Population: Male or female subjects aged 60 years or older at the time of the vaccination, free of an acute aggravation of the health status as established by clinical examination before entering into the study, were enrolled. Subjects with a history of hypersensitivity to a previous dose of influenza vaccine or with a confirmed influenza infection within the last 12 months were excluded from the study. Written informed consent was obtained from the subject before any study-specific procedures.

Number of Subjects:	**Lot 1 Group**	**Lot 2 Group**	**Lot 3 Group**	**Flu Group**	**Pooled Lots Group**
Planned, N	840	840	840	560	2520
Randomised, N (Total Vaccinated cohort)	850	850	854	570	2554
Completed (Day 30), n (%)	844 (99.3)	848 (99.8)	848 (99.3)	565 (99.1)	2540 (99.5)
Total Number Subjects Withdrawn, n (%)	6 (0.7)	2 (0.2)	6 (0.7)	5 (0.9)	14 (0.5)
Withdrawn due to Adverse Events, n (%)	1 (0.1)	1 (0.1)	0 (0.0)	1 (0.2)	2 (0.1)

Withdrawn due to Lack of Efficacy, n (%)	Not Applicable				
Withdrawn for other reasons, n (%)	5 (0.6)	1 (0.1)	6 (0.7)	4 (0.7)	12 (0.5)
Demographics	**Lot 1 Group**	**Lot 2 Group**	**Lot 3 Group**	**Flu Group**	**Pooled Lots Group**
N (Total Vaccinated cohort)	850	850	854	570	2554
Females:Males	475:375	451:399	479:375	340:230	1405:1149
Mean Age, years (SD)	68.4 (6.17)	68.8 (6.43)	68.7 (6.54)	68.3 (6.15)	68.6 (6.38)
White - Caucasian, n (%)	846 (99.5)	845 (99.4)	847 (99.2)	566 (99.3)	2538 (99.4)

Total cohort for extension phase (study 107214): 3083 subjects (838 in Lot 1, 840 in Lot 2, 846 in Lot 3 and 559 in Flu Group) were present at Day 180.

Primary Efficacy Results:
Adjusted ratios of A/New Caledonia, A/New York, B/Malaysia GMTs, 21 days after vaccination. (ATP cohort for immunogenicity)

Antibody	**Group 1**			**Group 2**			**Adjusted GMT ratio**			
									90% CI *	
	Group description	**N**	**Adjusted GMT**	**Group description**	**N**	**Adjusted GMT**	**Ratio order**	**Value**	**LL**	**UL**
A/New Caledonia	Lot 1	491	122.5	Lot 2	487	118.0	Lot 1 /Lot 2	1.04	0.92	1.17
	Lot 1	491	122.5	Lot 3	492	133.1	Lot 1 /Lot 3	0.92	0.81	1.04
	Lot 2	487	118.0	Lot 3	492	133.1	Lot 2 /Lot 3	0.89	0.78	1.00
A/New York	Lot 1	491	189.0	Lot 2	487	191.6	Lot 1 /Lot 2	0.99	0.87	1.12
	Lot 1	491	189.0	Lot 3	492	187.1	Lot 1 /Lot 3	1.01	0.89	1.15
	Lot 2	487	191.6	Lot 3	492	187.1	Lot 2 /Lot 3	1.02	0.90	1.16
B/Malaysia	Lot 1	491	244.6	Lot 2	487	229.0	Lot 1 /Lot 2	1.07	0.95	1.20
	Lot 1	491	244.6	Lot 3	492	236.4	Lot 1 /Lot 3	1.03	0.92	1.16
	Lot 2	487	229.0	Lot 3	492	236.4	Lot 2 /Lot 3	0.97	0.86	1.08

Adjusted GMT = geometric mean antibody titre adjusted for baseline titre
N = Number of subjects with both pre- and post-vaccination results available
90% CI = 90% confidence interval for the adjusted GMT ratio (ANCOVA model: adjustment for baseline titre - pooled variance with more than 2 groups); LL = lower limit, UL = upper limit
*Lot-to lot consistency criterion: 90% CI within [0.67,1.50] for the 9 comparisons between each pair of lots.

Primary Efficacy Results:
Seropositivity rates and GMTs for HI antibody titre at each time point (ATP cohort for immunogenicity)

				≥ 1:10				**GMT***		
						95% CI			**95% CI**	
Strain	**Group**	**Timing**	**N**	**n**	**%**	**LL**	**UL**	**value**	**LL**	**UL**
A/New Caledonia	Lot 1*	PRE	494	402	81.4	77.7	84.7	26.7	24.0	29.7
		PI(D21)	492	485	98.6	97.1	99.4	121.4	108.9	135.3
	Lot 2*	PRE	494	412	83.4	79.8	86.6	28.5	25.6	31.7
		PI(D21)	488	486	99.6	98.5	100	119.1	107.5	132.0
	Lot 3*	PRE	499	416	83.4	79.8	86.5	28.6	25.7	31.8
		PI(D21)	492	488	99.2	97.9	99.8	133.8	120.4	148.8
	Flu	PRE	106	87	82.1	73.4	88.8	25.7	20.4	32.3
		PI(D21)	106	103	97.2	92.0	99.4	130.6	100.3	170.1
	Pooled Lots	PRE	1487	1230	82.7	80.7	84.6	27.9	26.2	29.7
		PI(D21)	1472	1459	99.1	98.5	99.5	124.6	117.3	132.4
A/New York	Lot 1*	PRE	494	385	77.9	74.0	81.5	24.2	21.6	27.0
		PI(D21)	492	485	98.6	97.1	99.4	189.3	168.3	213.0
	Lot 2*	PRE	494	380	76.9	73.0	80.6	23.9	21.4	26.7
		PI(D21)	488	487	99.8	98.9	100	192.3	171.7	215.5
	Lot 3*	PRE	499	382	76.6	72.6	80.2	24.3	21.6	27.3
		PI(D21)	492	488	99.2	97.9	99.8	187.3	167.5	209.5
	Flu	PRE	106	84	79.2	70.3	86.5	26.2	20.5	33.5
		PI(D21)	106	102	96.2	90.6	99.0	110.9	85.0	144.7
	Pooled	PRE	1487	1147	77.1	74.9	79.2	24.1	22.6	25.7

	Lots	PI(D21)	1472	1460	99.2	98.6	99.6	189.6	177.5	202.6
B/Malaysia	Lot 1*	PRE	494	402	81.4	77.7	84.7	29.6	26.4	33.1
		PI(D21)	492	488	99.2	97.9	99.8	243.0	218.4	270.2
	Lot 2*	PRE	494	413	83.6	80.0	86.8	29.7	26.7	33.1
		PI(D21)	488	488	100	99.2	100	229.9	208.3	253.7
	Lot 3*	PRE	499	415	83.2	79.6	86.3	31.8	28.3	35.6
		PI(D21)	492	491	99.8	98.9	100	238.7	216.5	263.3
	Flu	PRE	106	80	75.5	66.2	83.3	27.7	21.5	35.8
		PI(D21)	106	104	98.1	93.4	99.8	167.0	131.6	211.8
	Pooled Lots	PRE	1487	1230	82.7	80.7	84.6	30.3	28.4	32.4
		PI(D21)	1472	1467	99.7	99.2	99.9	237.1	223.7	251.4

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 at Day 0
PI(D21) = post-vaccination at Day 21
*Primary variables

Primary Efficacy Results:
Seroconversion rate (SCR) for HI antibody titres at Day 21 (ATP cohort for immunogenicity)

Strain	**Group**	**N**	**SCR**			
			n	**%**	**95%CI**	
					LL	**UL**
A/New Caledonia	Lot 1*	491	214	43.6	39.1	48.1
	Lot 2*	487	205	42.1	37.7	46.6
	Lot 3*	492	233	47.4	42.9	51.9
	Flu	106	47	44.3	34.7	54.3
	Pooled Lots	1470	652	44.4	41.8	46.9
A/New York	Lot 1*	491	308	62.7	58.3	67.0
	Lot 2*	487	309	63.4	59.0	67.7
	Lot 3*	492	313	63.6	59.2	67.9
	Flu	106	49	46.2	36.5	56.2
	Pooled Lots	1470	930	63.3	60.7	65.7
B/Malaysia	Lot 1*	491	333	67.8	63.5	71.9
	Lot 2*	487	317	65.1	60.7	69.3
	Lot 3*	492	326	66.3	61.9	70.4
	Flu	106	59	55.7	45.7	65.3
	Pooled Lots	1470	976	66.4	63.9	68.8

N = number of subjects with available results
n (%) = number (percentage) of seroconverted subjects
Seroconversion defined as:
For initially seronegative subjects (with a pre-vaccination serum HI titre <1:10), HI titre ≥ 1:40 after vaccination
For initially seropositive subjects(with a pre-vaccination serum HI titre ≥1:10), HI titre after vaccination ≥ 4 fold the pre-vaccination titre
95% CI = 95% confidence interval, LL = Lower Limit, UL = Upper Limit
*Primary outcome

Primary Efficacy Results:
Seroprotection rates (SPR) for HI antibody titres at each time point (ATP cohort for immunogenicity)

Strain	**Group**	**Timing**	**N**	**SPR**			
				n	**%**	**95%CI**	
						LL	**UL**
A/New Caledonia	Lot 1*	PRE	494	221	44.7	40.3	49.2
		PI(D21)	491	439	89.4	86.3	92.0
	Lot 2*	PRE	494	220	44.5	40.1	49.0
		PI(D21)	487	433	88.9	85.8	91.6
	Lot 3*	PRE	499	229	45.9	41.5	50.4
		PI(D21)	492	454	92.3	89.6	94.5

	Flu	PRE	106	46	43.4	33.8	53.4
		PI(D21)	106	94	88.7	81.1	94.0
	Pooled Lots	PRE	1487	670	45.1	42.5	47.6
		PI(D21)	1470	1326	90.2	88.6	91.7
A/New York	Lot 1*	PRE	494	197	39.9	35.5	44.3
		PI(D21)	491	451	91.9	89.1	94.1
	Lot 2*	PRE	494	201	40.7	36.3	45.2
		PI(D21)	487	447	91.8	89.0	94.1
	Lot 3*	PRE	499	200	40.1	35.8	44.5
		PI(D21)	492	454	92.3	89.6	94.5
	Flu	PRE	106	47	44.3	34.7	54.3
		PI(D21)	106	89	84.0	75.6	90.4
	Pooled Lots	PRE	1487	598	40.2	37.7	42.8
		PI(D21)	1470	1352	92.0	90.5	93.3
B/Malaysia	Lot 1*	PRE	494	240	48.6	44.1	53.1
		PI(D21)	491	474	96.5	94.5	98.0
	Lot 2*	PRE	494	230	46.6	42.1	51.1
		PI(D21)	487	475	97.5	95.7	98.7
	Lot 3*	PRE	499	236	47.3	42.8	51.8
		PI(D21)	492	481	97.8	96.0	98.9
	Flu	PRE	106	52	49.1	39.2	59.0
		PI(D21)	106	97	91.5	84.5	96.0
	Pooled Lots	PRE	1487	706	47.5	44.9	50.1
		PI(D21)	1470	1430	97.3	96.3	98.0

N = Number of subjects with available results
n (%) = Number (percentage) of seroprotected subjects (HI titre $\geq$ 1:40)
95% CI = 95% confidence interval, LL = Lower Limit, UL = Upper Limit
PRE = pre-vaccination at Day 0
PI(D21) = post-vaccination at Day 21
*Primary outcome

Primary Efficacy Results:
Seroconversion factor (SCF) for HI antibody titre at Day 21 (ATP cohort for immunogenicity)

Strain	**Group**	**N**	**SCF**	**95%CI**	
				LL	**UL**
A/New Caledonia	Lot 1*	491	4.6	4.0	5.2
	Lot 2*	487	4.2	3.7	4.7
	Lot 3*	492	4.7	4.1	5.4
	Flu	106	5.1	3.7	7.1
	Pooled Lots	1470	4.5	4.2	4.8
A/New York	Lot 1*	491	7.9	6.9	9.0
	Lot 2*	487	7.9	7.0	9.1
	Lot 3*	492	7.7	6.8	8.8
	Flu	106	4.2	3.2	5.5
	Pooled Lots	1470	7.8	7.3	8.5
B/Malaysia	Lot 1*	491	8.2	7.2	9.3
	Lot 2*	487	7.6	6.8	8.5
	Lot 3*	492	7.6	6.7	8.6
	Flu	106	6.0	4.6	7.9
	Pooled Lots	1470	7.8	7.3	8.4

N = number of subjects with available results
SCF = fold increase in serum HI GMT on Day 21 compared to Day 0
95% CI = 95% confidence interval, LL = Lower Limit, UL = Upper Limit
*Primary outcome

Primary Efficacy Results:
Incidence of solicited local symptoms reported during the 7-day (Days 0-6) post-vaccination period (Total Vaccinated

cohort)

Symptom	Intensity	Lot 1 Group (N=847)				Lot 2 Group (N=850)				Lot 3 Group (N=851)			
				95 % CI				95 % CI				95 % CI	
		n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
Ecchymosis	Any	22	2.6	1.6	3.9	34	4.0	2.8	5.5	30	3.5	2.4	5.0
	> 50 mm	1	0.1	0.0	0.7	2	0.2	0.0	0.8	3	0.4	0.1	1.0
Pain	Any	470	55.5	52.1	58.9	449	52.8	49.4	56.2	456	53.6	50.2	57.0
	Grade 3	9	1.1	0.5	2.0	13	1.5	0.8	2.6	13	1.5	0.8	2.6
Redness	Any	324	38.3	35.0	41.6	297	34.9	31.7	38.3	338	39.7	36.4	43.1
	> 50 mm	103	12.2	10.0	14.6	80	9.4	7.5	11.6	115	13.5	11.3	16.0
Swelling	Any	241	28.5	25.4	31.6	208	24.5	21.6	27.5	238	28.0	25.0	31.1
	> 50 mm	54	6.4	4.8	8.2	46	5.4	4.0	7.2	59	6.9	5.3	8.9

		Flu Group (N=568)				Pooled Lots Group (N=2548)			
				95 % CI				95 % CI	
		n	%	LL	UL	n	%	LL	UL
Ecchymosis	Any	17	3.0	1.8	4.7	86	3.4	2.7	4.2
	> 50 mm	0	0.0	0.0	0.6	6	0.2	0.1	0.5
Pain	Any	170	29.9	26.2	33.9	1375	54.0	52.0	55.9
	Grade 3	3	0.5	0.1	1.5	35	1.4	1.0	1.9
Redness	Any	162	28.5	24.8	32.4	959	37.6	35.8	39.6
	> 50 mm	17	3.0	1.8	4.7	298	11.7	10.5	13.0
Swelling	Any	87	15.3	12.5	18.5	687	27.0	25.2	28.7
	> 50 mm	5	0.9	0.3	2.0	159	6.2	5.3	7.3

N = number of subjects with a documented dose
n (%) = number (percentage) of subjects reporting the symptom at least once
95% CI = exact 95% confidence interval; LL = Lower Limit, UL = Upper Limit
Any = incidence of a particular symptom regardless of grade intensity
Grade 3 pain = pain that prevented normal activity

Primary Efficacy Results:
Incidence of solicited general symptoms reported during the 7-day (Days 0-6) post-vaccination period (Total Vaccinated cohort)

Symptom	Intensity/Relationship	Lot 1 Group (N=847)				Lot 2 Group (N=850)				Lot 3 Group (N=852)			
				95 % CI				95 % CI				95 % CI	
		n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
Arthralgia	Any	130	15.3	13.0	18.0	133	15.6	13.3	18.3	133	15.6	13.2	18.2
	Grade 3	9	1.1	0.5	2.0	10	1.2	0.6	2.2	12	1.4	0.7	2.4
	Related	69	8.1	6.4	10.2	90	10.6	8.6	12.9	85	10.0	8.0	12.2
Fatigue	Any	251	29.6	26.6	32.8	210	24.7	21.8	27.7	233	27.3	24.4	30.5
	Grade 3	13	1.5	0.8	2.6	17	2.0	1.2	3.2	11	1.3	0.6	2.3
	Related	156	18.4	15.9	21.2	143	16.8	14.4	19.5	144	16.9	14.4	19.6
Fever (orally)	≥ 37.5°C	45	5.3	3.9	7.0	54	6.4	4.8	8.2	44	5.2	3.8	6.9
	> 39.0°C	0	0.0	0.0	0.4	3	0.4	0.1	1.0	1	0.1	0.0	0.7
	Related	35	4.1	2.9	5.7	34	4.0	2.8	5.5	28	3.3	2.2	4.7
Headache	Any	182	21.5	18.8	24.4	167	19.6	17.0	22.5	182	21.4	18.7	24.3
	Grade 3	8	0.9	0.4	1.9	11	1.3	0.6	2.3	8	0.9	0.4	1.8
	Related	100	11.8	9.7	14.2	109	12.8	10.6	15.3	111	13.0	10.8	15.5
Muscle aches	Any	254	30.0	26.9	33.2	234	27.5	24.6	30.7	245	28.8	25.7	31.9
	Grade 3	8	0.9	0.4	1.9	13	1.5	0.8	2.6	17	2.0	1.2	3.2
	Related	159	18.8	16.2	21.6	160	18.8	16.2	21.6	156	18.3	15.8	21.1
Shivering	Any	92	10.9	8.8	13.2	93	10.9	8.9	13.2	90	10.6	8.6	12.8
	Grade 3	8	0.9	0.4	1.9	11	1.3	0.6	2.3	9	1.1	0.5	2.0
	Related	51	6.0	4.5	7.8	62	7.3	5.6	9.3	45	5.3	3.9	7.0

		Flu Group (N=568)				Pooled Lots Group (N=2549)			
				95 % CI				95 % CI	
		n	%	LL	UL	n	%	LL	UL
Arthralgia	Any	47	8.3	6.1	10.9	396	15.5	14.1	17.0
	Grade 3	2	0.4	0.0	1.3	31	1.2	0.8	1.7
	Related	29	5.1	3.4	7.3	244	9.6	8.5	10.8
Fatigue	Any	101	17.8	14.7	21.2	694	27.2	25.5	29.0
	Grade 3	4	0.7	0.2	1.8	41	1.6	1.2	2.2
	Related	53	9.3	7.1	12.0	443	17.4	15.9	18.9
Fever (orally)	≥ 37.5°C	2	0.4	0.0	1.3	143	5.6	4.7	6.6
	> 39.0°C	0	0.0	0.0	0.6	4	0.2	0.0	0.4
	Related	1	0.2	0.0	1.0	97	3.8	3.1	4.6
Headache	Any	77	13.6	10.8	16.6	531	20.8	19.3	22.5
	Grade 3	3	0.5	0.1	1.5	27	1.1	0.7	1.5
	Related	38	6.7	4.8	9.1	320	12.6	11.3	13.9
Muscle aches	Any	79	13.9	11.2	17.0	733	28.8	27.0	30.6
	Grade 3	0	0.0	0.0	0.6	38	1.5	1.1	2.0
	Related	46	8.1	6.0	10.7	475	18.6	17.1	20.2
Shivering	Any	28	4.9	3.3	7.0	275	10.8	9.6	12.1
	Grade 3	0	0.0	0.0	0.6	28	1.1	0.7	1.6
	Related	13	2.3	1.2	3.9	158	6.2	5.3	7.2

N = number of subjects with a documented dose
n (%) = number (percentage) of subjects reporting the symptom at least once
95% CI = 95% confidence interval; LL = Lower Limit, UL = Upper Limit
Any = incidence of a particular symptom regardless of grade intensity or relationship with the study vaccination
Grade 3 symptom = symptom that prevented normal activity
Related = symptom considered by the investigator to have a causal relationship to study vaccination

Primary Efficacy Results:
Number (%) of subjects reporting the occurrence of new onset of chronic disease (NOCDs)* up to Day 180 (Total Vaccinated cohort)

NOCDs	**Lot 1 Group N = 850**	**Lot 2 Group N = 850**	**Lot 3 Group N = 854**	**Flu Group N = 570**	**Pooled Lots Group N = 2554**
Subjects with any NOCDs, n (%)	3 (0.4)	3 (0.4)	2 (0.2)	1 (0.2)	8 (0.3)
Type 2 diabetes mellitus	1 (0.1)	1 (0.1)	-	-	2 (0.1)
Diabetes mellitus	-	1 (0.1)	-	1 (0.2)	1 (0.0)
Asthma	-	1 (0.1)	-	-	1 (0.0)
Hypothyroidism	1 (0.1)	-	-	-	1 (0.0)
Mixed connective tissue disease	-	-	1 (0.1)	-	1 (0.0)
Polymyalgia rheumatica	1 (0.1)	-	-	-	1 (0.0)
Pulmonary fibrosis	-	-	1 (0.1)	-	1 (0.0)
Rheumatoid arthritis	-	-	1 (0.1)	-	1 (0.0)

-: Event absent
*Rare events, defined as events with an occurrence rate of 0.1 % and belonging to the NOCDs are presented in this table

Primary Efficacy Results:
Number (%) of subjects with adverse events related to medically significant conditions (MSCs)* up to Day 180 (Total Vaccinated cohort)

MSCs	**Lot 1 Group N = 850**	**Lot 2 Group N = 850**	**Lot 3 Group N = 854**	**Flu Group N = 570**	**Pooled Lots Group N = 2554**
Subjects with any MSC, n (%)	70 (8.2)	69 (8.1)	72 (8.4)	52 (9.1)	211 (8.3)
Bronchitis	3 (0.4)	7 (0.8)	2 (0.2)	3 (0.5)	12 (0.5)
Hypertension	4 (0.5)	3 (0.4)	1 (0.1)	4 (0.7)	8 (0.3)

Back pain	1 (0.1)	2 (0.2)	4 (0.5)	3 (0.5)	7 (0.3)
Osteoarthritis	2 (0.2)	6 (0.7)	-	2 (0.4)	8 (0.3)
Angina pectoris	4 (0.5)	2 (0.2)	1 (0.1)	-	7 (0.3)
Depression	1 (0.1)	3 (0.4)	2 (0.2)	-	6 (0.2)
Pneumonia	1 (0.1)	2 (0.2)	2 (0.2)	1 (0.2)	5 (0.2)
Sciatica	3 (0.4)	1 (0.1)	2 (0.2)	-	6 (0.2)
Arthralgia	1 (0.1)	1 (0.1)	2 (0.2)	1 (0.2)	4 (0.2)
Syncope	2 (0.2)	2 (0.2)	1 (0.1)	-	5 (0.2)
Arrhythmia	-	1 (0.1)	2 (0.2)	1 (0.2)	3 (0.1)
Arthritis	-	1 (0.1)	1 (0.1)	2 (0.4)	2 (0.1)
Asthma	-	3 (0.4)	1 (0.1)	-	4 (0.2)
Blood cholesterol increased	-	2 (0.2)	1 (0.1)	1 (0.2)	3 (0.1)
Chest pain	-	2 (0.2)	1 (0.1)	1 (0.2)	3 (0.1)
Cystitis	1 (0.1)	-	2 (0.2)	1 (0.2)	3 (0.1)
Herpes zoster	1 (0.1)	-	3 (0.4)	-	4 (0.2)
Hypercholesterolaemia	2 (0.2)	-	1 (0.1)	1 (0.2)	3 (0.1)
Urinary tract infection	1 (0.1)	1 (0.1)	1 (0.1)	1 (0.2)	3 (0.1)
Cataract operation	1 (0.1)	1 (0.1)	1 (0.1)	-	3 (0.1)
Cholelithiasis	2 (0.2)	-	-	1 (0.2)	2 (0.1)
Colonic polyp	-	1 (0.1)	-	2 (0.4)	1 (0.0)
Coronary artery disease	-	2 (0.2)	1 (0.1)	-	3 (0.1)
Depressive delusion	2 (0.2)	1 (0.1)	-	-	3 (0.1)
Diabetes mellitus	1 (0.1)	1 (0.1)	-	1 (0.2)	2 (0.1)
Dizziness	2 (0.2)	-	1 (0.1)	-	3 (0.1)
Gastritis	1 (0.1)	-	1 (0.1)	1 (0.2)	2 (0.1)
Gastrooesophageal reflux disease	-	1 (0.1)	2 (0.2)	-	3 (0.1)
Rib fracture	-	1 (0.1)	1 (0.1)	1 (0.2)	2 (0.1)
Tonsillitis	2 (0.2)	-	1 (0.1)	-	3 (0.1)
Anaemia	2 (0.2)	-	-	-	2 (0.1)
Asthenia	-	1 (0.1)	-	1 (0.2)	1 (0.0)
Benign prostatic hyperplasia	1 (0.1)	-	-	1 (0.2)	1 (0.0)
Bile duct stone	1 (0.1)	-	-	1 (0.2)	1 (0.0)
Cardiac failure	-	-	2 (0.2)	-	2 (0.1)
Cardiovascular disorder	-	2 (0.2)	-	-	2 (0.1)
Cataract	-	1 (0.1)	1 (0.1)	-	2 (0.1)
Cerebral infarction	-	1 (0.1)	1 (0.1)	-	2 (0.1)
Cerebrovascular accident	1 (0.1)	1 (0.1)	-	-	2 (0.1)
Circulatory collapse	1 (0.1)	-	1 (0.1)	-	2 (0.1)
Constipation	-	-	2 (0.2)	-	2 (0.1)
Erythema	-	-	1 (0.1)	1 (0.2)	1 (0.0)
Femoral neck fracture	-	-	2 (0.2)	-	2 (0.1)
Headache	1 (0.1)	-	-	1 (0.2)	1 (0.0)
Hip fracture	-	-	1 (0.1)	1 (0.2)	1 (0.0)
Hyperlipidaemia	1 (0.1)	1 (0.1)	-	-	2 (0.1)
Hyperthyroidism	1 (0.1)	-	1 (0.1)	-	2 (0.1)
Lung neoplasm malignant	-	1 (0.1)	1 (0.1)	-	2 (0.1)
Nasopharyngitis	1 (0.1)	-	1 (0.1)	-	2 (0.1)
Neck pain	-	1 (0.1)	1 (0.1)	-	2 (0.1)
Nephrolithiasis	-	1 (0.1)	-	1 (0.2)	1 (0.0)
Pain in extremity	-	-	1 (0.1)	1 (0.2)	1 (0.0)
Pertussis	1 (0.1)	1 (0.1)	-	-	2 (0.1)
Prostate cancer	-	2 (0.2)	-	-	2 (0.1)
Pyrexia	1 (0.1)	-	-	1 (0.2)	1 (0.0)
Renal cell carcinoma stage unspecified	-	-	1 (0.1)	1 (0.2)	1 (0.0)
Type 2 diabetes mellitus	1 (0.1)	1 (0.1)	-	-	2 (0.1)

Venous stasis	-	1 (0.1)	-	1 (0.2)	1 (0.0)
Abdominal discomfort	-	1 (0.1)	-	-	1 (0.0)
Abdominal pain	-	-	1 (0.1)	-	1 (0.0)
Acute coronary syndrome	-	-	-	1 (0.2)	-
Acute myocardial infarction	-	1 (0.1)	-	-	1 (0.0)
Anal haemorrhage	-	1 (0.1)	-	-	1 (0.0)
Ankle fracture	-	1 (0.1)	-	-	1 (0.0)
Anoxia	-	-	-	1 (0.2)	-
Aortic stenosis	1 (0.1)	-	-	-	1 (0.0)
Arteriosclerosis coronary artery	-	-	-	1 (0.2)	-
Atrial fibrillation	-	-	1 (0.1)	-	1 (0.0)
Atrial flutter	-	-	1 (0.1)	-	1 (0.0)
Basal cell carcinoma	-	-	1 (0.1)	-	1 (0.0)
Bladder cancer	-	-	-	1 (0.2)	-
Breast cancer	1 (0.1)	-	-	-	1 (0.0)
Breast cancer recurrent	1 (0.1)	-	-	-	1 (0.0)
Bursitis	-	1 (0.1)	-	-	1 (0.0)
Cardiac fibrillation	1 (0.1)	-	-	-	1 (0.0)
Cardiac murmur	-	-	1 (0.1)	-	1 (0.0)
Cellulitis	-	-	1 (0.1)	-	1 (0.0)
Cerumen impaction	-	-	1 (0.1)	-	1 (0.0)
Cholecystitis infective	-	-	1 (0.1)	-	1 (0.0)
Chronic obstructive pulmonary disease	-	-	1 (0.1)	-	1 (0.0)
Clavicle fracture	-	-	-	1 (0.2)	-
Conjunctival haemorrhage	-	1 (0.1)	-	-	1 (0.0)
Conjunctivitis	-	-	1 (0.1)	-	1 (0.0)
Contusion	-	-	-	1 (0.2)	-
Cough	-	-	-	1 (0.2)	-
Cyst removal	-	-	-	1 (0.2)	-
Dermal cyst	1 (0.1)	-	-	-	1 (0.0)
Dermatitis allergic	1 (0.1)	-	-	-	1 (0.0)
Diabetic neuropathy	-	-	1 (0.1)	-	1 (0.0)
Diarrhoea haemorrhagic	-	-	-	1 (0.2)	-
Diverticulitis	1 (0.1)	-	-	-	1 (0.0)
Dyspnoea	1 (0.1)	-	-	-	1 (0.0)
Dyspnoea exertional	1 (0.1)	-	-	-	1 (0.0)
Eczema	-	-	1 (0.1)	-	1 (0.0)
Endometrial cancer	1 (0.1)	-	-	-	1 (0.0)
Enteritis	-	-	-	1 (0.2)	-
Epilepsy	1 (0.1)	-	-	-	1 (0.0)
Excoriation	-	-	1 (0.1)	-	1 (0.0)
Exostosis	-	-	-	1 (0.2)	-
Eye pain	-	-	-	1 (0.2)	-
Eyelid operation	-	-	1 (0.1)	-	1 (0.0)
Facial bones fracture	-	-	-	1 (0.2)	-
Fibrous histiocytoma	-	1 (0.1)	-	-	1 (0.0)
Foot deformity	1 (0.1)	-	-	-	1 (0.0)
Forearm fracture	-	1 (0.1)	-	-	1 (0.0)
Foreign body trauma	1 (0.1)	-	-	-	1 (0.0)
Gallstone ileus	-	-	-	1 (0.2)	-
Gastric cancer	-	1 (0.1)	-	-	1 (0.0)
Gastroenteritis	-	1 (0.1)	-	-	1 (0.0)
General physical health deterioration	1 (0.1)	-	-	-	1 (0.0)
Haemorrhoids	-	-	-	1 (0.2)	-
Hand fracture	-	-	1 (0.1)	-	1 (0.0)

Hepatic neoplasm malignant	-	-	1 (0.1)		1 (0.0)
Hypersensitivity	1 (0.1)	-	-	-	1 (0.0)
Hyperuricaemia	-	-	1 (0.1)	-	1 (0.0)
Hypothyroidism	1 (0.1)	-	-	-	1 (0.0)
Iliac artery stenosis	1 (0.1)	-	-	-	1 (0.0)
Impetigo	-	-	-	1 (0.2)	-
Inguinal hernia repair	-	-	-	1 (0.2)	-
Intermittent claudication	1 (0.1)	-	-	-	1 (0.0)
Intervertebral disc protrusion	-	1 (0.1)	-	-	1 (0.0)
Iron deficiency anaemia	1 (0.1)	-	-	-	1 (0.0)
Laceration	-	-	1 (0.1)	-	1 (0.0)
Lung infection	1 (0.1)	-	-	-	1 (0.0)
Malaise	-	1 (0.1)	-	-	1 (0.0)
Malignant melanoma	1 (0.1)	-	-	-	1 (0.0)
Meniscus lesion	-	-	-	1 (0.2)	-
Mitral valve incompetence	-	-	1 (0.1)	-	1 (0.0)
Mitral valve repair	-	-	1 (0.1)	-	1 (0.0)
Mixed connective tissue disease	-	-	1 (0.1)	-	1 (0.0)
Musculoskeletal pain	-	-	1 (0.1)	-	1 (0.0)
Myocardial infarction	-	-	-	1 (0.2)	-
Neoplasm prostate	-	-	-	1 (0.2)	-
Nephrotic syndrome	-	1 (0.1)	-	-	1 (0.0)
Oedema peripheral	1 (0.1)	-	-	-	1 (0.0)
Oesophageal carcinoma	-	-	-	1 (0.2)	-
Onychomycosis	1 (0.1)	-	-	-	1 (0.0)
Oral candidiasis	-	1 (0.1)	-	-	1 (0.0)
Otitis externa	-	1 (0.1)	-	-	1 (0.0)
Pain	-	1 (0.1)	-	-	1 (0.0)
Palpitations	-	-	1 (0.1)	-	1 (0.0)
Pancreatitis	1 (0.1)	-	-	-	1 (0.0)
Pancreatitis acute	-	-	-	1 (0.2)	-
Peripheral vascular disorder	1 (0.1)	-	-	-	1 (0.0)
Polymyalgia rheumatica	1 (0.1)	-	-	-	1 (0.0)
Prostatitis	-	1 (0.1)	-	-	1 (0.0)
Prostatomegaly	1 (0.1)	-	-	-	1 (0.0)
Pulmonary fibrosis	-	-	1 (0.1)	-	1 (0.0)
Pulmonary tuberculosis	-	1 (0.1)	-	-	1 (0.0)
Radius fracture	-	-	-	1 (0.2)	-
Reflux gastritis	-	1 (0.1)	-	-	1 (0.0)
Renal failure chronic	1 (0.1)	-	-	-	1 (0.0)
Restless legs syndrome	-	-	1 (0.1)	-	1 (0.0)
Rheumatoid arthritis	-	-	1 (0.1)	-	1 (0.0)
Rhinitis	-	1 (0.1)	-	-	1 (0.0)
Rhinitis allergic	1 (0.1)	-	-	-	1 (0.0)
Rotator cuff syndrome	-	-	1 (0.1)	-	1 (0.0)
Scoliosis	-	-	1 (0.1)	-	1 (0.0)
Skin ulcer	-	-	1 (0.1)	-	1 (0.0)
Small intestinal perforation	-	-	-	1 (0.2)	-
Spinal disorder	1 (0.1)	-	-	-	1 (0.0)
Stress	-	1 (0.1)	-	-	1 (0.0)
Suicide attempt	-	1 (0.1)	-	-	1 (0.0)
Tachyarrhythmia	-	1 (0.1)	-	-	1 (0.0)
Tachycardia paroxysmal	-	-	1 (0.1)	-	1 (0.0)
Tenderness	-	-	-	1 (0.2)	-
Tendonitis	-	-	-	1 (0.2)	-

Tinnitus	1 (0.1)	-	-	-	1 (0.0)
Tooth abscess	-	1 (0.1)	-	-	1 (0.0)
Tremor	-	-	-	1 (0.2)	-
Trigeminal neuralgia	-	-	1 (0.1)	-	1 (0.0)
Upper limb fracture	-	-	1 (0.1)	-	1 (0.0)
Upper respiratory tract infection	-	-	1 (0.1)	-	1 (0.0)
Uterine polyp	-	-	-	1 (0.2)	-
Vaginal discharge	1 (0.1)	-	-	-	1 (0.0)
Vaginal prolapse	-	-	1 (0.1)	-	1 (0.0)
Visual disturbance	-	-	-	1 (0.2)	-
Whiplash injury	-	1 (0.1)	-	-	1 (0.0)
Wound infection	1 (0.1)	-	-	-	1 (0.0)
-: MSC absent *Rare events, defined as events with an occurrence rate of 0.1 % and belonging to the MSCs are presented in this table					
Safety Results: Number (%) of subjects with unsolicited adverse events* reported within the 30-day (Days 0-29) post-vaccination period (Total Vaccinated cohort)					
Most frequent adverse events - On-Therapy (occurring within Days 0-29 following vaccination)	**Lot 1 Group N = 850**	**Lot 2 Group N = 850**	**Lot 3 Group N = 854**	**Flu Group N = 570**	**Pooled Lots Group N = 2554**
Subjects with any AE(s), n (%)	133 (15.6)	150 (17.6)	162 (19.0)	109 (19.1)	445 (17.4)
Subjects with any Grade 3 AE(s), n (%)	11 (1.3)	14 (1.6)	15 (1.8)	10 (1.8)	40 (1.6)
Subjects with any related AE(s), n (%)	47 (5.5)	57 (6.7)	65 (7.6)	16 (2.8)	169 (6.6)
Nasopharyngitis	18 (2.1)	12 (1.4)	17 (2.0)	11 (1.9)	47 (1.8)
Injection site pruritus	17 (2.0)	14 (1.6)	16 (1.9)	4 (0.7)	47 (1.8)
Nausea	9 (1.1)	11 (1.3)	12 (1.4)	6 (1.1)	32 (1.3)
Headache	6 (0.7)	3 (0.4)	6 (0.7)	11 (1.9)	15 (0.6)
Dizziness	10 (1.2)	4 (0.5)	6 (0.7)	4 (0.7)	20 (0.8)
Diarrhoea	6 (0.7)	7 (0.8)	7 (0.8)	3 (0.5)	20 (0.8)
Back pain	6 (0.7)	10 (1.2)	3 (0.4)	3 (0.5)	19 (0.7)
Cough	4 (0.5)	6 (0.7)	5 (0.6)	7 (1.2)	15 (0.6)
Pharyngolaryngeal pain	3 (0.4)	6 (0.7)	7 (0.8)	5 (0.9)	16 (0.6)
Arthralgia	5 (0.6)	6 (0.7)	1 (0.1)	1 (0.2)	12 (0.5)
Rhinitis	2 (0.2)	4 (0.5)	3 (0.4)	4 (0.7)	9 (0.4)
Bronchitis	4 (0.5)	4 (0.5)	4 (0.5)	-	12 (0.5)
Musculoskeletal pain	1 (0.1)	5 (0.6)	3 (0.4)	3 (0.5)	9 (0.4)
Pruritus	2 (0.2)	3 (0.4)	6 (0.7)	1 (0.2)	11 (0.4)
Vomiting	1 (0.1)	4 (0.5)	2 (0.2)	4 (0.7)	7 (0.3)
Musculoskeletal stiffness	1 (0.1)	6 (0.7)	2 (0.2)	1 (0.2)	9 (0.4)
Osteoarthritis	-	4 (0.5)	3 (0.4)	2 (0.4)	7 (0.3)
Urinary tract infection	-	3 (0.4)	4 (0.5)	2 (0.4)	7 (0.3)
Fatigue	3 (0.4)	1 (0.1)	1 (0.1)	3 (0.5)	5 (0.2)
Injection site warmth	2 (0.2)	2 (0.2)	3 (0.4)	1 (0.2)	7 (0.3)
Neck pain	3 (0.4)	3 (0.4)	2 (0.2)	-	8 (0.3)
Pain in extremity	3 (0.4)	2 (0.2)	2 (0.2)	1 (0.2)	7 (0.3)
Erythema	2 (0.2)	3 (0.4)	2 (0.2)	-	7 (0.3)
Hyperhidrosis	3 (0.4)	2 (0.2)	1 (0.1)	1 (0.2)	6 (0.2)
Insomnia	3 (0.4)	1 (0.1)	2 (0.2)	1 (0.2)	6 (0.2)
Myalgia	-	3 (0.4)	2 (0.2)	2 (0.4)	5 (0.2)
Upper respiratory tract infection	1 (0.1)	2 (0.2)	2 (0.2)	2 (0.4)	5 (0.2)
Vertigo	3 (0.4)	2 (0.2)	1 (0.1)	1 (0.2)	6 (0.2)
Abdominal pain	1 (0.1)	2 (0.2)	3 (0.4)	-	6 (0.2)
Injection site induration	3 (0.4)	1 (0.1)	2 (0.2)	-	6 (0.2)
Pneumonia	2 (0.2)	2 (0.2)	2 (0.2)	-	6 (0.2)

Seasonal allergy	2 (0.2)	2 (0.2)	1 (0.1)	1 (0.2)	5 (0.2)
Axillary pain	2 (0.2)	1 (0.1)	1 (0.1)	1 (0.2)	4 (0.2)
Hot flush	-	1 (0.1)	3 (0.4)	1 (0.2)	4 (0.2)
Sciatica	-	2 (0.2)	3 (0.4)	-	5 (0.2)
Influenza like illness	1 (0.1)	2 (0.2)	1 (0.1)	-	4 (0.2)
Muscle spasms	1 (0.1)	1 (0.1)	1 (0.1)	1 (0.2)	3 (0.1)
Nasal congestion	1 (0.1)	2 (0.2)	-	1 (0.2)	3 (0.1)
Oedema peripheral	1 (0.1)	-	3 (0.4)	-	4 (0.2)
Paraesthesia	2 (0.2)	1 (0.1)	1 (0.1)	-	4 (0.2)
Pharyngitis	1 (0.1)	2 (0.2)	1 (0.1)	-	4 (0.2)
Skin laceration	-	2 (0.2)	1 (0.1)	1 (0.2)	3 (0.1)
Sleep disorder	2 (0.2)	-	1 (0.1)	1 (0.2)	3 (0.1)
Toothache	1 (0.1)	1 (0.1)	1 (0.1)	1 (0.2)	3 (0.1)
Wound	1 (0.1)	1 (0.1)	-	2 (0.4)	2 (0.1)
Abdominal pain upper	1 (0.1)	1 (0.1)	-	1 (0.2)	2 (0.1)
Angina pectoris	-	-	1 (0.1)	2 (0.4)	1 (0.0)
Arthritis	2 (0.2)	1 (0.1)	-	-	3 (0.1)
Conjunctivitis	-	1 (0.1)	2 (0.2)	-	3 (0.1)
Cystitis	2 (0.2)	1 (0.1)	-	-	3 (0.1)
Dry mouth	1 (0.1)	1 (0.1)	1 (0.1)	-	3 (0.1)
Dyspepsia	2 (0.2)	-	1 (0.1)	-	3 (0.1)
Ear pain	-	1 (0.1)	-	2 (0.4)	1 (0.0)
Eczema	1 (0.1)	-	2 (0.2)	-	3 (0.1)
Feeling hot	2 (0.2)	-	1 (0.1)	-	3 (0.1)
Gastritis	1 (0.1)	-	1 (0.1)	1 (0.2)	2 (0.1)
Gastroenteritis	2 (0.2)	-	1 (0.1)	-	3 (0.1)
Gastroenteritis viral	1 (0.1)	-	2 (0.2)	-	3 (0.1)
Gastrooesophageal reflux disease	-	1 (0.1)	2 (0.2)	-	3 (0.1)
Inflammation	-	-	2 (0.2)	1 (0.2)	2 (0.1)
Injection site erythema	-	1 (0.1)	2 (0.2)	-	3 (0.1)
Injection site pain	-	-	2 (0.2)	1 (0.2)	2 (0.1)
Lymphadenopathy	-	1 (0.1)	1 (0.1)	1 (0.2)	2 (0.1)
Malaise	1 (0.1)	-	2 (0.2)	-	3 (0.1)
Oral herpes	1 (0.1)	-	2 (0.2)	-	3 (0.1)
Pyrexia	-	3 (0.4)	-	-	3 (0.1)
Rash	-	1 (0.1)	-	2 (0.4)	1 (0.0)
Rhinorrhoea	-	1 (0.1)	2 (0.2)	-	3 (0.1)
Sinusitis	-	-	1 (0.1)	2 (0.4)	1 (0.0)
Sneezing	2 (0.2)	-	1 (0.1)	-	3 (0.1)
Blood pressure increased	-	-	2 (0.2)	-	2 (0.1)
Cardiac flutter	1 (0.1)	1 (0.1)	-	-	2 (0.1)
Chest pain	2 (0.2)	-	-	-	2 (0.1)
Chills	-	-	1 (0.1)	1 (0.2)	1 (0.0)
Colitis	-	-	1 (0.1)	1 (0.2)	1 (0.0)
Dysphonia	-	1 (0.1)	1 (0.1)	-	2 (0.1)
Dysuria	-	2 (0.2)	-	-	2 (0.1)
Hyperlipidaemia	-	-	-	2 (0.4)	-
Hypertension	1 (0.1)	-	1 (0.1)	-	2 (0.1)
Influenza	-	1 (0.1)	1 (0.1)	-	2 (0.1)
Injection site discomfort	1 (0.1)	-	1 (0.1)	-	2 (0.1)
Injection site hypersensitivity	-	-	1 (0.1)	1 (0.2)	1 (0.0)
Injection site irritation	-	-	2 (0.2)	-	2 (0.1)
Joint sprain	-	1 (0.1)	1 (0.1)	-	2 (0.1)
Limb discomfort	-	1 (0.1)	1 (0.1)	-	2 (0.1)
Migraine	2 (0.2)	-	-	-	2 (0.1)

Oral mucosal blistering	-	1 (0.1)	1 (0.1)	-	2 (0.1)
Periarthritis	-	1 (0.1)	-	1 (0.2)	1 (0.0)
Radius fracture	-	-	1 (0.1)	1 (0.2)	1 (0.0)
Respiratory tract infection	-	1 (0.1)	-	1 (0.2)	1 (0.0)
Sialoadenitis	-	-	-	2 (0.4)	-
Skin ulcer	-	1 (0.1)	-	1 (0.2)	1 (0.0)
Swelling face	-	-	-	2 (0.4)	-
Syncope	-	-	1 (0.1)	1 (0.2)	1 (0.0)
Tachycardia	1 (0.1)	1 (0.1)	-	-	2 (0.1)
Tonsillitis	2 (0.2)	-	-	-	2 (0.1)
Tremor	-	1 (0.1)	-	1 (0.2)	1 (0.0)
Vaginal haemorrhage	-	-	-	2 (0.4)	-
Wound infection	-	1 (0.1)	-	1 (0.2)	1 (0.0)
Anxiety	-	-	1 (0.1)	-	1 (0.0)
Aphthous stomatitis	-	-	-	1 (0.2)	-
Arthropod bite	-	-	1 (0.1)	-	1 (0.0)
Asthenia	-	1 (0.1)	-	-	1 (0.0)
Asthenopia	-	1 (0.1)	-	-	1 (0.0)
Asthma	-	-	1 (0.1)	-	1 (0.0)
Bacterial infection	-	1 (0.1)	-	-	1 (0.0)
Benign prostatic hyperplasia	-	1 (0.1)	-	-	1 (0.0)
Bladder pain	-	-	1 (0.1)	-	1 (0.0)
Blood pressure diastolic increased	-	-	1 (0.1)	-	1 (0.0)
Bone pain	-	-	-	1 (0.2)	-
Breast cancer	1 (0.1)	-	-	-	1 (0.0)
Breast pain	1 (0.1)	-	-	-	1 (0.0)
Bronchitis chronic	-	1 (0.1)	-	-	1 (0.0)
Cardiac failure	-	-	1 (0.1)	-	1 (0.0)
Cardiac valve disease	1 (0.1)	-	-	-	1 (0.0)
Cataract	1 (0.1)	-	-	-	1 (0.0)
Cerebral infarction	1 (0.1)	-	-	-	1 (0.0)
Concussion	-	1 (0.1)	-	-	1 (0.0)
Conjunctivitis allergic	-	1 (0.1)	-	-	1 (0.0)
Conjunctivitis bacterial	1 (0.1)	-	-	-	1 (0.0)
Constipation	-	-	-	1 (0.2)	-
Contusion	-	-	1 (0.1)	-	1 (0.0)
Decreased appetite	-	-	1 (0.1)	-	1 (0.0)
Deep vein thrombosis	1 (0.1)	-	-	-	1 (0.0)
Depression	-	1 (0.1)	-	-	1 (0.0)
Dermatitis allergic	-	-	-	1 (0.2)	-
Discomfort	-	-	1 (0.1)	-	1 (0.0)
Disorientation	1 (0.1)	-	-	-	1 (0.0)
Diverticulum intestinal	-	1 (0.1)	-	-	1 (0.0)
Dizziness postural	1 (0.1)	-	-	-	1 (0.0)
Dysgeusia	-	1 (0.1)	-	-	1 (0.0)
Dysphagia	-	1 (0.1)	-	-	1 (0.0)
Ear discomfort	-	-	1 (0.1)	-	1 (0.0)
Ear infection	1 (0.1)	-	-	-	1 (0.0)
Encephalopathy	-	1 (0.1)	-	-	1 (0.0)
Epididymitis	-	-	1 (0.1)	-	1 (0.0)
Erosive oesophagitis	-	1 (0.1)	-	-	1 (0.0)
Eye pain	-	1 (0.1)	-	-	1 (0.0)
Eye swelling	1 (0.1)	-	-	-	1 (0.0)
Feeling cold	-	-	1 (0.1)	-	1 (0.0)
Flatulence	1 (0.1)	-	-	-	1 (0.0)

Flushing	-	1 (0.1)	-	-	1 (0.0)
Foot deformity	-	1 (0.1)	-	-	1 (0.0)
Foot fracture	1 (0.1)	-	-	-	1 (0.0)
Foot operation	-	-	1 (0.1)	-	1 (0.0)
Fracture	-	-	1 (0.1)	-	1 (0.0)
Furuncle	-	-	1 (0.1)	-	1 (0.0)
Genital infection fungal	-	1 (0.1)	-	-	1 (0.0)
Gingivitis ulcerative	1 (0.1)	-	-	-	1 (0.0)
Gout	-	-	1 (0.1)	-	1 (0.0)
Hand fracture	-	-	-	1 (0.2)	-
Heart rate abnormal	1 (0.1)	-	-	-	1 (0.0)
Heart rate irregular	1 (0.1)	-	-	-	1 (0.0)
Helicobacter gastritis	-	1 (0.1)	-	-	1 (0.0)
Herpes simplex	-	-	-	1 (0.2)	-
Herpes zoster	-	-	-	1 (0.2)	-
Hyperaemia	1 (0.1)	-	-	-	1 (0.0)
Hypersensitivity	-	1 (0.1)	-	-	1 (0.0)
Hypertensive crisis	1 (0.1)	-	-	-	1 (0.0)
Hypertriglyceridaemia	-	-	1 (0.1)	-	1 (0.0)
Hyperuricaemia	1 (0.1)	-	-	-	1 (0.0)
Ileus	-	-	-	1 (0.2)	-
Infection	-	-	1 (0.1)	-	1 (0.0)
Injection site bruising	1 (0.1)	-	-	-	1 (0.0)
Injection site haematoma	-	1 (0.1)	-	-	1 (0.0)
Injection site reaction	1 (0.1)	-	-	-	1 (0.0)
Injection site scab	-	-	1 (0.1)	-	1 (0.0)
Intercostal neuralgia	-	-	-	1 (0.2)	-
Intervertebral disc degeneration	-	-	-	1 (0.2)	-
Iron deficiency anaemia	-	-	1 (0.1)	-	1 (0.0)
Joint swelling	-	-	-	1 (0.2)	-
Lacrimation increased	1 (0.1)	-	-	-	1 (0.0)
Laryngitis	-	-	-	1 (0.2)	-
Limb operation	-	-	-	1 (0.2)	-
Local swelling	-	1 (0.1)	-	-	1 (0.0)
Localised infection	1 (0.1)	-	-	-	1 (0.0)
Lower limb fracture	-	-	1 (0.1)	-	1 (0.0)
Lower respiratory tract infection	-	-	-	1 (0.2)	-
Lymph node pain	1 (0.1)	-	-	-	1 (0.0)
Muscular weakness	-	1 (0.1)	-	-	1 (0.0)
Musculoskeletal discomfort	-	-	-	1 (0.2)	-
Myocardial infarction	-	-	-	1 (0.2)	-
Myocarditis	1 (0.1)	-	-	-	1 (0.0)
Nasal dryness	1 (0.1)	-	-	-	1 (0.0)
Ocular hyperaemia	-	1 (0.1)	-	-	1 (0.0)
Oedema	-	-	-	1 (0.2)	-
Oesophageal stenosis	-	-	1 (0.1)	-	1 (0.0)
Osteoporosis	1 (0.1)	-	-	-	1 (0.0)
Otitis externa	-	-	1 (0.1)	-	1 (0.0)
Otitis media acute	-	-	1 (0.1)	-	1 (0.0)
Pain	-	1 (0.1)	-	-	1 (0.0)
Palpitations	-	-	1 (0.1)	-	1 (0.0)
Periodontitis	-	-	1 (0.1)	-	1 (0.0)
Polyarteritis nodosa	-	-	-	1 (0.2)	-
Polyarthritis	-	-	1 (0.1)	-	1 (0.0)
Polyuria	-	1 (0.1)	-	-	1 (0.0)

Post concussion syndrome	-	1 (0.1)	-	-	1 (0.0)
Prostate cancer	-	-	-	1 (0.2)	-
Rash macular	-	1 (0.1)	-	-	1 (0.0)
Rash papular	-	-	1 (0.1)	-	1 (0.0)
Renal colic	-	-	-	1 (0.2)	-
Restlessness	-	-	1 (0.1)	-	1 (0.0)
Retinal artery embolism	-	1 (0.1)	-	-	1 (0.0)
Retinal detachment	-	1 (0.1)	-	-	1 (0.0)
Rhinitis seasonal	1 (0.1)	-	-	-	1 (0.0)
Rib fracture	-	-	1 (0.1)	-	1 (0.0)
Rotator cuff syndrome	-	-	1 (0.1)	-	1 (0.0)
Sensation of heaviness	-	1 (0.1)	-	-	1 (0.0)
Skin lesion	-	-	1 (0.1)	-	1 (0.0)
Sleep apnoea syndrome	-	1 (0.1)	-	-	1 (0.0)
Somnolence	-	-	1 (0.1)	-	1 (0.0)
Swelling	-	1 (0.1)	-	-	1 (0.0)
Thermal burn	-	-	1 (0.1)	-	1 (0.0)
Thirst	-	-	1 (0.1)	-	1 (0.0)
Tinea pedis	-	1 (0.1)	-	-	1 (0.0)
Tooth abscess	1 (0.1)	-	-	-	1 (0.0)
Torticollis	-	-	1 (0.1)	-	1 (0.0)
Tracheitis	-	-	1 (0.1)	-	1 (0.0)
Traumatic haematoma	-	1 (0.1)	-	-	1 (0.0)
Upper limb fracture	-	-	-	1 (0.2)	-
Urticaria	-	-	1 (0.1)	-	1 (0.0)
Vasoconstriction	1 (0.1)	-	-	-	1 (0.0)
Vestibular disorder	-	-	1 (0.1)	-	1 (0.0)
Viral infection	1 (0.1)	-	-	-	1 (0.0)
Viral upper respiratory tract infection	-	1 (0.1)	-	-	1 (0.0)
Vision blurred	-	-	1 (0.1)	-	1 (0.0)

-: AE absent
Grade 3 AE: AE that prevented normal activity
Related AE: AE considered by the investigator to be causally related to the study vaccination
*Rare events, defined as events with an occurrence rate of 0.1 % and belonging to the unsolicited AEs are presented in this table

Safety Results: Number (%) of subjects with Serious Adverse Events (SAEs)* within the 30-day (Days 0-29) post-vaccination period (Total Vaccinated cohort)

Serious adverse event, n (%) [n considered by the investigator to be related to study medication]

All SAEs	**Lot 1 Group N = 850**	**Lot 2 Group N = 850**	**Lot 3 Group N = 854**	**Flu Group N = 570**	**Pooled Lots Group N = 2554**
Subjects with any SAE(s), n (%) [n assessed by investigators as related]	4 (0.5) [0]	4 (0.5) [0]	3 (0.4) [0]	4 (0.7) [0]	11 (0.4) [0]
Urinary tract infection	0 (0.0) [0]	1 (0.1) [0]	1 (0.1) [0]	0 (0.0) [0]	2 (0.1) [0]
Abdominal pain	0 (0.0) [0]	1 (0.1) [0]	0 (0.0) [0]	0 (0.0) [0]	1 (0.0) [0]
Breast cancer	1 (0.1) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	1 (0.0) [0]
Cardiac valve disease	1 (0.1) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	1 (0.0) [0]
Foot fracture	1 (0.1) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	1 (0.0) [0]
Oesophageal stenosis	0 (0.0) [0]	0 (0.0) [0]	1 (0.1) [0]	0 (0.0) [0]	1 (0.0) [0]
Pneumonia	1 (0.1) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	1 (0.0) [0]
Radius fracture	0 (0.0) [0]	0 (0.0) [0]	1 (0.1) [0]	0 (0.0) [0]	1 (0.0) [0]
Retinal artery embolism	0 (0.0) [0]	1 (0.1) [0]	0 (0.0) [0]	0 (0.0) [0]	1 (0.0) [0]
Retinal detachment	0 (0.0) [0]	1 (0.1) [0]	0 (0.0) [0]	0 (0.0) [0]	1 (0.0) [0]
Skin ulcer	0 (0.0) [0]	1 (0.1) [0]	0 (0.0) [0]	0 (0.0) [0]	1 (0.0) [0]

Angina pectoris	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	1 (0.2) [0]	0 (0.0) [0]
Hand fracture	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	1 (0.2) [0]	0 (0.0) [0]
Ileus	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	1 (0.2) [0]	0 (0.0) [0]
Myocardial infarction	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	1 (0.2) [0]	0 (0.0) [0]
Fatal SAEs	**Lot 1 Group N = 850**	**Lot 2 Group N = 850**	**Lot 3 Group N = 854**	**Flu Group N = 570**	**Pooled Lots Group N = 2554**
Subjects with fatal SAE(s), n (%) [n assessed by investigator as related]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	1 (0.2) [0]	0 (0.0) [0]
Myocardial infarction	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	1 (0.2) [0]	0 (0.0) [0]
*Rare events, defined as events with an occurrence rate of 0.1 % and belonging to the SAEs are presented in this table.					
Safety Results: Number (%) of subjects with Serious Adverse Events (SAEs)* from Day 30 to Day 180 (Total cohort for extension phase)					
Serious adverse event, n (%) [n considered by the investigator to be related to study medication]					
All SAEs	**Lot 1 Group N = 844**	**Lot 2 Group N = 848**	**Lot 3 Group N = 848**	**Flu Group N = 565**	**Pooled Lots Group N = 2540**
Subjects with any SAE(s), n (%) [n assessed by investigators as related]	26 (3.1) [0]	20 (2.4) [1]	20 (2.4) [0]	17 (3.0) [0]	66 (2.6) [1]
Syncope	2 (0.2) [0]	2 (0.2) [0]	1 (0.1) [0]	0 (0.0) [0]	5 (0.2) [0]
Angina pectoris	4 (0.5) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	4 (0.2) [0]
Chest pain	0 (0.0) [0]	1 (0.1) [0]	1 (0.1) [0]	1 (0.2) [0]	2 (0.1) [0]
Cerebrovascular accident	1 (0.1) [0]	1 (0.1) [0]	0 (0.0) [0]	2 (0.4) [0]	2 (0.1) [0]
Cholelithiasis	2 (0.2) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	2 (0.1) [0]
Circulatory collapse	1 (0.1) [0]	0 (0.0) [0]	1 (0.1) [0]	0 (0.0) [0]	2 (0.1) [0]
Constipation	0 (0.0) [0]	0 (0.0) [0]	2 (0.2) [0]	0 (0.0) [0]	2 (0.1) [0]
Coronary artery disease	0 (0.0) [0]	2 (0.2) [0]	0 (0.0) [0]	0 (0.0) [0]	2 (0.1) [0]
Femoral neck fracture	0 (0.0) [0]	0 (0.0) [0]	2 (0.2) [0]	0 (0.0) [0]	2 (0.1) [0]
Lung neoplasm malignant	0 (0.0) [0]	1 (0.1) [0]	1 (0.1) [0]	0 (0.0) [0]	2 (0.1) [0]
Bile duct stone	1 (0.1) [0]	0 (0.0) [0]	0 (0.0) [0]	1 (0.2) [0]	1 (0.0) [0]
Colonic polyp	0 (0.0) [0]	1 (0.1) [0]	0 (0.0) [0]	1 (0.2) [0]	1 (0.0) [0]
Hip fracture	0 (0.0) [0]	0 (0.0) [0]	1 (0.1) [0]	1 (0.2) [0]	1 (0.0) [0]
Acute myocardial infarction	0 (0.0) [0]	1 (0.1) [0]	0 (0.0) [0]	0 (0.0) [0]	1 (0.0) [0]
Anaemia	1 (0.1) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	1 (0.0) [0]
Ankle fracture	0 (0.0) [0]	1 (0.1) [0]	0 (0.0) [0]	0 (0.0) [0]	1 (0.0) [0]
Aortic stenosis	1 (0.1) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	1 (0.0) [0]
Asthma	0 (0.0) [0]	0 (0.0) [0]	1 (0.1) [0]	0 (0.0) [0]	1 (0.0) [0]
Breast cancer	1 (0.1) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	1 (0.0) [0]
Cardiovascular disorder	0 (0.0) [0]	1 (0.1) [0]	0 (0.0) [0]	0 (0.0) [0]	1 (0.0) [0]
Cerebral infarction	0 (0.0) [0]	1 (0.1) [0]	0 (0.0) [0]	0 (0.0) [0]	1 (0.0) [0]
Cholecystitis infective	0 (0.0) [0]	0 (0.0) [0]	1 (0.1) [0]	0 (0.0) [0]	1 (0.0) [0]
Completed suicide	0 (0.0) [0]	0 (0.0) [0]	1 (0.1) [0]	0 (0.0) [0]	1 (0.0) [0]
Diverticulitis	1 (0.1) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	1 (0.0) [0]
Dyspnoea	1 (0.1) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	1 (0.0) [0]
Endometrial cancer	1 (0.1) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	1 (0.0) [0]
Excoriation	0 (0.0) [0]	0 (0.0) [0]	1 (0.1) [0]	0 (0.0) [0]	1 (0.0) [0]
Foot deformity	1 (0.1) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	1 (0.0) [0]
Forearm fracture	0 (0.0) [0]	1 (0.1) [0]	0 (0.0) [0]	0 (0.0) [0]	1 (0.0) [0]
Foreign body trauma	1 (0.1) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	1 (0.0) [0]
Gastric cancer	0 (0.0) [0]	1 (0.1) [0]	0 (0.0) [0]	0 (0.0) [0]	1 (0.0) [0]
Gastritis	1 (0.1) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	1 (0.0) [0]

General physical health deterioration	1 (0.1) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	1 (0.0) [0]
Hyperlipidaemia	0 (0.0) [0]	1 (0.1) [0]	0 (0.0) [0]	0 (0.0) [0]	1 (0.0) [0]
Hyperthyroidism	1 (0.1) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	1 (0.0) [0]
Iliac artery stenosis	1 (0.1) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	1 (0.0) [0]
Intervertebral disc protrusion	0 (0.0) [0]	1 (0.1) [0]	0 (0.0) [0]	0 (0.0) [0]	1 (0.0) [0]
Lung disorder	1 (0.1) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	1 (0.0) [0]
Malignant melanoma	1 (0.1) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	1 (0.0) [0]
Mixed connective tissue disease	0 (0.0) [0]	0 (0.0) [0]	1 (0.1) [0]	0 (0.0) [0]	1 (0.0) [0]
Nephrolithiasis	0 (0.0) [0]	1 (0.1) [0]	0 (0.0) [0]	0 (0.0) [0]	1 (0.0) [0]
Nephrotic syndrome	0 (0.0) [0]	1 (0.1) [1]	0 (0.0) [0]	0 (0.0) [0]	1 (0.0) [1]
Osteoarthritis	0 (0.0) [0]	1 (0.1) [0]	0 (0.0) [0]	0 (0.0) [0]	1 (0.0) [0]
Pancreatitis	1 (0.1) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	1 (0.0) [0]
Peripheral vascular disorder	1 (0.1) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	1 (0.0) [0]
Pneumonia	1 (0.1) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	1 (0.0) [0]
Prostate cancer	0 (0.0) [0]	1 (0.1) [0]	0 (0.0) [0]	0 (0.0) [0]	1 (0.0) [0]
Pulmonary fibrosis	0 (0.0) [0]	0 (0.0) [0]	1 (0.1) [0]	0 (0.0) [0]	1 (0.0) [0]
Renal cell carcinoma stage unspecified	0 (0.0) [0]	0 (0.0) [0]	1 (0.1) [0]	0 (0.0) [0]	1 (0.0) [0]
Scoliosis	0 (0.0) [0]	0 (0.0) [0]	1 (0.1) [0]	0 (0.0) [0]	1 (0.0) [0]
Spinal disorder	1 (0.1) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	1 (0.0) [0]
Stress	0 (0.0) [0]	1 (0.1) [0]	0 (0.0) [0]	0 (0.0) [0]	1 (0.0) [0]
Suicide attempt	0 (0.0) [0]	1 (0.1) [0]	0 (0.0) [0]	0 (0.0) [0]	1 (0.0) [0]
Tachyarrhythmia	0 (0.0) [0]	1 (0.1) [0]	0 (0.0) [0]	0 (0.0) [0]	1 (0.0) [0]
Tachycardia paroxysmal	0 (0.0) [0]	0 (0.0) [0]	1 (0.1) [0]	0 (0.0) [0]	1 (0.0) [0]
Trigeminal neuralgia	0 (0.0) [0]	0 (0.0) [0]	1 (0.1) [0]	0 (0.0) [0]	1 (0.0) [0]
Acute coronary syndrome	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	1 (0.2) [0]	0 (0.0) [0]
Aortic aneurysm	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	1 (0.2) [0]	0 (0.0) [0]
Arrhythmia	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	1 (0.2) [0]	0 (0.0) [0]
Arteriosclerosis coronary artery	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	1 (0.2) [0]	0 (0.0) [0]
Bladder cancer	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	1 (0.2) [0]	0 (0.0) [0]
Gallstone ileus	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	1 (0.2) [0]	0 (0.0) [0]
Hypertension	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	1 (0.2) [0]	0 (0.0) [0]
Neoplasm prostate	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	1 (0.2) [0]	0 (0.0) [0]
Oesophageal carcinoma	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	1 (0.2) [0]	0 (0.0) [0]
Pyrexia	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	1 (0.2) [0]	0 (0.0) [0]
Small intestinal perforation	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	1 (0.2) [0]	0 (0.0) [0]
Uterine polyp	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	1 (0.2) [0]	0 (0.0) [0]
Cardiac failure	1 (0.1) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	1 (0.0) [0]
Oedema	1 (0.1) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	1 (0.0) [0]
Hepatorenal failure	1 (0.1) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	1 (0.0) [0]
Myocardial infarction	0 (0.0) [0]	1 (0.1) [0]	0 (0.0) [0]	0 (0.0) [0]	1 (0.0) [0]
Diabetic gangrene	0 (0.0) [0]	0 (0.0) [0]	1 (0.1) [0]	0 (0.0) [0]	1 (0.0) [0]
Road traffic accident	0 (0.0) [0]	0 (0.0) [0]	1 (0.1) [0]	0 (0.0) [0]	1 (0.0) [0]
Rectal cancer	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	1 (0.2) [0]	0 (0.0) [0]
Pulmonary embolism	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	1 (0.2) [0]	0 (0.0) [0]
Thrombotic stroke	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	1 (0.2) [0]	0 (0.0) [0]
Fatal SAEs	**Lot 1 Group N = 844**	**Lot 2 Group N = 848**	**Lot 3 Group N = 848**	**Flu Group N = 565**	**Pooled Lots Group N = 2554**
Subjects with fatal sae(s), n (%) [n assessed by investigators as related]	3 (0.4) [0]	2 (0.2) [0]	3 (0.4) [0]	2 (0.4) [0]	8 (0.3) [0]
Cerebrovascular accident	1 (0.1) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	1 (0.0) [0]
Completed suicide	0 (0.0) [0]	0 (0.0) [0]	1 (0.1) [0]	0 (0.0) [0]	1 (0.0) [0]

Lung neoplasm malignant	0 (0.0) [0]	0 (0.0) [0]	1 (0.1) [0]	0 (0.0) [0]	1 (0.0) [0]
Aortic aneurysm	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	1 (0.2) [0]	0 (0.0) [0]
Oesophageal carcinoma	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	1 (0.2) [0]	0 (0.0) [0]
Cardiac failure	1 (0.1) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	1 (0.0) [0]
Oedema	1 (0.1) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	1 (0.0) [0]
Hepatorenal failure	1 (0.1) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	1 (0.0) [0]
Myocardial infarction	0 (0.0) [0]	1 (0.1) [0]	0 (0.0) [0]	0 (0.0) [0]	1 (0.1) [0]
Lung neoplasm malignant	0 (0.0) [0]	1 (0.1) [0]	0 (0.0) [0]	0 (0.0) [0]	1 (0.1) [0]
Road traffic accident	0 (0.0) [0]	0 (0.0) [0]	1 (0.1) [0]	0 (0.0) [0]	1 (0.1) [0]
*Rare events, defined as events with an occurrence rate of 0.1 % and belonging to the SAEs are presented in this table.					

Conclusion: Lot to lot consistency was confirmed.
At Day 21 after vaccination, 88.7% & 90.2%, 84.0% & 92.0% and 91.5% & 97.3% of subjects were seroprotected (HI titres $\geq$ 1:40) for A/New Caledonia, A/New York and B/Malaysia, in the Flu Group & the Pooled Lots Group, respectively.
In both groups, pain at the injection site was the most frequently reported local symptom; fatigue & muscle aches were the most frequently reported general symptoms in the Flu Group & the Pooled Lots Group, respectively.
Unsolicited AEs were reported by 109 (19.1%) & 445 (17.4%) subjects in the Flu Group & the Pooled Lots Group, respectively; for 10 (1.8%) & 40 (1.6%) subjects, the reported AEs were classified as Grade 3, while unsolicited AEs reported by 16 (2.8%) & 169 (6.6%) subjects in the Flu Group & the Pooled Lots Group, respectively, were assessed by the investigators as related to the study vaccination.
NOCDs was reported for 1 (0.2%) & 8 (0.3%) subjects in the Flu Group & the Pooled Lots Group, respectively. MSCs were reported in 52 (9.1%) & 211 (8.3%) subjects in the Flu Group & the Pooled Lots Group, respectively.
From Day 1 to Day 29, SAEs were reported for 4 (0.7%) & 11 (0.4%) subjects in the Flu Group & the Pooled Lots Group, respectively; one SAE in the Flu Group was fatal. Between Day 30 and Day 180, SAEs were reported for 17 (3.0%) & 66 (2.6%) subjects the Flu Group & the Pooled Lots Group, respectively; 2 SAEs in the Flu Group and 8 SAEs in the Pooled Lots Group were fatal; 1 non-fatal SAE (nephrotic syndrome) reported in the Lot 2 Group was considered by the investigator as related to the study vaccination.

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