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.: 108134 (Fluarix US-006)

Title: A randomized, double-blind, placebo-controlled, multi-country and multi-center, phase IV study to demonstrate the efficacy of GSK Biologicals' influenza vaccine (Fluarix™) administered intramuscularly in adults.
Fluarix™ (Flu): GlaxoSmithKline Biologicals' licensed influenza vaccine.

Rationale: The purpose of the study was to demonstrate the efficacy of a single dose of Flu vaccine in preventing influenza in adults during the 2006/2007 Influenza season.

Phase: IV

Study Period: 25 September 2006 to 7 June 2007.

Study Design: Multi-country, multi-center, randomized (1:1:1), double-blind, placebo-controlled study with 3 parallel groups.

Centers: 15 study centers: 1 in Czech Republic and 14 in Finland.

Indication: Immunization against influenza in male and female subjects aged 18 to 64 years.

Treatment: The study groups were as follows:

- Flu-1 Group: received Flu vaccine, lot 1.
- Flu-2 Group: received Flu vaccine, lot 2.
- Placebo Group: received a placebo.

The vaccines were administered as a single dose by intramuscular injection in the deltoid region of the non-dominant arm. For data analyses, Flu-1 and Flu-2 groups were pooled into Flu Group.

Objectives:
To demonstrate the efficacy of Flu vaccine in the prevention of culture confirmed influenza A and/or B cases, for vaccine antigenically matched strains, when compared to the placebo group.

Primary Outcome/Efficacy Variable:
Occurrence of culture confirmed influenza A and/or B, for vaccine antigenically matched strains

Secondary Outcome/Efficacy Variable(s):
Efficacy:

- Occurrence of culture confirmed influenza A and/or B, for any influenza strain.
- Occurrence of influenza like illness (ILI).
- Occurrence of laboratory confirmed influenza A and/or B (i.e. confirmed by virus culture and/or Reverse Transcriptase Polymerase Chain Reaction (RT-PCR)), for any influenza strain.
- Occurrence of laboratory confirmed* influenza A and/or B (i.e. confirmed by virus culture and/or RT-PCR), for vaccine antigenically matched strains.
- Number of days of fever, school/work absenteeism, medically attended visits and hospitalization related to culture confirmed influenza A and/or B.
- Occurrence of pneumonia related to laboratory confirmed influenza (i.e. starting within 6 weeks following the onset of laboratory confirmed influenza).
- Occurrence of any pneumonia.

*As the final classification of virus isolates as "vaccine-matching" or not, was done using the hemagglutination inhibition (HI) test, and required a virus isolate from culture; cases which were positive by RT-PCR and negative by culture could not be assessed as to whether the strain was "vaccine-matching" or not. The evaluation of the efficacy of Flu vaccine in the prevention of laboratory-confirmed influenza cases for vaccine antigenically matched strains was therefore not feasible and was conducted only for all strains (regardless of the "matching" status).
Immunogenicity in a subset of subjects:

- At Days 0 and 21 : serum HI antibody titer, against each of the three vaccine influenza strains

Safety:

- Occurrence and relationship to vaccination of serious adverse events (SAEs) during the entire study in all subjects.
- Occurrence, intensity and relationship to vaccination of unsolicited adverse events (AEs) during a 21-day follow-up period (i.e. day of vaccination and 20 subsequent days) after vaccination in a subset of subjects.

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

- The Total Vaccinated Cohort included all vaccinated subjects.
- The Total Vaccinated Cohort subset included all subjects with at least one vaccine administration documented and for whom unsolicited symptoms were collected.
- The ATP cohort for immunogenicity subset included all subjects who had received the study vaccine according to their random assignment, for whom the study vaccine had been administered according to protocol, who had not received a vaccine not foreseen or forbidden in the protocol, for whom the randomization code had not been broken, who met all eligibility criteria, complied with the procedures defined in the protocol, with no elimination criteria during the study and for whom data concerning immunogenicity measures were available.

Efficacy analysis:

The analysis was performed on the Total Vaccinated Cohort from the date of vaccination to the end of the study follow-up.

Inferential analysis

The attack rates in each treatment group and vaccine efficacy (VE) against culture-confirmed influenza A and/or B, for vaccine antigenically matched strains were calculated with 95% confidence interval (CI).

The primary objective was met if the lower limit of the 95% CI for the VE against culture-confirmed influenza A and/or B, for vaccine antigenically matched strains, was above 35%.

The VE was calculated as follows:

$$VE = 1 - \frac{n1/N1}{n2/N2} = 1 - \frac{n1}{rn2}$$

where:

n1 = number of cases in the vaccine group

N1 = number of subjects in the vaccine group

n2 = number of cases in the placebo group

N2 = number of subjects in the placebo group

r = N1/N2

Descriptive analysis

Attack rates and VE against the following measures were tabulated:

- culture confirmed influenza A and/or B, for any influenza strain
- laboratory confirmed influenza A and/or B, for any influenza strain
- ILI
- any pneumonia
- pneumonia related to laboratory confirmed influenza (i.e. starting within 6 weeks following the onset of laboratory confirmed influenza).

Descriptive statistics (frequency, percentage, mean and standard deviation) for the duration of fever, school/work absenteeism, medically attended visits and hospitalization related to culture confirmed influenza A and/or B for vaccine antigenically matched strains or any vaccine strain were tabulated per group.

Immunogenicity analysis:

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

For each group and each vaccine strain, geometric mean titers (GMTs) at Day 0 and Day 21 with 95% CI, seroconversion rates (SCR)[1] at Day 21 with exact 95% CI, seroconversion factor (SCF)[2] at Day 21 and seroprotection rates (SPR)[3] at Day 0 and Day 21 with exact 95% CI were tabulated.

[1]SCR was defined as the percentage of vaccinees who had either a pre-vaccination titer < 1:10 and a post-vaccination titer ≥ 1:40 or a pre-vaccination titer ≥ 1:10 and at least a four-fold increase in post-vaccination titer.

[2]SCF was defined as the fold increase in serum HI GMTs post-vaccination compared to Day 0.

[3]SPR was defined as the percentage of vaccinees with a serum HI titer ≥1:40.

Safety analysis:

The analysis of unsolicited AEs was performed on the Total Vaccinated Cohort subset and the analysis of SAEs was performed on the Total Vaccinated Cohort. The number and percentage of subjects reporting unsolicited AEs, classified by Medical Dictionary for Regulatory Activities (MedDRA) preferred terms, within 21 days after vaccination (Day 0-20), was tabulated, for each group. Similar tabulations were done for grade 3 unsolicited AEs and for unsolicited AEs causally related to vaccination. The occurrence of SAEs during the entire study period was tabulated per group, according to MedDRA preferred terms.

Study Population: Healthy male or female subjects between, and including, 18 and 64 years of age at the time of the vaccination. If the subject was female, she had to be of non-childbearing potential, or, if of childbearing potential, she had to be abstinent or to have used adequate contraceptive precautions for 30 days prior to vaccination, had a negative pregnancy test and had to agree to continue such precautions for 2 months after vaccination. High risk subjects with underlying diseases were to be excluded. Subjects who had been previously vaccinated against other influenza vaccine

for the season 2006-2007 were excluded. Written informed consent was obtained from the subject

Number of subjects	**Flu Group**	**Placebo Group**
Planned, N	5088	2544
Randomized, N (Total Vaccinated Cohort)	5103	2549
Completed, n (%)	4978 (97.6)	2493 (97.8)
Total Number Subjects Withdrawn, n (%)	125 (2.4)	56 (2.2)
Withdrawn due to Adverse Events, n (%)	0 (0.0)	0 (0.0)
Withdrawn due to Lack of Efficacy, n (%)	Not applicable	Not applicable
Withdrawn for other reasons, n (%)	125 (2.4)	56 (2.2)
Demographics	**Flu Group**	**Placebo Group**
N (Total Vaccinated Cohort)	5103	2549
Females: Males	3069:2034	1542:1007
Mean Age, years (SD)	40.0 (13.26)	39.7 (13.30)
White/Caucasian-European heritage, n (%)	5097 (99.9)	2547 (99.9)

Primary Efficacy Results:
Attack rates and VE against culture-confirmed influenza A and/or B for vaccine antigenically matched strains (Total Vaccinated Cohort)

Group	**N**	**n+**	**n**	**n/N**			**VE**		
				%	**95% CI**		**%**	**95% CI**	
					LL	**UL**		**LL**	**UL**
Flu	5103	49	49	1.0	0.7	1.3	66.9	51.9*	77.4
Placebo	2549	74	74	2.9	2.3	3.6	-	-	-

N = number of subjects included in each group
n+ = number of events in each group
n = number of subjects reporting at least one event in each group
AR = attack rate = n/N (%) = percentage of subjects reporting at least one event
VE (%) = vaccine efficacy
95% CI = 95% confidence interval, LL = Lower limit, UL = Upper limit
*Primary objective was demonstrated as the lower limit was above 35%

Secondary Outcome Variable (s):
Attack rates and vaccine efficacy for secondary efficacy variables (Total Vaccinated Cohort)

Vaccine efficacy against:	**Group**	**N**	**n+**	**n**	**n/N**			**VE**		
					%	**95% CI**		**%**	**95% CI**	
						LL	**UL**		**LL**	**UL**
Culture-confirmed influenza A and/or B for any strain	Flu	5103	63	63	1.2	0.9	1.6	61.6	46.0	72.8
	Placebo	2549	82	82	3.2	2.6	4.0	-	-	-
Laboratory-confirmed influenza A and / or B for any strain	Flu	5103	108	108	2.1	1.7	2.5	54.7	40.7	65.4
	Placebo	2549	119	119	4.7	3.9	5.6	-	-	-
Influenza like illness (ILI)	Flu	5103	746	654	12.8	11.9	13.8	17.9	6.8	27.6
	Placebo	2549	459	398	15.6	14.2	17.1	-	-	-
Pneumonia	Flu	5103	13	13	0.3	0.1	0.4	7.2	-174.6	65.6
	Placebo	2549	7	7	0.3	0.1	0.6	-	-	-
Pneumonia related to influenza (within 6 weeks of a laboratory-confirmed case)	Flu	5103	0	0	0.0	0.0	0.1	100	-166.0	100
	Placebo	2549	2	2	0.1	0.0	0.3	-	-	-

N = number of subjects included in each group
n+ = number of events in each group
n = number of subjects reporting at least one event in each group
AR = attack rate = n/N (%) = percentage of subjects reporting at least one event
VE (%) = vaccine efficacy
95% CI = 95% confidence interval, LL = Lower limit, UL = Upper limit

Secondary Outcome Variable (s):
Severity of culture-confirmed influenza A and/or B for any strain (Total Vaccinated Cohort)

Characteristics		**Flu Group N = 63**		**Placebo Group N = 82**		**Total N = 145**	
		Value	**%**	**Value**	**%**	**Value**	**%**

		or n		or n		or n	
Number of days with fever	Mean	3.3	-	3.4	-	3.3	-
	SD	1.5	-	1.7	-	1.6	-
Absenteeism from work/school	Yes	47.0	74.6	67.0	81.7	114.0	78.6
	No	13.0	20.6	10.0	12.2	23.0	15.9
	NA	3.0	4.8	5.0	6.1	8.0	5.5
Absenteeism from work/school	Mean	5.1	-	5.2	-	5.2	-
	SD	4.6	-	4.3	-	4.4	-
Medically attended	Yes	30	47.6	38	46.3	68	46.9
	No	33	52.4	44	53.7	77	53.1
Hospitalization	Yes	0	0.0	0	0.0	0	0.0
	No	63	100	82	100	145	100

N = number of subjects included in each group
n = number of subjects in a given category
% = n/N of subjects with available results x100
SD = standard deviation
NA = not applicable

Secondary Outcome Variable (s):
HI response: GMTs for H1N1, H3N2 and B antibodies (ATP cohort for immunogenicity)

Antibody	Group	Timing	N	GMT		
				value	95% CI	
					LL	UL
H1N1	Flu	PRE	291	27.0	22.8	32.0
		PI(D21)	291	541.0	451.0	649.0
	Placebo	PRE	148	29.8	23.1	38.4
		PI(D21)	148	34.7	27.2	44.4
H3N2	Flu	PRE	291	10.5	9.3	12.0
		PI(D21)	291	133.2	114.6	154.7
	Placebo	PRE	148	13.1	10.6	16.2
		PI(D21)	148	13.3	10.7	16.5
B	Flu	PRE	291	15.2	13.5	17.0
		PI(D21)	291	242.8	210.7	279.7
	Placebo	PRE	148	13.8	11.9	15.9
		PI(D21)	148	14.4	12.6	16.5

N = number of subjects with available results
95% CI = 95% confidence interval, LL = Lower Limit, UL = Upper Limit
PRE = pre-vaccination at Day 0
PI (D21) = post-vaccination at Day 21

Secondary Outcome Variable (s):
HI response: SCR for H1N1, H3N2 and B at Day 21 (ATP cohort for immunogenicity)

Vaccine strain	Group	N	SCR			
			n	%	95% CI	
					LL	UL
H1N1	Flu	291	222	76.3	71.0	81.1
	Placebo	148	2	1.4	0.2	4.8
H3N2	Flu	291	215	73.9	68.4	78.8
	Placebo	148	1	0.7	0.0	3.7
B	Flu	291	248	85.2	80.6	89.1
	Placebo	148	1	0.7	0.0	3.7

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

Secondary Outcome Variable (s):
HI response: SCF for H1N1, H3N2 and B at Day 21 (ATP cohort for immunogenicity)

Vaccine strain	Group	N	SCF		
			Value	95% CI	
				LL	UL
H1N1	Flu	291	20.0	16.2	24.7
	Placebo	148	1.2	1.1	1.3
H3N2	Flu	291	12.6	10.7	14.9
	Placebo	148	1.0	1.0	1.1
B	Flu	291	16.0	13.7	18.6
	Placebo	148	1.0	1.0	1.1

N = number of subjects with pre-and post-vaccination results available
SCF = seroconversion Factor or geometric mean ratio
95% CI = 95% confidence interval, LL = Lower Limit, UL = Upper Limit

Secondary Outcome Variable (s):
HI response: SPR for H1N1, H3N2 and B at Days 0 and 21 (ATP cohort for immunogenicity)

Vaccine strain	Group	Timing	N	SPR			
				n	%	95% CI	
						LL	UL
H1N1	Flu	PRE	291	107	36.8	31.2	42.6
		PI(D21)	291	284	97.6	95.1	99.0
	Placebo	PRE	148	59	39.9	31.9	48.2
		PI(D21)	148	66	44.6	36.4	53.0
H3N2	Flu	PRE	291	50	17.2	13.0	22.0
		PI(D21)	291	253	86.9	82.5	90.6
	Placebo	PRE	148	36	24.3	17.7	32.1
		PI(D21)	148	35	23.6	17.1	31.3
B	Flu	PRE	291	58	19.9	15.5	25.0
		PI(D21)	291	280	96.2	93.3	98.1
	Placebo	PRE	148	22	14.9	9.6	21.6
		PI(D21)	148	23	15.5	10.1	22.4

N = number of subjects with available results
n (%) = number (percentage) of seroprotected subjects
95% CI = 95% confidence interval, LL = Lower Limit, UL = Upper Limit
PRE = pre-vaccination at Day 0
PI (D21) = Post-vaccination at Day 21

Safety Results: Number (%) of subjects with unsolicited AEs (Total Vaccinated Cohort subset)

Most Frequent Adverse Events–On-Therapy- (occurring within Day 0-20 following vaccination)	**Flu Group N = 305**	**Placebo Group N = 155**
Subjects with any AE(s), n (%)	74 (24.3)	35 (22.6)
Subjects with grade 3* AE(s), n (%)	11 (3.6)	3 (1.9)
Subjects with related** AE(s), n (%)	35 (11.5)	14 (9.0)
Headache	31 (10.2)	14 (9.0)
Injection site pain	16 (5.2)	2 (1.3)
Rhinitis	6 (2.0)	5 (3.2)
Back pain	4 (1.3)	4 (2.6)
Pharyngolaryngeal pain	4 (1.3)	4 (2.6)
Myalgia	3 (1.0)	4 (2.6)
Neck pain	4 (1.3)	3 (1.9)
Arthralgia	4 (1.3)	2 (1.3)
Cough	3 (1.0)	3 (1.9)
Musculoskeletal pain	4 (1.3)	2 (1.3)
Dysmenorrhea	4 (1.3)	1(0.6)
Upper respiratory tract infection	-	5 (3.2)
Migraine	3 (1.0)	-

- : Adverse event absent or not meeting the counting rule
Counting rule: > 30 patients per treatment group and < 3 groups: display the most frequent 10 events in each group
* Grade 3 symptoms: symptoms which prevented normal, everyday activities.
** Related symptoms: symptoms with a reasonable possibility that the vaccination contributed to the symptom

Safety Results: Number (%) of subjects with SAEs (Total Vaccinated Cohort)

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

All SAEs	**Flu Group N = 5103**	**Placebo Group N = 2549**
Subjects with any SAE(s), n (%) [n related]	80 (1.6) [1]	47 (1.8) [0]
Abortion spontaneous	5 (0.1) [0]	1 (0.0) [0]
Breast cancer	4 (0.1) [0]	1 (0.0) [0]
Cholelithiasis	4 (0.1) [0]	1 (0.0) [0]
Ligament rupture	3 (0.1) [0]	1 (0.0) [0]
Appendicitis	3 (0.1) [0]	0 (0.0) [0]
Cervical dysplasia	3 (0.1) [0]	0 (0.0) [0]
Pneumonia	2 (0.0) [0]	1 (0.0) [0]
Abortion missed	1 (0.0) [0]	1 (0.0) [0]
Ankle fracture	1 (0.0) [0]	1 (0.0) [0]
Cholecystitis	2 (0.0) [0]	0 (0.0) [0]
Contusion	2 (0.0) [0]	0 (0.0) [0]
Depression	1 (0.0) [0]	1 (0.0) [0]
Gastroenteritis	1 (0.0) [0]	1 (0.0) [0]
Infectious mononucleosis	1 (0.0) [0]	1 (0.0) [0]
Intervertebral disc protrusion	1 (0.0) [0]	1 (0.0) [0]
Joint dislocation	0 (0.0) [0]	2 (0.1) [0]
Meniscus lesion	2 (0.0) [0]	0 (0.0) [0]
Peritonsillar abscess	1 (0.0) [0]	1 (0.0) [0]
Personality disorder	0 (0.0) [0]	2 (0.1) [0]
Sciatica	1 (0.0) [0]	1 (0.0) [0]
Subarachnoid hemorrhage	1 (0.0) [0]	1 (0.0) [0]
Tibia fracture	1 (0.0) [0]	1 (0.0) [0]
Abdominal pain	0 (0.0) [0]	1 (0.0) [0]
Abdominal pain upper	0 (0.0) [0]	1 (0.0) [0]
Acute sinusitis	1 (0.0) [0]	0 (0.0) [0]
Adnexitis	1 (0.0) [0]	0 (0.0) [0]
Anaphylactic reaction	1 (0.0) [1]	0 (0.0) [0]
Angina pectoris	0 (0.0) [0]	1 (0.0) [0]
Antepartum hemorrhage	0 (0.0) [0]	1 (0.0) [0]
Anxiety	0 (0.0) [0]	1 (0.0) [0]
Arterial thrombosis limb	1 (0.0) [0]	0 (0.0) [0]
Arthropathy	1 (0.0) [0]	0 (0.0) [0]
Bipolar disorder	1 (0.0) [0]	0 (0.0) [0]
Brain contusion	0 (0.0) [0]	1 (0.0) [0]
Bronchopneumonia	1 (0.0) [0]	0 (0.0) [0]
Clostridium difficile colitis	1 (0.0) [0]	0 (0.0) [0]
Colon cancer	1 (0.0) [0]	0 (0.0) [0]
Concussion	1 (0.0) [0]	0 (0.0) [0]
Crohn's disease	1 (0.0) [0]	0 (0.0) [0]
Diverticulitis	0 (0.0) [0]	1 (0.0) [0]
Diverticulum	1 (0.0) [0]	0 (0.0) [0]
Ectopic pregnancy	0 (0.0) [0]	1 (0.0) [0]
Endolymphatic hydrops	0 (0.0) [0]	1 (0.0) [0]
Endometrial cancer	1 (0.0) [0]	0 (0.0) [0]
Endometriosis	1 (0.0) [0]	0 (0.0) [0]
Enterocolitis	0 (0.0) [0]	1 (0.0) [0]

Epiglottitis	0 (0.0) [0]	1 (0.0) [0]
Epilepsy	1 (0.0) [0]	0 (0.0) [0]
Erysipelas	1 (0.0) [0]	0 (0.0) [0]
Facial bones fracture	1 (0.0) [0]	0 (0.0) [0]
Foot fracture	0 (0.0) [0]	1 (0.0) [0]
Gastritis	0 (0.0) [0]	1 (0.0) [0]
Hemarthrosis	0 (0.0) [0]	1 (0.0) [0]
Hand fracture	1 (0.0) [0]	0 (0.0) [0]
Herpes virus infection	1 (0.0) [0]	0 (0.0) [0]
Humerus fracture	1 (0.0) [0]	0 (0.0) [0]
Hydrocholecystis	1 (0.0) [0]	0 (0.0) [0]
Hypertension	0 (0.0) [0]	1 (0.0) [0]
Hyperthyroidism	1 (0.0) [0]	0 (0.0) [0]
Hypothyroidism	0 (0.0) [0]	1 (0.0) [0]
Inguinal hernia	1 (0.0) [0]	0 (0.0) [0]
Insulinoma	0 (0.0) [0]	1 (0.0) [0]
Intervertebral disc displacement	1 (0.0) [0]	0 (0.0) [0]
Intra-uterine death	0 (0.0) [0]	1 (0.0) [0]
Jaw fracture	1 (0.0) [0]	0 (0.0) [0]
Lymphadenopathy	0 (0.0) [0]	1 (0.0) [0]
Malignant melanoma	1 (0.0) [0]	0 (0.0) [0]
Metrorrhagia	1 (0.0) [0]	0 (0.0) [0]
Multiple injuries	1 (0.0) [0]	0 (0.0) [0]
Musculoskeletal pain	1 (0.0) [0]	0 (0.0) [0]
Nephrolithiasis	1 (0.0) [0]	0 (0.0) [0]
Oedematous pancreatitis	1 (0.0) [0]	0 (0.0) [0]
Osteoarthritis	1 (0.0) [0]	0 (0.0) [0]
Ovarian cyst	1 (0.0) [0]	0 (0.0) [0]
Ovarian cyst ruptured	1 (0.0) [0]	0 (0.0) [0]
Ovarian torsion	1 (0.0) [0]	0 (0.0) [0]
Pancreatitis acute	0 (0.0) [0]	1 (0.0) [0]
Pelvic pain	1 (0.0) [0]	0 (0.0) [0]
Peripheral embolism	1 (0.0) [0]	0 (0.0) [0]
Phimosis	1 (0.0) [0]	0 (0.0) [0]
Pneumonia mycoplasmal	0 (0.0) [0]	1 (0.0) [0]
Post procedural hemorrhage	0 (0.0) [0]	1 (0.0) [0]
Precancerous cells present	1 (0.0) [0]	0 (0.0) [0]
Prostate cancer	0 (0.0) [0]	1 (0.0) [0]
Pulmonary embolism	1 (0.0) [0]	0 (0.0) [0]
Radius fracture	1 (0.0) [0]	0 (0.0) [0]
Rash	0 (0.0) [0]	1 (0.0) [0]
Respiratory failure	0 (0.0) [0]	1 (0.0) [0]
Rheumatoid arthritis	0 (0.0) [0]	1 (0.0) [0]
Rotator cuff syndrome	1 (0.0) [0]	0 (0.0) [0]
Salivary gland adenoma	0 (0.0) [0]	1 (0.0) [0]
Sinusitis	1 (0.0) [0]	0 (0.0) [0]
Syncope vasovagal	0 (0.0) [0]	1 (0.0) [0]
Tendon rupture	0 (0.0) [0]	1 (0.0) [0]
Testis cancer	0 (0.0) [0]	1 (0.0) [0]
Thermal burn	1 (0.0) [0]	0 (0.0) [0]
Thrombophlebitis	0 (0.0) [0]	1 (0.0) [0]
Type 1 diabetes mellitus	1 (0.0) [0]	0 (0.0) [0]
Umbilical hernia	0 (0.0) [0]	1 (0.0) [0]
Uterine polyp	1 (0.0) [0]	0 (0.0) [0]
Venous thrombosis	0 (0.0) [0]	1 (0.0) [0]

Fatal SAEs	Flu Group N = 5103	Placebo Group N = 2549
Subjects with fatal SAE(s), n (%) [n related]	0 (0.0) [0]	0 (0.0) [0]

Conclusion:
For results on immunogenicity, please refer to the publication section.
During the 21-day post-vaccination period, unsolicited AEs were reported by 74 (24.3%) and 35 (22.6%) subjects in the Flu and Placebo groups, respectively; unsolicited AEs reported by 11 (3.6%) subjects in the Flu Group and by 3 (1.9%) subjects in the Placebo Group were classified as Grade 3, while unsolicited AEs reported by 35 (11.5%) subjects in the Flu Group and by 14 (9.0%) subjects in the Placebo Group were considered by the investigators to be related to the study vaccination. SAEs were reported by 80 (1.6%) and 47 (1.8%) subjects in the Flu and Placebo groups, respectively. One SAE in the Flu Group (anaphylactic reaction) was considered by the investigator to be related to the study vaccination. No fatal SAEs were reported throughout the study.

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