Clinical trial results:
A Randomized, Single-Blind, Placebo-Controlled, Phase 2 Trial of the Safety, Immunogenicity, and Tolerability of Meningococcal Serogroup B (MnB) rLP2086 Vaccine at Doses of 60 µg, 120 µg, and 200 µg in Healthy Adolescents Aged 11 to 18 Years

Summary

EudraCT number	2008-007789-51
Trial protocol	PL ES Outside EU/EEA
Global end of trial date	27 March 2014

Results information

Result version number	v1 (current)
This version publication date	29 June 2016
First version publication date	29 July 2015

Trial information

Trial identification

Sponsor protocol code	6108A1-2001-WW

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT00808028
WHO universal trial number (UTN)	-
Other trial identifiers	Alias: B1971005

Notes:

Sponsors

Sponsor organisation name	Pfizer Inc
Sponsor organisation address	235 E 42nd Street, New York, United States, NY 10017
Public contact	Pfizer Clinical Trials.gov Call Centre, Pfizer Inc, 001 45678899, ClinicalTrials.gov_Inquiries@pfizer.com
Scientific contact	Pfizer Clinical Trials.gov Call Centre, Pfizer Inc, 001 45678899, ClinicalTrials.gov_Inquiries@pfizer.com

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	Yes
EMA paediatric investigation plan number(s)	EMEA-001037-PIP02-11
Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	No
Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	No

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	28 May 2015
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	27 March 2014
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To assess the immunogenicity of 60 microgram (mcg), 120 mcg, and 200 mcg recombinant lipoprotein 2086 (rLP2086) vaccine as measured by serum bactericidal assays (SBA) performed with MnB strains expressing LP2086 subfamily A and B proteins in healthy adolescents aged 11 to 18 years.

Protection of trial subjects:

The study was in compliance with the ethical principles derived from the Declaration of Helsinki and in compliance with all International Conference on Harmonization (ICH) Good Clinical Practice (GCP) Guidelines. All the local regulatory requirements pertinent to safety of trial subjects were followed.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	09 February 2009
Long term follow-up planned	Yes
Long term follow-up rationale	Efficacy
Long term follow-up duration	48 Months
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Spain: 89
Country: Number of subjects enrolled	Australia: 139
Country: Number of subjects enrolled	Poland: 311
Worldwide total number of subjects	539
EEA total number of subjects	400

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	60
Adolescents (12-17 years)	443

Adults (18-64 years)	36
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

This study was conducted at 25 sites in 3 countries. Study start date was 9 February 2009 and end date was 27 March 2014.

Period 1

Period 1 title	Stage 1 (6 months)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Single blind
Roles blinded	Subject

Arms

Are arms mutually exclusive?	Yes
Arm title	Control- Stage 1

Arm description:

Given on a 0, 2-, 6-month schedule in Stage 1 and follow-up to 48 months in Stage 2.

Arm type	Placebo
Investigational medicinal product name	Normal Saline
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Subjects received normal saline on a 0, 2-, 6-month schedule.

Arm title	rLP2086 60 mcg- Stage 1

Arm description:

Given on a 0, 2-, 6-month schedule in Stage 1.

Arm type	Experimental
Investigational medicinal product name	Bivalent Recombinant lipoprotein 2086 (rLP2086)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Subjects received rLP2086 60 mcg on a 0-, 2-, 6- month schedule.

Arm title	rLP2086 120 mcg- Stage 1

Arm description:

Given on a 0, 2-, 6-month schedule in Stage 1 and follow-up to 48 months in Stage 2.

Arm type	Experimental
Investigational medicinal product name	Bivalent Recombinant lipoprotein 2086 (rLP2086)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:
Subjects received rLP2086 120 mcg on a 0-, 2-, 6- month schedule.

Arm title	rLP2086 200 mcg- Stage 1

Arm description:
Given on a 0, 2-, 6-month schedule in Stage 1 and follow-up to 48 months in Stage 2.

Arm type	Experimental
Investigational medicinal product name	Bivalent Recombinant lipoprotein 2086 (rLP2086)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:
Subjects received rLP2086 200 mcg on a 0-, 2-, 6- month schedule.

Number of subjects in period 1	Control- Stage 1	rLP2086 60 mcg- Stage 1	rLP2086 120 mcg- Stage 1
Started	121	22	198
Completed	116	21	191
Not completed	5	1	7
Consent withdrawn by subject	3	-	2
Adverse Event	-	-	1
Parent/legal guardian request	-	1	1
Unspecified	1	-	2
Protocol Violation	-	-	-
Lost to follow-up	1	-	1

Number of subjects in period 1	rLP2086 200 mcg- Stage 1
Started	198
Completed	183
Not completed	15
Consent withdrawn by subject	5
Adverse Event	2
Parent/legal guardian request	3
Unspecified	4
Protocol Violation	1
Lost to follow-up	-

Period 2	
Period 2 title	Stage 2 (Followed up to 48 Months)
Is this the baseline period?	No
Allocation method	Not applicable
Blinding used	Not blinded

Arms	
Are arms mutually exclusive?	Yes
Arm title	Control- Stage 2

Arm description:

Follow-up to 48 months.

Arm type	No intervention

No investigational medicinal product assigned in this arm

Arm title	rLP2086 120 mcg- Stage 2

Arm description:

Follow-up to 48 months.

Arm type	No intervention

No investigational medicinal product assigned in this arm

Arm title	rLP2086 200 mcg- Stage 2

Arm description:

Follow-up to 48 months.

Arm type	No intervention

No investigational medicinal product assigned in this arm

Number of subjects in period 2[1]	Control- Stage 2	rLP2086 120 mcg- Stage 2	rLP2086 200 mcg- Stage 2
Started	80	170	151
Completed	69	141	128
Not completed	11	29	23
Consent withdrawn by subject	6	9	11
Adverse Event	1	1	-
Failed to return	2	5	4
Death	-	1	-
Non-compliance	-	1	-
Protocol Violation	-	1	-
Unspecified	-	1	1
Lost to follow-up	2	8	7
Parent's or guardian request	-	2	-

Notes:

[1] - The number of subjects starting the period is not consistent with the number completing the preceding period. It is expected the number of subjects starting the subsequent period will be the same as the number completing the preceding period.
Justification: Out of 511 completed subjects in Stage 1, 89 did not enter Stage 2.

Baseline characteristics

Reporting groups	
Reporting group title	Control- Stage 1
Reporting group description:	
Given on a 0, 2-, 6-month schedule in Stage 1 and follow-up to 48 months in Stage 2.	
Reporting group title	rLP2086 60 mcg- Stage 1
Reporting group description:	
Given on a 0, 2-, 6-month schedule in Stage 1.	
Reporting group title	rLP2086 120 mcg- Stage 1
Reporting group description:	
Given on a 0, 2-, 6-month schedule in Stage 1 and follow-up to 48 months in Stage 2.	
Reporting group title	rLP2086 200 mcg- Stage 1
Reporting group description:	
Given on a 0, 2-, 6-month schedule in Stage 1 and follow-up to 48 months in Stage 2.	

Reporting group values	Control- Stage 1	rLP2086 60 mcg- Stage 1	rLP2086 120 mcg- Stage 1
Number of subjects	121	22	198
Age categorical Units: Subjects			
Age continuous Units: years			
arithmetic mean	13.8	13.3	14.3
standard deviation	± 2.05	± 1.84	± 2.11
Gender categorical Units: Subjects			
Female	61	11	113
Male	60	11	85

Reporting group values	rLP2086 200 mcg- Stage 1	Total	
Number of subjects	198	539	
Age categorical Units: Subjects			
Age continuous Units: years			
arithmetic mean	14		
standard deviation	± 2.01	-	
Gender categorical Units: Subjects			
Female	103	288	
Male	95	251	

End points

End points reporting groups

Reporting group title	Control- Stage 1
Reporting group description: Given on a 0, 2-, 6-month schedule in Stage 1 and follow-up to 48 months in Stage 2.	
Reporting group title	rLP2086 60 mcg- Stage 1
Reporting group description: Given on a 0, 2-, 6-month schedule in Stage 1.	
Reporting group title	rLP2086 120 mcg- Stage 1
Reporting group description: Given on a 0, 2-, 6-month schedule in Stage 1 and follow-up to 48 months in Stage 2.	
Reporting group title	rLP2086 200 mcg- Stage 1
Reporting group description: Given on a 0, 2-, 6-month schedule in Stage 1 and follow-up to 48 months in Stage 2.	
Reporting group title	Control- Stage 2
Reporting group description: Follow-up to 48 months.	
Reporting group title	rLP2086 120 mcg- Stage 2
Reporting group description: Follow-up to 48 months.	
Reporting group title	rLP2086 200 mcg- Stage 2
Reporting group description: Follow-up to 48 months.	

Primary: Percentage of Subjects With at Least 4-fold Rise in Recombinant Lipoprotein 2086 (rLP2086) specific Serum Bactericidal Assay Using Human Complement (hSBA) Titer: Before vaccination 1 up to 1 month after vaccination 2

End point title	Percentage of Subjects With at Least 4-fold Rise in Recombinant Lipoprotein 2086 (rLP2086) specific Serum Bactericidal Assay Using Human Complement (hSBA) Titer: Before vaccination 1 up to 1 month after vaccination 2[1]
End point description: Modified- Intent-to-treat (mITT) population included all randomized subjects who received at least 1 vaccination and had at least 1 valid and determinate assay result.	
End point type	Primary
End point timeframe: Before vaccination 1 up to 1 month after vaccination 2	

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Statistical analysis has been provided separately as an attachment.

End point values	Control- Stage 1	rLP2086 60 mcg- Stage 1	rLP2086 120 mcg- Stage 1	rLP2086 200 mcg- Stage 1
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	119[2]	22[3]	195[4]	192[5]
Units: Titer				
number (not applicable)				
Subfamily A Strain A05 (N=80, 18, 115, 106)	1.3	88.9	83.5	87.7

Subfamily B Strain B02 (N= 84, 21, 121, 114)	0	71.4	59.5	59.6

Notes:

[2] - Subjects evaluable for this measure during specified time period.

[3] - Subjects evaluable for this measure during specified time period.

[4] - Subjects evaluable for this measure during specified time period.

[5] - Subjects evaluable for this measure during specified time period.

Attachments (see zip file)	Statistical analysis for Endpoint 1/Statistical analysis for

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Subjects With at Least 4-fold Rise in Recombinant Lipoprotein 2086 (rLP2086) Specific Serum Bactericidal Assay Using Human Complement (hSBA) Titer: Before Vaccination 1 up to 1 Month After Vaccination 3

End point title	Percentage of Subjects With at Least 4-fold Rise in Recombinant Lipoprotein 2086 (rLP2086) Specific Serum Bactericidal Assay Using Human Complement (hSBA) Titer: Before Vaccination 1 up to 1 Month After Vaccination 3[6]

End point description:

mITT population included all randomized subjects who received at least 1 vaccination and had at least 1 valid and determinate assay result.

End point type	Primary

End point timeframe:

Before vaccination 1 up to 1 month after vaccination 3

Notes:

[6] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Statistical analysis has been provided separately as an attachment.

End point values	Control- Stage 1	rLP2086 60 mcg- Stage 1	rLP2086 120 mcg- Stage 1	rLP2086 200 mcg- Stage 1
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	119[7]	22[8]	195[9]	192[10]
Units: percentage of subjects				
number (not applicable)				
Subfamily A Strain A05 (N=73, 19, 111,100)	5.5	89.5	92.8	94
Subfamily B Strain B02 (N=79, 21, 112,105)	1.3	81	86.6	84.8

Notes:

[7] - Subjects evaluable for this measure during specified time period.

[8] - Subjects evaluable for this measure during specified time period.

[9] - Subjects evaluable for this measure during specified time period.

[10] - Subjects evaluable for this measure during specified time period.

Attachments (see zip file)	Statistical Analysis for Endpoint 2/Statistical analysis for

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Subjects With Atleast One Adverse Event (AE): Stage 1	
End point title	Percentage of Subjects With Atleast One Adverse Event (AE): Stage 1[11]

End point description:

Safety population included subjects who received at least 1 dose of study vaccine.

End point type	Primary

End point timeframe:

Vaccination 1 upto 1 Month after vaccination 3

Notes:

[11] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Only descriptive data was planned to be reported for this endpoint.

End point values	Control- Stage 1	rLP2086 60 mcg- Stage 1	rLP2086 120 mcg- Stage 1	rLP2086 200 mcg- Stage 1
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	121	22	198	195
Units: percentage of subjects				
number (not applicable)				
Stage 1: Vaccination phase	44.6	81.8	38.9	47.2
Stage 1: 6-month follow up	4.1	18.2	1.5	2.6

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Subjects With Atleast One Adverse Event: Stage 2	
End point title	Percentage of Subjects With Atleast One Adverse Event: Stage 2[12]

End point description:

Safety population included subjects who received at least 1 dose of study vaccine.

End point type	Primary

End point timeframe:

6 month after vaccination 3 up to 48 months

Notes:

[12] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Only descriptive data was planned to be reported for this endpoint.

End point values	Control- Stage 2	rLP2086 120 mcg- Stage 2	rLP2086 200 mcg- Stage 2	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	80	170	151	
Units: percentage of subjects				
number (not applicable)	2.5	4.1	2	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects Achieving Serum Bactericidal Assay Using Human Complement (hSBA) Titer Level Greater Than or Equal To (>=) Prespecified Titer Level

End point title	Percentage of Subjects Achieving Serum Bactericidal Assay Using Human Complement (hSBA) Titer Level Greater Than or Equal To (>=) Prespecified Titer Level

End point description:

mITT population included all randomized subjects who received at least 1 vaccination and had at least 1 valid and determinate assay result. Here, 'N' signifies those subjects who were evaluable for this measure during specified time period.

End point type	Secondary

End point timeframe:

1 month before vaccination 1, 1 month after vaccination 2, 3

End point values	Control- Stage 1	rLP2086 60 mcg- Stage 1	rLP2086 120 mcg- Stage 1	rLP2086 200 mcg- Stage 1
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	119	22	195	192
Units: percentage of subjects				
number (not applicable)				
A04 Predose 1;1:32 (N= 64, 15, 90, 92)	10.9	0	10	12
A04 Predose 1;1:64 (N= 64, 15, 90, 92)	3.1	0	7.8	5.4
A04 Predose 1;1:128 (N= 64, 15, 90, 9 2)	0	0	1.1	0
A04 1- -month postdose 2;1:32 (N= 69, 21,	4.3	95.2	98.3	91.3
A04 1- -month postdose 2;1:64 (N= 69, 21,	1.4	85.7	82.6	72.2
A04 1- -month postdose 2;1:128 (N=69, 21,	1.4	52.4	44.3	42.6
A04 1- -month postdose 3; 1:32 (N= 57, 19,	8.8	94.7	100	99
A04 1- -month postdose 3; 1:64 (N= 57, 19,	5.3	94.7	95.4	90.9
A04 1- -month postdose 3; 1:128 (N= 57, 19,	3.5	68.4	67.6	67.7
A05 Predose 1;1:16 (N= 81, 21, 122, 1 14)	12.3	4.8	9	6.1
A05 Predose 1;1:32 (N= 81, 21, 122, 1 14)	7.4	4.8	5.7	4.4
A05 Predose 1;1:64 (N= 81, 21, 122, 1 14)	4.9	0	2.5	1.8
A05 Predose 1;1:128 (N= 81, 21, 122, 114)	1.2	0	0.8	0
A05 1- -month postdose 2;1:16 (N= 83, 18,	7.2	88.9	89	90.9
A05 1- -month postdose 2;1:32 (N= 83, 18,	3.6	88.9	85.6	81.8
A05 1-- month postdose 2;1:64 (N= 83, 18,	1.2	83.3	59.3	64.5
A05 1-- month postdose 2;1:128 (N= 83, 18,	0	33.3	28	40

A05 1--month postdose 3;1:16 (N= 76, 20,	11.8	90	96.5	96.2
A05 1--month postdose 3;1:32 (N= 76, 20,	7.9	90	94.7	95.2
A05 1--month postdose 3;1:64 (N= 76, 20,	3.9	85	89.5	87.5
A05 1--month postdose 3;1:128 (N= 76, 20,	1.3	40	68.4	60.6
A56 Predose 1;1:16 (N= 80, 21, 119, 115)	10	4.8	7.6	6.1
A56 Predose 1;1:32 (N= 80, 21, 119, 115)	7.5	4.8	5	4.3
A56 Predose 1;1:64 (N= 80, 21, 119, 115)	2.5	0	0.8	3.5
A56 Predose 1;1:128 (N= 80, 21, 119, 115)	1.3	0	0	0
A56 1--month postdose 2;1:16 (N= 81, 20,	12.3	85	94.9	96.3
A56 1--month postdose 2;1:32 (N= 81, 20,	11.1	85	90.6	88.8
A56 1--month postdose 2;1:64 (N= 81, 20,	9.9	80	80.3	71
A56 1--month postdose 2;1:128 (N=81, 20,	2.5	45	39.3	45.8
A56 1--month postdose 3 ;1:16 (N=78, 21,	11.5	95.2	97.4	95.5
A56 1--month postdose 3;1:32 (N= 78, 21,	9	85.7	93.9	93.8
A56 1--month postdose 3;1:64 (N= 78, 21,	3.8	71.4	91.2	84.8
A56 1-month postdose 3;1:128 (N= 78, 21, 114, 112)	2.6	61.9	74.6	67
B02 Predose 1;1:16 (N= 84, 22, 124, 118)	3.6	0	1.6	2.5
B02 Predose 1;1:32 (N= 84, 22, 124, 118)	1.2	0	0.8	1.7
B02 Predose 1;1:64 (N= 84, 22, 124, 118)	0	0	0.8	0
B02 Predose 1;1:128 (N= 84, 22, 124, 118)	0	0	0.8	0
B02 1-month postdose 2 ;1:16 (N= 84, 21, 122, 114)	1.2	76.2	68.9	65.8
B02 1-month postdose 2 ;1:32 (N= 84, 21, 122, 114)	0	57.1	45.9	48.2
B02 1-month postdose 2 ;1:64 (N= 84, 21, 122, 114)	0	42.9	25.4	21.9
B02 1-month postdose 2;1:128 (N= 84, 21, 122, 114)	0	14.3	7.4	8.8
B02 1-month postdose 3 ;1:16 (N= 79, 21, 113, 105)	3.8	85.7	90.3	85.7
B02 1-month postdose 3 ;1:32 (N= 79, 21, 113, 105)	1.3	81	78.8	79
B02 1-month postdose 3 ;1:64 (N= 79, 21, 113, 105)	0	57.1	52.2	60
B02 1-month postdose 3;1:128 (N= 79, 21, 113, 105)	0	42.9	19.5	19
B03 Predose 1;1:16 (N= 83, 22, 118, 117)	2.4	0	2.5	2.6
B03 Predose 1;1:32 (N= 83, 22, 118, 117)	2.4	0	2.5	2.6
B03 Predose 1;1:64 (N= 83, 22, 118, 117)	1.2	0	0	0.9

B03 Predose 1;1:128 (N= 83, 22, 118, 117)	0	0	0	0
B03 1-month postdose 2;1:16 (N= 84, 19, 102, 96)	2.4	21.1	32.4	30.2
B03 1-month postdose 2;1:32 (N= 84, 19, 102, 96)	2.4	21.1	30.4	28.1
B03 1-month postdose 2;1:64 (N= 84, 19, 102, 96)	1.2	5.3	22.5	19.8
B03 1-month postdose 2;1:128 (N= 84, 19, 102, 96)	0	0	10.8	8.3
B03 1-month postdose 3;1:16 (N= 68, 15, 86, 81)	5.9	53.3	75.6	67.9
B03 1-month postdose 3;1:32 (N= 68, 15, 86, 81)	4.4	53.3	75.6	66.7
B03 1-month postdose 3;1:64 (N= 68, 15, 86, 81)	1.5	46.7	60.5	58
B03 1-month postdose 3;1:128 (N= 68, 15, 86, 81)	0	26.7	27.9	24.7
B44 Predose 1 ;1:8 (N= 81, 22, 120, 116)	2.5	0	3.3	2.6
B44 Predose 1 ;1:16 (N= 81, 22, 120, 116)	1.2	0	1.7	2.6
B44 Predose 1 ;1:32 (N= 81, 22, 120, 116)	0	0	0	1.7
B44 Predose 1 ;1:64 (N= 81, 22, 120, 116)	0	0	0	0.9
B44 Predose 1 ;1:128 (N= 81, 22, 120, 116)	0	0	0	0.9
B44 1-month postdose 2;1:8 (n= 81, 21, 115, 106)	1.2	61.9	68.7	70.8
B44 1-month postdose 2;1:16 (N= 81, 21, 115, 106)	0	61.9	60.9	64.2
B44 1-month postdose 2;1:32 (N= 81, 21, 115, 106)	0	47.6	43.5	42.5
B44 1-month postdose 2;1:64 (N= 81, 21, 115, 106)	0	23.8	22.6	25.5
B44 1-month postdose 2;1:128 (N= 81, 21, 115, 106)	0	0	6.1	11.3
B44 1-month postdose 3;1:8 (N= 83, 21, 115, 111)	4.8	76.2	88.7	86.5
B44 1-month postdose 3; 1:16 (N= 83, 21, 115, 111)	1.2	76.2	86.1	85.6
B44 1-month postdose 3;1:32 (N= 83, 21, 115, 111)	0	76.2	80.9	80.2
B44 1-month postdose 3;1:64 (N= 83, 21, 115, 111)	0	47.6	53.9	61.3
B44 1-month postdose 3;1:128 (N= 83, 21, 115, 111)	0	9.5	22.6	19.8

Statistical analyses

No statistical analyses for this end point

Other pre-specified: Immunogloblulin G (IgG) Measured by Geometric Mean Titer (GMT) for Sub Family A and Sub Family B

End point title	Immunogloblulin G (IgG) Measured by Geometric Mean Titer (GMT) for Sub Family A and Sub Family B

End point description:

mITT population included all randomized subjects who received at least 1 vaccination and had at least 1 valid and determinate assay result.

End point type	Other pre-specified

End point timeframe:

Before Vaccination 1, 1 month after vaccination 2, 1 month after vaccination 3

End point values	Control- Stage 1	rLP2086 60 mcg- Stage 1	rLP2086 120 mcg- Stage 1	rLP2086 200 mcg- Stage 1
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	119[13]	22[14]	195[15]	192[16]
Units: Titer				
geometric mean (confidence interval 95%)				
Subfamily(Sf) A Predose 1(N=106, 22, 156, 173)	3.6 (2.6 to 5.1)	4.3 (1.6 to 11.7)	7.2 (5.3 to 9.8)	4.9 (3.8 to 6.4)
Sf A 1-month postdose 2(N=104, 22, 168, 166)	4.9 (3.5 to 6.9)	984.6 (663.8 to 1460.4)	1115.5 (962.8 to 1292.5)	1285.8 (1082.3 to 1527.7)
Sf A 1-month postdose 3(N=98, 20, 158, 148)	5.8 (3.9 to 8.5)	3120.3 (1959.5 to 4968.8)	2289.5 (1967 to 2664.9)	2342.6 (2003.9 to 2738.5)
Sf B Predose 1(N=106, 22, 155, 172)	3.5 (2.6 to 4.6)	4.2 (1.4 to 12.7)	5.4 (4.1 to 7.2)	3.9 (3 to 5)
Sf B 1-month postdose 2(N=104, 22, 168, 166)	3.7 (2.7 to 5)	405.8 (298.74 to 551.4)	816.5 (701 to 951.1)	852 (729.1 to 995.6)
Sf B 1-month postdose 3(N=98, 20, 158, 148)	4.1 (2.9 to 5.7)	3264.2 (2502.3 to 4258.1)	2246.8 (1988.1 to 2539.2)	2553.3 (2256 to 2889.7)

Notes:

[13] - Subjects evaluable for this measure during specified time period.

[14] - Subjects evaluable for this measure during specified time period.

[15] - Subjects evaluable for this measure during specified time period.

[16] - Subjects evaluable for this measure during specified time period.

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

AE reported from Vaccination 1 up to 48 months after vaccincation 3 and SAE reported from Vaccination 1 up to 48 months after vaccination 1

Assessment type	Non-systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	17.0

Reporting groups

Reporting group title	Control- Stage 1

Reporting group description:

Given on a 0, 2-, 6-month schedule in Stage 1.

Reporting group title	rLP2086 60 microgram (mcg)- Stage 1

Reporting group description:

Given on a 0, 2-, 6-month schedule in Stage 1 .

Reporting group title	rLP2086 120 mcg- Stage 1

Reporting group description:

Given on a 0, 2-, 6-month schedule in Stage 1.

Reporting group title	rLP2086 200 mcg- Stage 1

Reporting group description:

Given on a 0, 2-, 6- month schedule in Stage 1.

Reporting group title	Control-Stage 1 Follow-up

Reporting group description:

Given on a 0, 2-, 6-month schedule in Stage 1, were then followed up to 6 months in Stage 1.

Reporting group title	rLP2086 60 mcg- Stage 1 Follow up

Reporting group description:

Given on a 0, 2-, 6-month schedule in Stage 1, were then followed up to 6 months in Stage 1.

Reporting group title	rLP2086 120 mcg- Stage 1 Follow up

Reporting group description:

Given on a 0, 2-, 6-month schedule in Stage 1, were then followed up to 6 months in Stage 1.

Reporting group title	rLP2086 200 mcg-Stage 1 Follow up

Reporting group description:

Given on a 0, 2-, 6-month schedule in Stage 1, were then followed up to 6 months in Stage 1

Reporting group title	Control- Stage 2

Reporting group description:

Given on a 0, 2-, 6-month schedule in Stage 1, werethen followed up to 6 monthsin Stage 1 and further up to 48 months in Stage 2.

Reporting group title	rLP2086 120 mcg- Stage 2

Reporting group description:

Given on a 0, 2-, 6-month schedule in Stage 1, were then followed up to 6 months in Stage 1 and further up to 48 months in Stage 2.

Reporting group title	rLP2086 200 mcg- Stage 2

Reporting group description:

Given on a 0, 2-, 6-month schedule in Stage 1, were then followed up to 6 months in Stage 1 and further up to 48 months in Stage 2.

Serious adverse events	Control- Stage 1	rLP2086 60 microgram (mcg)- Stage 1	rLP2086 120 mcg- Stage 1
Total subjects affected by serious adverse events			
subjects affected / exposed	3 / 121 (2.48%)	1 / 22 (4.55%)	3 / 198 (1.52%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Cerebellar tumour			
subjects affected / exposed	0 / 121 (0.00%)	0 / 22 (0.00%)	0 / 198 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CNS germinoma			
subjects affected / exposed	0 / 121 (0.00%)	0 / 22 (0.00%)	0 / 198 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Abdominal injury			
subjects affected / exposed	0 / 121 (0.00%)	0 / 22 (0.00%)	0 / 198 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chest injury			
subjects affected / exposed	0 / 121 (0.00%)	0 / 22 (0.00%)	0 / 198 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Concussion			
subjects affected / exposed	0 / 121 (0.00%)	0 / 22 (0.00%)	1 / 198 (0.51%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Forearm fracture			
subjects affected / exposed	1 / 121 (0.83%)	0 / 22 (0.00%)	0 / 198 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Jaw fracture			

subjects affected / exposed	0 / 121 (0.00%)	0 / 22 (0.00%)	1 / 198 (0.51%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Limb injury			
subjects affected / exposed	0 / 121 (0.00%)	0 / 22 (0.00%)	1 / 198 (0.51%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hand fracture			
subjects affected / exposed	0 / 121 (0.00%)	0 / 22 (0.00%)	0 / 198 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Alcohol poisoning			
subjects affected / exposed	0 / 121 (0.00%)	0 / 22 (0.00%)	0 / 198 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Head injury			
subjects affected / exposed	0 / 121 (0.00%)	0 / 22 (0.00%)	0 / 198 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ligament sprain			
subjects affected / exposed	0 / 121 (0.00%)	0 / 22 (0.00%)	0 / 198 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Road traffic accident			
subjects affected / exposed	0 / 121 (0.00%)	0 / 22 (0.00%)	0 / 198 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Hypertension			
subjects affected / exposed	0 / 121 (0.00%)	0 / 22 (0.00%)	0 / 198 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			

Headache			
subjects affected / exposed	0 / 121 (0.00%)	1 / 22 (4.55%)	0 / 198 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Lymphadenitis			
subjects affected / exposed	1 / 121 (0.83%)	0 / 22 (0.00%)	0 / 198 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Anaphylactic reaction			
subjects affected / exposed	0 / 121 (0.00%)	0 / 22 (0.00%)	0 / 198 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
Ovarian cyst			
subjects affected / exposed	0 / 121 (0.00%)	0 / 22 (0.00%)	1 / 198 (0.51%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Asthma			
subjects affected / exposed	0 / 121 (0.00%)	0 / 22 (0.00%)	0 / 198 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cough			
subjects affected / exposed	1 / 121 (0.83%)	0 / 22 (0.00%)	0 / 198 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rhinitis allergic			
subjects affected / exposed	0 / 121 (0.00%)	0 / 22 (0.00%)	0 / 198 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Depression			

subjects affected / exposed	0 / 121 (0.00%)	0 / 22 (0.00%)	0 / 198 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Appendicitis			
subjects affected / exposed	0 / 121 (0.00%)	1 / 22 (4.55%)	0 / 198 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis			
subjects affected / exposed	0 / 121 (0.00%)	0 / 22 (0.00%)	0 / 198 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mononucleosis syndrome			
subjects affected / exposed	0 / 121 (0.00%)	0 / 22 (0.00%)	0 / 198 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	0 / 121 (0.00%)	0 / 22 (0.00%)	0 / 198 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sinusitis			
subjects affected / exposed	0 / 121 (0.00%)	0 / 22 (0.00%)	0 / 198 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eczema impetiginous			
subjects affected / exposed	0 / 121 (0.00%)	0 / 22 (0.00%)	0 / 198 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Perirectal abscess			
subjects affected / exposed	0 / 121 (0.00%)	0 / 22 (0.00%)	0 / 198 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pilonidal cyst			

subjects affected / exposed	0 / 121 (0.00%)	0 / 22 (0.00%)	0 / 198 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tonsillitis			
subjects affected / exposed	0 / 121 (0.00%)	0 / 22 (0.00%)	0 / 198 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tonsillitis streptococcal			
subjects affected / exposed	0 / 121 (0.00%)	0 / 22 (0.00%)	0 / 198 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	rLP2086 200 mcg-Stage 1	Control-Stage 1 Follow-up	rLP2086 60 mcg-Stage 1 Follow up
Total subjects affected by serious adverse events			
subjects affected / exposed	8 / 195 (4.10%)	0 / 121 (0.00%)	1 / 22 (4.55%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Cerebellar tumour			
subjects affected / exposed	0 / 195 (0.00%)	0 / 121 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CNS germinoma			
subjects affected / exposed	0 / 195 (0.00%)	0 / 121 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Abdominal injury			
subjects affected / exposed	1 / 195 (0.51%)	0 / 121 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chest injury			

subjects affected / exposed	1 / 195 (0.51%)	0 / 121 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Concussion			
subjects affected / exposed	0 / 195 (0.00%)	0 / 121 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Forearm fracture			
subjects affected / exposed	0 / 195 (0.00%)	0 / 121 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Jaw fracture			
subjects affected / exposed	0 / 195 (0.00%)	0 / 121 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Limb injury			
subjects affected / exposed	0 / 195 (0.00%)	0 / 121 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hand fracture			
subjects affected / exposed	0 / 195 (0.00%)	0 / 121 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Alcohol poisoning			
subjects affected / exposed	0 / 195 (0.00%)	0 / 121 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Head injury			
subjects affected / exposed	0 / 195 (0.00%)	0 / 121 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ligament sprain			

subjects affected / exposed	0 / 195 (0.00%)	0 / 121 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Road traffic accident			
subjects affected / exposed	0 / 195 (0.00%)	0 / 121 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Hypertension			
subjects affected / exposed	1 / 195 (0.51%)	0 / 121 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Headache			
subjects affected / exposed	0 / 195 (0.00%)	0 / 121 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Lymphadenitis			
subjects affected / exposed	0 / 195 (0.00%)	0 / 121 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Anaphylactic reaction			
subjects affected / exposed	1 / 195 (0.51%)	0 / 121 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
Ovarian cyst			
subjects affected / exposed	0 / 195 (0.00%)	0 / 121 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Asthma			

subjects affected / exposed	1 / 195 (0.51%)	0 / 121 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cough			
subjects affected / exposed	0 / 195 (0.00%)	0 / 121 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rhinitis allergic			
subjects affected / exposed	0 / 195 (0.00%)	0 / 121 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Depression			
subjects affected / exposed	1 / 195 (0.51%)	0 / 121 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Appendicitis			
subjects affected / exposed	1 / 195 (0.51%)	0 / 121 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis			
subjects affected / exposed	1 / 195 (0.51%)	0 / 121 (0.00%)	1 / 22 (4.55%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mononucleosis syndrome			
subjects affected / exposed	1 / 195 (0.51%)	0 / 121 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	1 / 195 (0.51%)	0 / 121 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sinusitis			

subjects affected / exposed	0 / 195 (0.00%)	0 / 121 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eczema impetiginous			
subjects affected / exposed	0 / 195 (0.00%)	0 / 121 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Perirectal abscess			
subjects affected / exposed	0 / 195 (0.00%)	0 / 121 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pilonidal cyst			
subjects affected / exposed	0 / 195 (0.00%)	0 / 121 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tonsillitis			
subjects affected / exposed	0 / 195 (0.00%)	0 / 121 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tonsillitis streptococcal			
subjects affected / exposed	0 / 195 (0.00%)	0 / 121 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	rLP2086 120 mcg-Stage 1 Follow up	rLP2086 200 mcg-Stage 1 Follow up	Control- Stage 2
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 198 (0.51%)	2 / 195 (1.03%)	1 / 80 (1.25%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Cerebellar tumour			
subjects affected / exposed	0 / 198 (0.00%)	1 / 195 (0.51%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

CNS germinoma			
subjects affected / exposed	0 / 198 (0.00%)	0 / 195 (0.00%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Abdominal injury			
subjects affected / exposed	0 / 198 (0.00%)	0 / 195 (0.00%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chest injury			
subjects affected / exposed	0 / 198 (0.00%)	0 / 195 (0.00%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Concussion			
subjects affected / exposed	0 / 198 (0.00%)	0 / 195 (0.00%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Forearm fracture			
subjects affected / exposed	0 / 198 (0.00%)	0 / 195 (0.00%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Jaw fracture			
subjects affected / exposed	0 / 198 (0.00%)	0 / 195 (0.00%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Limb injury			
subjects affected / exposed	0 / 198 (0.00%)	0 / 195 (0.00%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hand fracture			
subjects affected / exposed	0 / 198 (0.00%)	1 / 195 (0.51%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Alcohol poisoning			
subjects affected / exposed	0 / 198 (0.00%)	0 / 195 (0.00%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Head injury			
subjects affected / exposed	0 / 198 (0.00%)	0 / 195 (0.00%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ligament sprain			
subjects affected / exposed	0 / 198 (0.00%)	0 / 195 (0.00%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Road traffic accident			
subjects affected / exposed	0 / 198 (0.00%)	0 / 195 (0.00%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Hypertension			
subjects affected / exposed	0 / 198 (0.00%)	0 / 195 (0.00%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Headache			
subjects affected / exposed	0 / 198 (0.00%)	0 / 195 (0.00%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Lymphadenitis			
subjects affected / exposed	0 / 198 (0.00%)	0 / 195 (0.00%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Anaphylactic reaction			

subjects affected / exposed	0 / 198 (0.00%)	0 / 195 (0.00%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
Ovarian cyst			
subjects affected / exposed	0 / 198 (0.00%)	0 / 195 (0.00%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Asthma			
subjects affected / exposed	0 / 198 (0.00%)	0 / 195 (0.00%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cough			
subjects affected / exposed	0 / 198 (0.00%)	0 / 195 (0.00%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rhinitis allergic			
subjects affected / exposed	1 / 198 (0.51%)	0 / 195 (0.00%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Depression			
subjects affected / exposed	0 / 198 (0.00%)	0 / 195 (0.00%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Appendicitis			
subjects affected / exposed	0 / 198 (0.00%)	0 / 195 (0.00%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis			

subjects affected / exposed	0 / 198 (0.00%)	0 / 195 (0.00%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mononucleosis syndrome			
subjects affected / exposed	0 / 198 (0.00%)	0 / 195 (0.00%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	0 / 198 (0.00%)	0 / 195 (0.00%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sinusitis			
subjects affected / exposed	1 / 198 (0.51%)	0 / 195 (0.00%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eczema impetiginous			
subjects affected / exposed	0 / 198 (0.00%)	0 / 195 (0.00%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Perirectal abscess			
subjects affected / exposed	0 / 198 (0.00%)	0 / 195 (0.00%)	1 / 80 (1.25%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pilonidal cyst			
subjects affected / exposed	0 / 198 (0.00%)	0 / 195 (0.00%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tonsillitis			
subjects affected / exposed	0 / 198 (0.00%)	0 / 195 (0.00%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tonsillitis streptococcal			

subjects affected / exposed	0 / 198 (0.00%)	0 / 195 (0.00%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	rLP2086 120 mcg-Stage 2	rLP2086 200 mcg-Stage 2	
Total subjects affected by serious adverse events			
subjects affected / exposed	6 / 170 (3.53%)	3 / 151 (1.99%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events	0	0	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Cerebellar tumour			
subjects affected / exposed	0 / 170 (0.00%)	0 / 151 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
CNS germinoma			
subjects affected / exposed	1 / 170 (0.59%)	0 / 151 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Injury, poisoning and procedural complications			
Abdominal injury			
subjects affected / exposed	0 / 170 (0.00%)	0 / 151 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chest injury			
subjects affected / exposed	0 / 170 (0.00%)	0 / 151 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Concussion			
subjects affected / exposed	0 / 170 (0.00%)	0 / 151 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Forearm fracture			

subjects affected / exposed	0 / 170 (0.00%)	0 / 151 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Jaw fracture			
subjects affected / exposed	0 / 170 (0.00%)	0 / 151 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Limb injury			
subjects affected / exposed	0 / 170 (0.00%)	0 / 151 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hand fracture			
subjects affected / exposed	0 / 170 (0.00%)	0 / 151 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Alcohol poisoning			
subjects affected / exposed	1 / 170 (0.59%)	0 / 151 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Head injury			
subjects affected / exposed	1 / 170 (0.59%)	0 / 151 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ligament sprain			
subjects affected / exposed	0 / 170 (0.00%)	1 / 151 (0.66%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Road traffic accident			
subjects affected / exposed	1 / 170 (0.59%)	0 / 151 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular disorders			
Hypertension			

subjects affected / exposed	0 / 170 (0.00%)	0 / 151 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nervous system disorders			
Headache			
subjects affected / exposed	0 / 170 (0.00%)	0 / 151 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood and lymphatic system disorders			
Lymphadenitis			
subjects affected / exposed	0 / 170 (0.00%)	0 / 151 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Immune system disorders			
Anaphylactic reaction			
subjects affected / exposed	0 / 170 (0.00%)	0 / 151 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Reproductive system and breast disorders			
Ovarian cyst			
subjects affected / exposed	0 / 170 (0.00%)	0 / 151 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory, thoracic and mediastinal disorders			
Asthma			
subjects affected / exposed	0 / 170 (0.00%)	0 / 151 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cough			
subjects affected / exposed	0 / 170 (0.00%)	0 / 151 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rhinitis allergic			

subjects affected / exposed	0 / 170 (0.00%)	0 / 151 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Psychiatric disorders			
Depression			
subjects affected / exposed	1 / 170 (0.59%)	0 / 151 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
Appendicitis			
subjects affected / exposed	0 / 170 (0.00%)	0 / 151 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastroenteritis			
subjects affected / exposed	0 / 170 (0.00%)	0 / 151 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mononucleosis syndrome			
subjects affected / exposed	0 / 170 (0.00%)	0 / 151 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia			
subjects affected / exposed	0 / 170 (0.00%)	0 / 151 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sinusitis			
subjects affected / exposed	0 / 170 (0.00%)	0 / 151 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Eczema impetiginous			
subjects affected / exposed	1 / 170 (0.59%)	0 / 151 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Perirectal abscess			

subjects affected / exposed	0 / 170 (0.00%)	0 / 151 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pilonidal cyst			
subjects affected / exposed	0 / 170 (0.00%)	1 / 151 (0.66%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tonsillitis			
subjects affected / exposed	1 / 170 (0.59%)	0 / 151 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tonsillitis streptococcal			
subjects affected / exposed	0 / 170 (0.00%)	1 / 151 (0.66%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

Frequency threshold for reporting non-serious adverse events: 0 %

Non-serious adverse events	Control- Stage 1	rLP2086 60 microgram (mcg)- Stage 1	rLP2086 120 mcg- Stage 1
Total subjects affected by non-serious adverse events			
subjects affected / exposed	54 / 121 (44.63%)	18 / 22 (81.82%)	75 / 198 (37.88%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Fibroma			
subjects affected / exposed	0 / 121 (0.00%)	1 / 22 (4.55%)	0 / 198 (0.00%)
occurrences (all)	0	1	0
General disorders and administration site conditions			
Influenza like illness			
subjects affected / exposed	4 / 121 (3.31%)	1 / 22 (4.55%)	2 / 198 (1.01%)
occurrences (all)	4	1	2
Injection site pain			
subjects affected / exposed	0 / 121 (0.00%)	0 / 22 (0.00%)	1 / 198 (0.51%)
occurrences (all)	0	0	1
Pyrexia			

subjects affected / exposed	1 / 121 (0.83%)	0 / 22 (0.00%)	0 / 198 (0.00%)
occurrences (all)	1	0	0
Injection site swelling			
subjects affected / exposed	0 / 121 (0.00%)	0 / 22 (0.00%)	1 / 198 (0.51%)
occurrences (all)	0	0	2
Chest pain			
subjects affected / exposed	0 / 121 (0.00%)	0 / 22 (0.00%)	1 / 198 (0.51%)
occurrences (all)	0	0	1
Hypothermia			
subjects affected / exposed	0 / 121 (0.00%)	0 / 22 (0.00%)	1 / 198 (0.51%)
occurrences (all)	0	0	1
Injection site dermatitis			
subjects affected / exposed	0 / 121 (0.00%)	1 / 22 (4.55%)	0 / 198 (0.00%)
occurrences (all)	0	1	0
Injection site erythema			
subjects affected / exposed	0 / 121 (0.00%)	0 / 22 (0.00%)	0 / 198 (0.00%)
occurrences (all)	0	0	0
Injection site haematoma			
subjects affected / exposed	0 / 121 (0.00%)	0 / 22 (0.00%)	0 / 198 (0.00%)
occurrences (all)	0	0	0
Injection site pallor			
subjects affected / exposed	0 / 121 (0.00%)	0 / 22 (0.00%)	1 / 198 (0.51%)
occurrences (all)	0	0	1
Injection site paraesthesia			
subjects affected / exposed	0 / 121 (0.00%)	1 / 22 (4.55%)	0 / 198 (0.00%)
occurrences (all)	0	1	0
Injection site pruritus			
subjects affected / exposed	0 / 121 (0.00%)	1 / 22 (4.55%)	0 / 198 (0.00%)
occurrences (all)	0	1	0
Vaccination site pallor			
subjects affected / exposed	0 / 121 (0.00%)	0 / 22 (0.00%)	0 / 198 (0.00%)
occurrences (all)	0	0	0
Vessel puncture site haematoma			
subjects affected / exposed	0 / 121 (0.00%)	1 / 22 (4.55%)	0 / 198 (0.00%)
occurrences (all)	0	1	0
Immune system disorders			

Allergy to animal			
subjects affected / exposed	0 / 121 (0.00%)	0 / 22 (0.00%)	0 / 198 (0.00%)
occurrences (all)	0	0	0
Allergy to chemicals			
subjects affected / exposed	0 / 121 (0.00%)	1 / 22 (4.55%)	0 / 198 (0.00%)
occurrences (all)	0	1	0
Seasonal allergy			
subjects affected / exposed	0 / 121 (0.00%)	0 / 22 (0.00%)	1 / 198 (0.51%)
occurrences (all)	0	0	1
Reproductive system and breast disorders			
Dysmenorrhoea			
subjects affected / exposed	2 / 121 (1.65%)	0 / 22 (0.00%)	0 / 198 (0.00%)
occurrences (all)	2	0	0
Penile discharge			
subjects affected / exposed	0 / 121 (0.00%)	0 / 22 (0.00%)	0 / 198 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Oropharyngeal pain			
subjects affected / exposed	4 / 121 (3.31%)	2 / 22 (9.09%)	2 / 198 (1.01%)
occurrences (all)	4	2	2
Rhinorrhoea			
subjects affected / exposed	6 / 121 (4.96%)	0 / 22 (0.00%)	3 / 198 (1.52%)
occurrences (all)	6	0	4
Cough			
subjects affected / exposed	3 / 121 (2.48%)	1 / 22 (4.55%)	2 / 198 (1.01%)
occurrences (all)	3	1	2
Asthma			
subjects affected / exposed	0 / 121 (0.00%)	0 / 22 (0.00%)	2 / 198 (1.01%)
occurrences (all)	0	0	4
Rhinitis allergic			
subjects affected / exposed	0 / 121 (0.00%)	1 / 22 (4.55%)	1 / 198 (0.51%)
occurrences (all)	0	1	2
Asthma exercise induced			
subjects affected / exposed	0 / 121 (0.00%)	0 / 22 (0.00%)	0 / 198 (0.00%)
occurrences (all)	0	0	0
Epistaxis			

subjects affected / exposed	0 / 121 (0.00%)	0 / 22 (0.00%)	0 / 198 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Abnormal behaviour			
subjects affected / exposed	0 / 121 (0.00%)	1 / 22 (4.55%)	0 / 198 (0.00%)
occurrences (all)	0	1	0
Investigations			
Blood iron decreased			
subjects affected / exposed	0 / 121 (0.00%)	0 / 22 (0.00%)	2 / 198 (1.01%)
occurrences (all)	0	0	2
Electrocardiogram QT prolonged			
subjects affected / exposed	0 / 121 (0.00%)	0 / 22 (0.00%)	0 / 198 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Contusion			
subjects affected / exposed	2 / 121 (1.65%)	1 / 22 (4.55%)	1 / 198 (0.51%)
occurrences (all)	2	1	1
Thermal burn			
subjects affected / exposed	1 / 121 (0.83%)	1 / 22 (4.55%)	1 / 198 (0.51%)
occurrences (all)	1	1	1
Skin laceration			
subjects affected / exposed	0 / 121 (0.00%)	1 / 22 (4.55%)	0 / 198 (0.00%)
occurrences (all)	0	1	0
Arthropod bite			
subjects affected / exposed	1 / 121 (0.83%)	1 / 22 (4.55%)	0 / 198 (0.00%)
occurrences (all)	1	1	0
Concussion			
subjects affected / exposed	2 / 121 (1.65%)	0 / 22 (0.00%)	0 / 198 (0.00%)
occurrences (all)	2	0	0
Foot fracture			
subjects affected / exposed	1 / 121 (0.83%)	1 / 22 (4.55%)	0 / 198 (0.00%)
occurrences (all)	1	1	0
Joint sprain			
subjects affected / exposed	1 / 121 (0.83%)	1 / 22 (4.55%)	0 / 198 (0.00%)
occurrences (all)	1	1	0
Procedural pain			

subjects affected / exposed	0 / 121 (0.00%)	0 / 22 (0.00%)	2 / 198 (1.01%)
occurrences (all)	0	0	2
Radius fracture			
subjects affected / exposed	0 / 121 (0.00%)	1 / 22 (4.55%)	0 / 198 (0.00%)
occurrences (all)	0	2	0
Road traffic accident			
subjects affected / exposed	0 / 121 (0.00%)	0 / 22 (0.00%)	1 / 198 (0.51%)
occurrences (all)	0	0	1
Soft tissue injury			
subjects affected / exposed	0 / 121 (0.00%)	0 / 22 (0.00%)	0 / 198 (0.00%)
occurrences (all)	0	0	0
Whiplash injury			
subjects affected / exposed	0 / 121 (0.00%)	0 / 22 (0.00%)	1 / 198 (0.51%)
occurrences (all)	0	0	1
Wrist fracture			
subjects affected / exposed	0 / 121 (0.00%)	0 / 22 (0.00%)	1 / 198 (0.51%)
occurrences (all)	0	0	1
Ankle fracture			
subjects affected / exposed	1 / 121 (0.83%)	0 / 22 (0.00%)	0 / 198 (0.00%)
occurrences (all)	2	0	0
Back injury			
subjects affected / exposed	0 / 121 (0.00%)	0 / 22 (0.00%)	0 / 198 (0.00%)
occurrences (all)	0	0	0
Chemical burn of skin			
subjects affected / exposed	1 / 121 (0.83%)	0 / 22 (0.00%)	0 / 198 (0.00%)
occurrences (all)	1	0	0
Chest injury			
subjects affected / exposed	0 / 121 (0.00%)	0 / 22 (0.00%)	1 / 198 (0.51%)
occurrences (all)	0	0	1
Foreign body			
subjects affected / exposed	1 / 121 (0.83%)	0 / 22 (0.00%)	0 / 198 (0.00%)
occurrences (all)	1	0	0
Head injury			
subjects affected / exposed	0 / 121 (0.00%)	0 / 22 (0.00%)	1 / 198 (0.51%)
occurrences (all)	0	0	1
Ligament injury			

subjects affected / exposed	1 / 121 (0.83%)	0 / 22 (0.00%)	0 / 198 (0.00%)
occurrences (all)	1	0	0
Poisoning			
subjects affected / exposed	0 / 121 (0.00%)	0 / 22 (0.00%)	1 / 198 (0.51%)
occurrences (all)	0	0	1
Post concussion syndrome			
subjects affected / exposed	0 / 121 (0.00%)	0 / 22 (0.00%)	1 / 198 (0.51%)
occurrences (all)	0	0	1
Post procedural haematoma			
subjects affected / exposed	1 / 121 (0.83%)	0 / 22 (0.00%)	0 / 198 (0.00%)
occurrences (all)	1	0	0
Skeletal injury			
subjects affected / exposed	0 / 121 (0.00%)	0 / 22 (0.00%)	0 / 198 (0.00%)
occurrences (all)	0	0	0
Ulna fracture			
subjects affected / exposed	1 / 121 (0.83%)	0 / 22 (0.00%)	0 / 198 (0.00%)
occurrences (all)	1	0	0
Hand fracture			
subjects affected / exposed	0 / 121 (0.00%)	0 / 22 (0.00%)	0 / 198 (0.00%)
occurrences (all)	0	0	0
Limb injury			
subjects affected / exposed	0 / 121 (0.00%)	0 / 22 (0.00%)	0 / 198 (0.00%)
occurrences (all)	0	0	0
Upper limb fracture			
subjects affected / exposed	0 / 121 (0.00%)	0 / 22 (0.00%)	0 / 198 (0.00%)
occurrences (all)	0	0	0
Congenital, familial and genetic disorders			
Factor V Leiden mutation			
subjects affected / exposed	0 / 121 (0.00%)	0 / 22 (0.00%)	0 / 198 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Palpitations			
subjects affected / exposed	0 / 121 (0.00%)	0 / 22 (0.00%)	1 / 198 (0.51%)
occurrences (all)	0	0	1
Nervous system disorders			

Headache			
subjects affected / exposed	8 / 121 (6.61%)	2 / 22 (9.09%)	3 / 198 (1.52%)
occurrences (all)	10	2	4
Syncope			
subjects affected / exposed	0 / 121 (0.00%)	0 / 22 (0.00%)	0 / 198 (0.00%)
occurrences (all)	0	0	0
Migraine			
subjects affected / exposed	1 / 121 (0.83%)	0 / 22 (0.00%)	0 / 198 (0.00%)
occurrences (all)	1	0	0
Burning sensation mucosal			
subjects affected / exposed	0 / 121 (0.00%)	0 / 22 (0.00%)	0 / 198 (0.00%)
occurrences (all)	0	0	0
Presyncope			
subjects affected / exposed	0 / 121 (0.00%)	1 / 22 (4.55%)	0 / 198 (0.00%)
occurrences (all)	0	1	0
Tremor			
subjects affected / exposed	0 / 121 (0.00%)	0 / 22 (0.00%)	1 / 198 (0.51%)
occurrences (all)	0	0	1
Blood and lymphatic system disorders			
Lymphadenopathy			
subjects affected / exposed	1 / 121 (0.83%)	0 / 22 (0.00%)	0 / 198 (0.00%)
occurrences (all)	2	0	0
Ear and labyrinth disorders			
Ear pain			
subjects affected / exposed	1 / 121 (0.83%)	0 / 22 (0.00%)	0 / 198 (0.00%)
occurrences (all)	1	0	0
Vertigo			
subjects affected / exposed	0 / 121 (0.00%)	0 / 22 (0.00%)	1 / 198 (0.51%)
occurrences (all)	0	0	1
Eye disorders			
Conjunctivitis			
subjects affected / exposed	0 / 121 (0.00%)	0 / 22 (0.00%)	3 / 198 (1.52%)
occurrences (all)	0	0	3
Eye inflammation			
subjects affected / exposed	1 / 121 (0.83%)	0 / 22 (0.00%)	0 / 198 (0.00%)
occurrences (all)	1	0	0
Eyelid cyst			

subjects affected / exposed	0 / 121 (0.00%)	0 / 22 (0.00%)	1 / 198 (0.51%)
occurrences (all)	0	0	1
Photophobia			
subjects affected / exposed	0 / 121 (0.00%)	0 / 22 (0.00%)	1 / 198 (0.51%)
occurrences (all)	0	0	1
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	2 / 121 (1.65%)	0 / 22 (0.00%)	2 / 198 (1.01%)
occurrences (all)	2	0	2
Diarrhoea			
subjects affected / exposed	0 / 121 (0.00%)	1 / 22 (4.55%)	1 / 198 (0.51%)
occurrences (all)	0	1	1
Dyspepsia			
subjects affected / exposed	0 / 121 (0.00%)	0 / 22 (0.00%)	1 / 198 (0.51%)
occurrences (all)	0	0	1
Glossodynia			
subjects affected / exposed	1 / 121 (0.83%)	0 / 22 (0.00%)	0 / 198 (0.00%)
occurrences (all)	1	0	0
Dental caries			
subjects affected / exposed	0 / 121 (0.00%)	0 / 22 (0.00%)	1 / 198 (0.51%)
occurrences (all)	0	0	1
Food poisoning			
subjects affected / exposed	0 / 121 (0.00%)	0 / 22 (0.00%)	0 / 198 (0.00%)
occurrences (all)	0	0	0
Gingivitis			
subjects affected / exposed	0 / 121 (0.00%)	0 / 22 (0.00%)	0 / 198 (0.00%)
occurrences (all)	0	0	0
Inguinal hernia			
subjects affected / exposed	0 / 121 (0.00%)	0 / 22 (0.00%)	0 / 198 (0.00%)
occurrences (all)	0	0	0
Irritable bowel syndrome			
subjects affected / exposed	0 / 121 (0.00%)	0 / 22 (0.00%)	1 / 198 (0.51%)
occurrences (all)	0	0	1
Mouth ulceration			
subjects affected / exposed	0 / 121 (0.00%)	1 / 22 (4.55%)	0 / 198 (0.00%)
occurrences (all)	0	1	0

Tooth impacted			
subjects affected / exposed	0 / 121 (0.00%)	0 / 22 (0.00%)	0 / 198 (0.00%)
occurrences (all)	0	0	0
Toothache			
subjects affected / exposed	1 / 121 (0.83%)	0 / 22 (0.00%)	0 / 198 (0.00%)
occurrences (all)	1	0	0
Vomiting			
subjects affected / exposed	1 / 121 (0.83%)	0 / 22 (0.00%)	0 / 198 (0.00%)
occurrences (all)	1	0	0
Skin and subcutaneous tissue disorders			
Dermatitis			
subjects affected / exposed	1 / 121 (0.83%)	0 / 22 (0.00%)	1 / 198 (0.51%)
occurrences (all)	1	0	1
Acne			
subjects affected / exposed	0 / 121 (0.00%)	0 / 22 (0.00%)	1 / 198 (0.51%)
occurrences (all)	0	0	1
Dermatitis allergic			
subjects affected / exposed	1 / 121 (0.83%)	0 / 22 (0.00%)	0 / 198 (0.00%)
occurrences (all)	1	0	0
Scar			
subjects affected / exposed	0 / 121 (0.00%)	1 / 22 (4.55%)	1 / 198 (0.51%)
occurrences (all)	0	1	1
Alopecia			
subjects affected / exposed	0 / 121 (0.00%)	0 / 22 (0.00%)	1 / 198 (0.51%)
occurrences (all)	0	0	1
Dermatitis atopic			
subjects affected / exposed	0 / 121 (0.00%)	0 / 22 (0.00%)	1 / 198 (0.51%)
occurrences (all)	0	0	1
Dermatitis contact			
subjects affected / exposed	0 / 121 (0.00%)	0 / 22 (0.00%)	1 / 198 (0.51%)
occurrences (all)	0	0	1
Drug eruption			
subjects affected / exposed	0 / 121 (0.00%)	0 / 22 (0.00%)	0 / 198 (0.00%)
occurrences (all)	0	0	0
Hangnail			

subjects affected / exposed	1 / 121 (0.83%)	0 / 22 (0.00%)	0 / 198 (0.00%)
occurrences (all)	1	0	0
Ingrowing nail			
subjects affected / exposed	1 / 121 (0.83%)	0 / 22 (0.00%)	0 / 198 (0.00%)
occurrences (all)	1	0	0
Photosensitivity reaction			
subjects affected / exposed	0 / 121 (0.00%)	0 / 22 (0.00%)	0 / 198 (0.00%)
occurrences (all)	0	0	0
Rash			
subjects affected / exposed	0 / 121 (0.00%)	0 / 22 (0.00%)	0 / 198 (0.00%)
occurrences (all)	0	0	0
Urticaria			
subjects affected / exposed	1 / 121 (0.83%)	0 / 22 (0.00%)	0 / 198 (0.00%)
occurrences (all)	1	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	1 / 121 (0.83%)	0 / 22 (0.00%)	1 / 198 (0.51%)
occurrences (all)	1	0	1
Back pain			
subjects affected / exposed	0 / 121 (0.00%)	1 / 22 (4.55%)	1 / 198 (0.51%)
occurrences (all)	0	1	1
Arthropathy			
subjects affected / exposed	0 / 121 (0.00%)	0 / 22 (0.00%)	0 / 198 (0.00%)
occurrences (all)	0	0	0
Costochondritis			
subjects affected / exposed	1 / 121 (0.83%)	0 / 22 (0.00%)	0 / 198 (0.00%)
occurrences (all)	1	0	0
Muscle contracture			
subjects affected / exposed	0 / 121 (0.00%)	0 / 22 (0.00%)	1 / 198 (0.51%)
occurrences (all)	0	0	1
Myalgia			
subjects affected / exposed	0 / 121 (0.00%)	0 / 22 (0.00%)	0 / 198 (0.00%)
occurrences (all)	0	0	0
Neck pain			

subjects affected / exposed	0 / 121 (0.00%)	0 / 22 (0.00%)	0 / 198 (0.00%)
occurrences (all)	0	0	0
Pain in extremity			
subjects affected / exposed	1 / 121 (0.83%)	0 / 22 (0.00%)	0 / 198 (0.00%)
occurrences (all)	1	0	0
Tendonitis			
subjects affected / exposed	1 / 121 (0.83%)	0 / 22 (0.00%)	0 / 198 (0.00%)
occurrences (all)	1	0	0
Torticollis			
subjects affected / exposed	0 / 121 (0.00%)	0 / 22 (0.00%)	0 / 198 (0.00%)
occurrences (all)	0	0	0
Rheumatoid arthritis			
subjects affected / exposed	0 / 121 (0.00%)	0 / 22 (0.00%)	0 / 198 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Upper respiratory tract infection			
subjects affected / exposed	20 / 121 (16.53%)	13 / 22 (59.09%)	28 / 198 (14.14%)
occurrences (all)	27	16	35
Pharyngitis			
subjects affected / exposed	5 / 121 (4.13%)	0 / 22 (0.00%)	4 / 198 (2.02%)
occurrences (all)	5	0	4
Tonsillitis			
subjects affected / exposed	1 / 121 (0.83%)	1 / 22 (4.55%)	5 / 198 (2.53%)
occurrences (all)	1	1	5
Gastroenteritis			
subjects affected / exposed	3 / 121 (2.48%)	0 / 22 (0.00%)	5 / 198 (2.53%)
occurrences (all)	3	0	6
Nasopharyngitis			
subjects affected / exposed	0 / 121 (0.00%)	0 / 22 (0.00%)	8 / 198 (4.04%)
occurrences (all)	0	0	9
Bronchitis			
subjects affected / exposed	1 / 121 (0.83%)	0 / 22 (0.00%)	3 / 198 (1.52%)
occurrences (all)	1	0	3
Respiratory tract infection			
subjects affected / exposed	4 / 121 (3.31%)	0 / 22 (0.00%)	2 / 198 (1.01%)
occurrences (all)	4	0	2

Rhinitis			
subjects affected / exposed	1 / 121 (0.83%)	0 / 22 (0.00%)	4 / 198 (2.02%)
occurrences (all)	1	0	4
Viral infection			
subjects affected / exposed	2 / 121 (1.65%)	4 / 22 (18.18%)	1 / 198 (0.51%)
occurrences (all)	2	4	1
Ear infection			
subjects affected / exposed	0 / 121 (0.00%)	0 / 22 (0.00%)	1 / 198 (0.51%)
occurrences (all)	0	0	1
Influenza			
subjects affected / exposed	1 / 121 (0.83%)	0 / 22 (0.00%)	1 / 198 (0.51%)
occurrences (all)	1	0	1
Laryngitis			
subjects affected / exposed	0 / 121 (0.00%)	1 / 22 (4.55%)	1 / 198 (0.51%)
occurrences (all)	0	1	1
Lower respiratory tract infection			
subjects affected / exposed	3 / 121 (2.48%)	0 / 22 (0.00%)	0 / 198 (0.00%)
occurrences (all)	3	0	0
Urinary tract infection			
subjects affected / exposed	0 / 121 (0.00%)	0 / 22 (0.00%)	0 / 198 (0.00%)
occurrences (all)	0	0	0
Acute tonsillitis			
subjects affected / exposed	1 / 121 (0.83%)	0 / 22 (0.00%)	1 / 198 (0.51%)
occurrences (all)	1	0	1
H1N1 influenza			
subjects affected / exposed	0 / 121 (0.00%)	0 / 22 (0.00%)	1 / 198 (0.51%)
occurrences (all)	0	0	1
Mumps			
subjects affected / exposed	0 / 121 (0.00%)	0 / 22 (0.00%)	2 / 198 (1.01%)
occurrences (all)	0	0	2
Otitis media			
subjects affected / exposed	1 / 121 (0.83%)	0 / 22 (0.00%)	0 / 198 (0.00%)
occurrences (all)	1	0	0
Respiratory tract infection viral			
subjects affected / exposed	1 / 121 (0.83%)	0 / 22 (0.00%)	0 / 198 (0.00%)
occurrences (all)	1	0	0

Sinusitis			
subjects affected / exposed	0 / 121 (0.00%)	1 / 22 (4.55%)	0 / 198 (0.00%)
occurrences (all)	0	1	0
Acarodermatitis			
subjects affected / exposed	0 / 121 (0.00%)	0 / 22 (0.00%)	0 / 198 (0.00%)
occurrences (all)	0	0	0
Cellulitis			
subjects affected / exposed	0 / 121 (0.00%)	0 / 22 (0.00%)	1 / 198 (0.51%)
occurrences (all)	0	0	1
Gastritis viral			
subjects affected / exposed	1 / 121 (0.83%)	0 / 22 (0.00%)	0 / 198 (0.00%)
occurrences (all)	1	0	0
Gastroenteritis viral			
subjects affected / exposed	0 / 121 (0.00%)	1 / 22 (4.55%)	0 / 198 (0.00%)
occurrences (all)	0	1	0
Herpes simplex			
subjects affected / exposed	0 / 121 (0.00%)	0 / 22 (0.00%)	1 / 198 (0.51%)
occurrences (all)	0	0	1
Impetigo			
subjects affected / exposed	1 / 121 (0.83%)	0 / 22 (0.00%)	0 / 198 (0.00%)
occurrences (all)	1	0	0
Pertussis			
subjects affected / exposed	0 / 121 (0.00%)	0 / 22 (0.00%)	0 / 198 (0.00%)
occurrences (all)	0	0	0
Pneumonia			
subjects affected / exposed	1 / 121 (0.83%)	0 / 22 (0.00%)	0 / 198 (0.00%)
occurrences (all)	1	0	0
Pulpitis dental			
subjects affected / exposed	1 / 121 (0.83%)	0 / 22 (0.00%)	0 / 198 (0.00%)
occurrences (all)	1	0	0
Pyelonephritis			
subjects affected / exposed	0 / 121 (0.00%)	0 / 22 (0.00%)	1 / 198 (0.51%)
occurrences (all)	0	0	1
Subcutaneous abscess			
subjects affected / exposed	0 / 121 (0.00%)	0 / 22 (0.00%)	1 / 198 (0.51%)
occurrences (all)	0	0	1

Viral upper respiratory tract infection			
subjects affected / exposed	0 / 121 (0.00%)	0 / 22 (0.00%)	0 / 198 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	0 / 121 (0.00%)	0 / 22 (0.00%)	0 / 198 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	rLP2086 200 mcg-Stage 1	Control-Stage 1 Follow-up	rLP2086 60 mcg-Stage 1 Follow up
Total subjects affected by non-serious adverse events			
subjects affected / exposed	91 / 195 (46.67%)	5 / 121 (4.13%)	3 / 22 (13.64%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Fibroma			
subjects affected / exposed	0 / 195 (0.00%)	0 / 121 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Influenza like illness			
subjects affected / exposed	4 / 195 (2.05%)	0 / 121 (0.00%)	0 / 22 (0.00%)
occurrences (all)	4	0	0
Injection site pain			
subjects affected / exposed	3 / 195 (1.54%)	0 / 121 (0.00%)	0 / 22 (0.00%)
occurrences (all)	3	0	0
Pyrexia			
subjects affected / exposed	2 / 195 (1.03%)	0 / 121 (0.00%)	0 / 22 (0.00%)
occurrences (all)	2	0	0
Injection site swelling			
subjects affected / exposed	1 / 195 (0.51%)	0 / 121 (0.00%)	0 / 22 (0.00%)
occurrences (all)	1	0	0
Chest pain			
subjects affected / exposed	0 / 195 (0.00%)	0 / 121 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Hypothermia			
subjects affected / exposed	0 / 195 (0.00%)	0 / 121 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Injection site dermatitis			

subjects affected / exposed	0 / 195 (0.00%)	0 / 121 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Injection site erythema			
subjects affected / exposed	1 / 195 (0.51%)	0 / 121 (0.00%)	0 / 22 (0.00%)
occurrences (all)	1	0	0
Injection site haematoma			
subjects affected / exposed	1 / 195 (0.51%)	0 / 121 (0.00%)	0 / 22 (0.00%)
occurrences (all)	1	0	0
Injection site pallor			
subjects affected / exposed	0 / 195 (0.00%)	0 / 121 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Injection site paraesthesia			
subjects affected / exposed	0 / 195 (0.00%)	0 / 121 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Injection site pruritus			
subjects affected / exposed	0 / 195 (0.00%)	0 / 121 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Vaccination site pallor			
subjects affected / exposed	1 / 195 (0.51%)	0 / 121 (0.00%)	0 / 22 (0.00%)
occurrences (all)	1	0	0
Vessel puncture site haematoma			
subjects affected / exposed	0 / 195 (0.00%)	0 / 121 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			
Allergy to animal			
subjects affected / exposed	1 / 195 (0.51%)	0 / 121 (0.00%)	0 / 22 (0.00%)
occurrences (all)	1	0	0
Allergy to chemicals			
subjects affected / exposed	0 / 195 (0.00%)	0 / 121 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Seasonal allergy			
subjects affected / exposed	0 / 195 (0.00%)	0 / 121 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			

Dysmenorrhoea			
subjects affected / exposed	2 / 195 (1.03%)	0 / 121 (0.00%)	0 / 22 (0.00%)
occurrences (all)	2	0	0
Penile discharge			
subjects affected / exposed	1 / 195 (0.51%)	0 / 121 (0.00%)	0 / 22 (0.00%)
occurrences (all)	1	0	0
Respiratory, thoracic and mediastinal disorders			
Oropharyngeal pain			
subjects affected / exposed	4 / 195 (2.05%)	0 / 121 (0.00%)	0 / 22 (0.00%)
occurrences (all)	4	0	0
Rhinorrhoea			
subjects affected / exposed	1 / 195 (0.51%)	0 / 121 (0.00%)	0 / 22 (0.00%)
occurrences (all)	1	0	0
Cough			
subjects affected / exposed	1 / 195 (0.51%)	0 / 121 (0.00%)	0 / 22 (0.00%)
occurrences (all)	1	0	0
Asthma			
subjects affected / exposed	2 / 195 (1.03%)	0 / 121 (0.00%)	0 / 22 (0.00%)
occurrences (all)	2	0	0
Rhinitis allergic			
subjects affected / exposed	1 / 195 (0.51%)	0 / 121 (0.00%)	0 / 22 (0.00%)
occurrences (all)	1	0	0
Asthma exercise induced			
subjects affected / exposed	1 / 195 (0.51%)	0 / 121 (0.00%)	0 / 22 (0.00%)
occurrences (all)	1	0	0
Epistaxis			
subjects affected / exposed	1 / 195 (0.51%)	0 / 121 (0.00%)	0 / 22 (0.00%)
occurrences (all)	1	0	0
Psychiatric disorders			
Abnormal behaviour			
subjects affected / exposed	0 / 195 (0.00%)	0 / 121 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Investigations			
Blood iron decreased			
subjects affected / exposed	0 / 195 (0.00%)	0 / 121 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0

Electrocardiogram QT prolonged			
subjects affected / exposed	0 / 195 (0.00%)	1 / 121 (0.83%)	0 / 22 (0.00%)
occurrences (all)	0	1	0
Injury, poisoning and procedural complications			
Contusion			
subjects affected / exposed	0 / 195 (0.00%)	0 / 121 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Thermal burn			
subjects affected / exposed	1 / 195 (0.51%)	1 / 121 (0.83%)	0 / 22 (0.00%)
occurrences (all)	1	1	0
Skin laceration			
subjects affected / exposed	2 / 195 (1.03%)	0 / 121 (0.00%)	0 / 22 (0.00%)
occurrences (all)	2	0	0
Arthropod bite			
subjects affected / exposed	0 / 195 (0.00%)	0 / 121 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Concussion			
subjects affected / exposed	0 / 195 (0.00%)	0 / 121 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Foot fracture			
subjects affected / exposed	0 / 195 (0.00%)	0 / 121 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Joint sprain			
subjects affected / exposed	0 / 195 (0.00%)	0 / 121 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Procedural pain			
subjects affected / exposed	0 / 195 (0.00%)	0 / 121 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Radius fracture			
subjects affected / exposed	1 / 195 (0.51%)	0 / 121 (0.00%)	0 / 22 (0.00%)
occurrences (all)	1	0	0
Road traffic accident			
subjects affected / exposed	1 / 195 (0.51%)	0 / 121 (0.00%)	0 / 22 (0.00%)
occurrences (all)	1	0	0
Soft tissue injury			

subjects affected / exposed	2 / 195 (1.03%)	0 / 121 (0.00%)	0 / 22 (0.00%)
occurrences (all)	2	0	0
Whiplash injury			
subjects affected / exposed	1 / 195 (0.51%)	0 / 121 (0.00%)	0 / 22 (0.00%)
occurrences (all)	1	0	0
Wrist fracture			
subjects affected / exposed	1 / 195 (0.51%)	0 / 121 (0.00%)	0 / 22 (0.00%)
occurrences (all)	1	0	0
Ankle fracture			
subjects affected / exposed	0 / 195 (0.00%)	0 / 121 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Back injury			
subjects affected / exposed	1 / 195 (0.51%)	0 / 121 (0.00%)	0 / 22 (0.00%)
occurrences (all)	1	0	0
Chemical burn of skin			
subjects affected / exposed	0 / 195 (0.00%)	0 / 121 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Chest injury			
subjects affected / exposed	0 / 195 (0.00%)	0 / 121 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Foreign body			
subjects affected / exposed	0 / 195 (0.00%)	0 / 121 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Head injury			
subjects affected / exposed	0 / 195 (0.00%)	0 / 121 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Ligament injury			
subjects affected / exposed	0 / 195 (0.00%)	0 / 121 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Poisoning			
subjects affected / exposed	0 / 195 (0.00%)	0 / 121 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Post concussion syndrome			
subjects affected / exposed	0 / 195 (0.00%)	0 / 121 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Post procedural haematoma			

subjects affected / exposed	0 / 195 (0.00%)	0 / 121 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Skeletal injury			
subjects affected / exposed	1 / 195 (0.51%)	0 / 121 (0.00%)	0 / 22 (0.00%)
occurrences (all)	1	0	0
Ulna fracture			
subjects affected / exposed	0 / 195 (0.00%)	0 / 121 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Hand fracture			
subjects affected / exposed	0 / 195 (0.00%)	1 / 121 (0.83%)	0 / 22 (0.00%)
occurrences (all)	0	1	0
Limb injury			
subjects affected / exposed	0 / 195 (0.00%)	1 / 121 (0.83%)	0 / 22 (0.00%)
occurrences (all)	0	1	0
Upper limb fracture			
subjects affected / exposed	0 / 195 (0.00%)	1 / 121 (0.83%)	0 / 22 (0.00%)
occurrences (all)	0	1	0
Congenital, familial and genetic disorders			
Factor V Leiden mutation			
subjects affected / exposed	0 / 195 (0.00%)	0 / 121 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Palpitations			
subjects affected / exposed	0 / 195 (0.00%)	0 / 121 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Headache			
subjects affected / exposed	2 / 195 (1.03%)	0 / 121 (0.00%)	0 / 22 (0.00%)
occurrences (all)	2	0	0
Syncope			
subjects affected / exposed	4 / 195 (2.05%)	0 / 121 (0.00%)	0 / 22 (0.00%)
occurrences (all)	4	0	0
Migraine			
subjects affected / exposed	1 / 195 (0.51%)	0 / 121 (0.00%)	0 / 22 (0.00%)
occurrences (all)	2	0	0
Burning sensation mucosal			

subjects affected / exposed	1 / 195 (0.51%)	0 / 121 (0.00%)	0 / 22 (0.00%)
occurrences (all)	1	0	0
Presyncope			
subjects affected / exposed	0 / 195 (0.00%)	0 / 121 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Tremor			
subjects affected / exposed	0 / 195 (0.00%)	0 / 121 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Lymphadenopathy			
subjects affected / exposed	1 / 195 (0.51%)	0 / 121 (0.00%)	0 / 22 (0.00%)
occurrences (all)	1	0	0
Ear and labyrinth disorders			
Ear pain			
subjects affected / exposed	0 / 195 (0.00%)	0 / 121 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Vertigo			
subjects affected / exposed	0 / 195 (0.00%)	0 / 121 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Conjunctivitis			
subjects affected / exposed	2 / 195 (1.03%)	0 / 121 (0.00%)	0 / 22 (0.00%)
occurrences (all)	2	0	0
Eye inflammation			
subjects affected / exposed	0 / 195 (0.00%)	0 / 121 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Eyelid cyst			
subjects affected / exposed	0 / 195 (0.00%)	0 / 121 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Photophobia			
subjects affected / exposed	0 / 195 (0.00%)	0 / 121 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	3 / 195 (1.54%)	0 / 121 (0.00%)	0 / 22 (0.00%)
occurrences (all)	3	0	0
Diarrhoea			

subjects affected / exposed	4 / 195 (2.05%)	0 / 121 (0.00%)	0 / 22 (0.00%)
occurrences (all)	4	0	0
Dyspepsia			
subjects affected / exposed	1 / 195 (0.51%)	0 / 121 (0.00%)	0 / 22 (0.00%)
occurrences (all)	1	0	0
Glossodynia			
subjects affected / exposed	1 / 195 (0.51%)	0 / 121 (0.00%)	0 / 22 (0.00%)
occurrences (all)	1	0	0
Dental caries			
subjects affected / exposed	0 / 195 (0.00%)	0 / 121 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Food poisoning			
subjects affected / exposed	1 / 195 (0.51%)	0 / 121 (0.00%)	0 / 22 (0.00%)
occurrences (all)	1	0	0
Gingivitis			
subjects affected / exposed	1 / 195 (0.51%)	0 / 121 (0.00%)	0 / 22 (0.00%)
occurrences (all)	1	0	0
Inguinal hernia			
subjects affected / exposed	1 / 195 (0.51%)	0 / 121 (0.00%)	0 / 22 (0.00%)
occurrences (all)	1	0	0
Irritable bowel syndrome			
subjects affected / exposed	0 / 195 (0.00%)	0 / 121 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Mouth ulceration			
subjects affected / exposed	0 / 195 (0.00%)	0 / 121 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Tooth impacted			
subjects affected / exposed	1 / 195 (0.51%)	0 / 121 (0.00%)	0 / 22 (0.00%)
occurrences (all)	1	0	0
Toothache			
subjects affected / exposed	0 / 195 (0.00%)	0 / 121 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	0 / 195 (0.00%)	0 / 121 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			

Dermatitis			
subjects affected / exposed	1 / 195 (0.51%)	0 / 121 (0.00%)	0 / 22 (0.00%)
occurrences (all)	1	0	0
Acne			
subjects affected / exposed	1 / 195 (0.51%)	0 / 121 (0.00%)	0 / 22 (0.00%)
occurrences (all)	1	0	0
Dermatitis allergic			
subjects affected / exposed	1 / 195 (0.51%)	0 / 121 (0.00%)	0 / 22 (0.00%)
occurrences (all)	1	0	0
Scar			
subjects affected / exposed	0 / 195 (0.00%)	0 / 121 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Alopecia			
subjects affected / exposed	0 / 195 (0.00%)	0 / 121 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Dermatitis atopic			
subjects affected / exposed	0 / 195 (0.00%)	0 / 121 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Dermatitis contact			
subjects affected / exposed	0 / 195 (0.00%)	0 / 121 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Drug eruption			
subjects affected / exposed	1 / 195 (0.51%)	0 / 121 (0.00%)	0 / 22 (0.00%)
occurrences (all)	2	0	0
Hangnail			
subjects affected / exposed	0 / 195 (0.00%)	0 / 121 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Ingrowing nail			
subjects affected / exposed	0 / 195 (0.00%)	0 / 121 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Photosensitivity reaction			
subjects affected / exposed	1 / 195 (0.51%)	0 / 121 (0.00%)	0 / 22 (0.00%)
occurrences (all)	1	0	0
Rash			
subjects affected / exposed	1 / 195 (0.51%)	0 / 121 (0.00%)	0 / 22 (0.00%)
occurrences (all)	1	0	0

Urticaria			
subjects affected / exposed	0 / 195 (0.00%)	0 / 121 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	1 / 195 (0.51%)	0 / 121 (0.00%)	0 / 22 (0.00%)
occurrences (all)	1	0	0
Back pain			
subjects affected / exposed	0 / 195 (0.00%)	0 / 121 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Arthropathy			
subjects affected / exposed	1 / 195 (0.51%)	0 / 121 (0.00%)	0 / 22 (0.00%)
occurrences (all)	1	0	0
Costochondritis			
subjects affected / exposed	0 / 195 (0.00%)	0 / 121 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Muscle contracture			
subjects affected / exposed	0 / 195 (0.00%)	0 / 121 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Myalgia			
subjects affected / exposed	1 / 195 (0.51%)	0 / 121 (0.00%)	1 / 22 (4.55%)
occurrences (all)	1	0	1
Neck pain			
subjects affected / exposed	1 / 195 (0.51%)	0 / 121 (0.00%)	0 / 22 (0.00%)
occurrences (all)	1	0	0
Pain in extremity			
subjects affected / exposed	0 / 195 (0.00%)	0 / 121 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Tendonitis			
subjects affected / exposed	0 / 195 (0.00%)	0 / 121 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Torticollis			
subjects affected / exposed	1 / 195 (0.51%)	0 / 121 (0.00%)	0 / 22 (0.00%)
occurrences (all)	1	0	0
Rheumatoid arthritis			

subjects affected / exposed	0 / 195 (0.00%)	0 / 121 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Upper respiratory tract infection			
subjects affected / exposed	21 / 195 (10.77%)	0 / 121 (0.00%)	1 / 22 (4.55%)
occurrences (all)	29	0	1
Pharyngitis			
subjects affected / exposed	10 / 195 (5.13%)	0 / 121 (0.00%)	0 / 22 (0.00%)
occurrences (all)	11	0	0
Tonsillitis			
subjects affected / exposed	7 / 195 (3.59%)	0 / 121 (0.00%)	0 / 22 (0.00%)
occurrences (all)	11	0	0
Gastroenteritis			
subjects affected / exposed	4 / 195 (2.05%)	0 / 121 (0.00%)	0 / 22 (0.00%)
occurrences (all)	4	0	0
Nasopharyngitis			
subjects affected / exposed	3 / 195 (1.54%)	0 / 121 (0.00%)	0 / 22 (0.00%)
occurrences (all)	3	0	0
Bronchitis			
subjects affected / exposed	4 / 195 (2.05%)	0 / 121 (0.00%)	0 / 22 (0.00%)
occurrences (all)	5	0	0
Respiratory tract infection			
subjects affected / exposed	1 / 195 (0.51%)	0 / 121 (0.00%)	0 / 22 (0.00%)
occurrences (all)	1	0	0
Rhinitis			
subjects affected / exposed	2 / 195 (1.03%)	0 / 121 (0.00%)	0 / 22 (0.00%)
occurrences (all)	2	0	0
Viral infection			
subjects affected / exposed	0 / 195 (0.00%)	0 / 121 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Ear infection			
subjects affected / exposed	2 / 195 (1.03%)	0 / 121 (0.00%)	0 / 22 (0.00%)
occurrences (all)	2	0	0
Influenza			
subjects affected / exposed	1 / 195 (0.51%)	0 / 121 (0.00%)	0 / 22 (0.00%)
occurrences (all)	1	0	0

Laryngitis			
subjects affected / exposed	1 / 195 (0.51%)	0 / 121 (0.00%)	0 / 22 (0.00%)
occurrences (all)	1	0	0
Lower respiratory tract infection			
subjects affected / exposed	0 / 195 (0.00%)	0 / 121 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Urinary tract infection			
subjects affected / exposed	3 / 195 (1.54%)	1 / 121 (0.83%)	0 / 22 (0.00%)
occurrences (all)	3	1	0
Acute tonsillitis			
subjects affected / exposed	0 / 195 (0.00%)	0 / 121 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
H1N1 influenza			
subjects affected / exposed	1 / 195 (0.51%)	0 / 121 (0.00%)	0 / 22 (0.00%)
occurrences (all)	1	0	0
Mumps			
subjects affected / exposed	0 / 195 (0.00%)	0 / 121 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Otitis media			
subjects affected / exposed	1 / 195 (0.51%)	0 / 121 (0.00%)	1 / 22 (4.55%)
occurrences (all)	1	0	1
Respiratory tract infection viral			
subjects affected / exposed	1 / 195 (0.51%)	0 / 121 (0.00%)	0 / 22 (0.00%)
occurrences (all)	1	0	0
Sinusitis			
subjects affected / exposed	1 / 195 (0.51%)	0 / 121 (0.00%)	0 / 22 (0.00%)
occurrences (all)	1	0	0
Acarodermatitis			
subjects affected / exposed	1 / 195 (0.51%)	0 / 121 (0.00%)	0 / 22 (0.00%)
occurrences (all)	1	0	0
Cellulitis			
subjects affected / exposed	0 / 195 (0.00%)	0 / 121 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Gastritis viral			
subjects affected / exposed	0 / 195 (0.00%)	0 / 121 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0

Gastroenteritis viral			
subjects affected / exposed	0 / 195 (0.00%)	0 / 121 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Herpes simplex			
subjects affected / exposed	0 / 195 (0.00%)	0 / 121 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Impetigo			
subjects affected / exposed	0 / 195 (0.00%)	0 / 121 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Pertussis			
subjects affected / exposed	1 / 195 (0.51%)	0 / 121 (0.00%)	0 / 22 (0.00%)
occurrences (all)	1	0	0
Pneumonia			
subjects affected / exposed	0 / 195 (0.00%)	0 / 121 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Pulpitis dental			
subjects affected / exposed	0 / 195 (0.00%)	0 / 121 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Pyelonephritis			
subjects affected / exposed	0 / 195 (0.00%)	0 / 121 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Subcutaneous abscess			
subjects affected / exposed	0 / 195 (0.00%)	0 / 121 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Viral upper respiratory tract infection			
subjects affected / exposed	1 / 195 (0.51%)	0 / 121 (0.00%)	0 / 22 (0.00%)
occurrences (all)	1	0	0
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	1 / 195 (0.51%)	0 / 121 (0.00%)	0 / 22 (0.00%)
occurrences (all)	1	0	0

Non-serious adverse events	rLP2086 120 mcg-Stage 1 Follow up	rLP2086 200 mcg-Stage 1 Follow up	Control- Stage 2
Total subjects affected by non-serious adverse events			
subjects affected / exposed	2 / 198 (1.01%)	4 / 195 (2.05%)	1 / 80 (1.25%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			

Fibroma			
subjects affected / exposed	0 / 198 (0.00%)	0 / 195 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Influenza like illness			
subjects affected / exposed	0 / 198 (0.00%)	0 / 195 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Injection site pain			
subjects affected / exposed	0 / 198 (0.00%)	0 / 195 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
subjects affected / exposed	0 / 198 (0.00%)	0 / 195 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Injection site swelling			
subjects affected / exposed	0 / 198 (0.00%)	0 / 195 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Chest pain			
subjects affected / exposed	0 / 198 (0.00%)	0 / 195 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Hypothermia			
subjects affected / exposed	0 / 198 (0.00%)	0 / 195 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Injection site dermatitis			
subjects affected / exposed	0 / 198 (0.00%)	0 / 195 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Injection site erythema			
subjects affected / exposed	0 / 198 (0.00%)	0 / 195 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Injection site haematoma			
subjects affected / exposed	0 / 198 (0.00%)	0 / 195 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Injection site pallor			
subjects affected / exposed	0 / 198 (0.00%)	0 / 195 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Injection site paraesthesia			

subjects affected / exposed	0 / 198 (0.00%)	0 / 195 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Injection site pruritus			
subjects affected / exposed	0 / 198 (0.00%)	0 / 195 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Vaccination site pallor			
subjects affected / exposed	0 / 198 (0.00%)	0 / 195 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Vessel puncture site haematoma			
subjects affected / exposed	0 / 198 (0.00%)	0 / 195 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			
Allergy to animal			
subjects affected / exposed	0 / 198 (0.00%)	0 / 195 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Allergy to chemicals			
subjects affected / exposed	0 / 198 (0.00%)	0 / 195 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Seasonal allergy			
subjects affected / exposed	0 / 198 (0.00%)	0 / 195 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Dysmenorrhoea			
subjects affected / exposed	0 / 198 (0.00%)	0 / 195 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Penile discharge			
subjects affected / exposed	0 / 198 (0.00%)	0 / 195 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Oropharyngeal pain			
subjects affected / exposed	0 / 198 (0.00%)	0 / 195 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Rhinorrhoea			
subjects affected / exposed	0 / 198 (0.00%)	0 / 195 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Cough			

subjects affected / exposed	0 / 198 (0.00%)	0 / 195 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Asthma			
subjects affected / exposed	0 / 198 (0.00%)	0 / 195 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Rhinitis allergic			
subjects affected / exposed	0 / 198 (0.00%)	0 / 195 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Asthma exercise induced			
subjects affected / exposed	0 / 198 (0.00%)	0 / 195 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Epistaxis			
subjects affected / exposed	0 / 198 (0.00%)	0 / 195 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Abnormal behaviour			
subjects affected / exposed	0 / 198 (0.00%)	0 / 195 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Investigations			
Blood iron decreased			
subjects affected / exposed	0 / 198 (0.00%)	0 / 195 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Electrocardiogram QT prolonged			
subjects affected / exposed	0 / 198 (0.00%)	1 / 195 (0.51%)	0 / 80 (0.00%)
occurrences (all)	0	1	0
Injury, poisoning and procedural complications			
Contusion			
subjects affected / exposed	0 / 198 (0.00%)	0 / 195 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Thermal burn			
subjects affected / exposed	0 / 198 (0.00%)	0 / 195 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Skin laceration			
subjects affected / exposed	0 / 198 (0.00%)	0 / 195 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Arthropod bite			

subjects affected / exposed	0 / 198 (0.00%)	0 / 195 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Concussion			
subjects affected / exposed	0 / 198 (0.00%)	0 / 195 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Foot fracture			
subjects affected / exposed	0 / 198 (0.00%)	0 / 195 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Joint sprain			
subjects affected / exposed	0 / 198 (0.00%)	0 / 195 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Procedural pain			
subjects affected / exposed	0 / 198 (0.00%)	0 / 195 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Radius fracture			
subjects affected / exposed	0 / 198 (0.00%)	0 / 195 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Road traffic accident			
subjects affected / exposed	0 / 198 (0.00%)	0 / 195 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Soft tissue injury			
subjects affected / exposed	0 / 198 (0.00%)	1 / 195 (0.51%)	0 / 80 (0.00%)
occurrences (all)	0	1	0
Whiplash injury			
subjects affected / exposed	0 / 198 (0.00%)	0 / 195 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Wrist fracture			
subjects affected / exposed	0 / 198 (0.00%)	0 / 195 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Ankle fracture			
subjects affected / exposed	0 / 198 (0.00%)	0 / 195 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Back injury			
subjects affected / exposed	0 / 198 (0.00%)	0 / 195 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Chemical burn of skin			

subjects affected / exposed	0 / 198 (0.00%)	0 / 195 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Chest injury			
subjects affected / exposed	0 / 198 (0.00%)	0 / 195 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Foreign body			
subjects affected / exposed	0 / 198 (0.00%)	0 / 195 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Head injury			
subjects affected / exposed	0 / 198 (0.00%)	1 / 195 (0.51%)	0 / 80 (0.00%)
occurrences (all)	0	1	0
Ligament injury			
subjects affected / exposed	0 / 198 (0.00%)	0 / 195 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Poisoning			
subjects affected / exposed	0 / 198 (0.00%)	0 / 195 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Post concussion syndrome			
subjects affected / exposed	0 / 198 (0.00%)	0 / 195 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Post procedural haematoma			
subjects affected / exposed	0 / 198 (0.00%)	0 / 195 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Skeletal injury			
subjects affected / exposed	0 / 198 (0.00%)	0 / 195 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Ulna fracture			
subjects affected / exposed	0 / 198 (0.00%)	0 / 195 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Hand fracture			
subjects affected / exposed	0 / 198 (0.00%)	0 / 195 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Limb injury			
subjects affected / exposed	0 / 198 (0.00%)	0 / 195 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Upper limb fracture			

subjects affected / exposed	0 / 198 (0.00%)	0 / 195 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Congenital, familial and genetic disorders			
Factor V Leiden mutation			
subjects affected / exposed	0 / 198 (0.00%)	0 / 195 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Palpitations			
subjects affected / exposed	0 / 198 (0.00%)	0 / 195 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Headache			
subjects affected / exposed	0 / 198 (0.00%)	0 / 195 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Syncope			
subjects affected / exposed	0 / 198 (0.00%)	0 / 195 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Migraine			
subjects affected / exposed	0 / 198 (0.00%)	0 / 195 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Burning sensation mucosal			
subjects affected / exposed	0 / 198 (0.00%)	0 / 195 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Presyncope			
subjects affected / exposed	0 / 198 (0.00%)	0 / 195 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Tremor			
subjects affected / exposed	0 / 198 (0.00%)	0 / 195 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Lymphadenopathy			
subjects affected / exposed	0 / 198 (0.00%)	0 / 195 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
Ear pain			

subjects affected / exposed	0 / 198 (0.00%)	0 / 195 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Vertigo			
subjects affected / exposed	0 / 198 (0.00%)	0 / 195 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Conjunctivitis			
subjects affected / exposed	0 / 198 (0.00%)	0 / 195 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Eye inflammation			
subjects affected / exposed	0 / 198 (0.00%)	0 / 195 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Eyelid cyst			
subjects affected / exposed	0 / 198 (0.00%)	0 / 195 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Photophobia			
subjects affected / exposed	0 / 198 (0.00%)	0 / 195 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	0 / 198 (0.00%)	0 / 195 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Diarrhoea			
subjects affected / exposed	0 / 198 (0.00%)	0 / 195 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Dyspepsia			
subjects affected / exposed	0 / 198 (0.00%)	0 / 195 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Glossodynia			
subjects affected / exposed	0 / 198 (0.00%)	0 / 195 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Dental caries			
subjects affected / exposed	0 / 198 (0.00%)	0 / 195 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Food poisoning			

subjects affected / exposed	0 / 198 (0.00%)	0 / 195 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Gingivitis			
subjects affected / exposed	0 / 198 (0.00%)	0 / 195 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Inguinal hernia			
subjects affected / exposed	0 / 198 (0.00%)	0 / 195 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Irritable bowel syndrome			
subjects affected / exposed	0 / 198 (0.00%)	0 / 195 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Mouth ulceration			
subjects affected / exposed	0 / 198 (0.00%)	0 / 195 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Tooth impacted			
subjects affected / exposed	0 / 198 (0.00%)	0 / 195 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Toothache			
subjects affected / exposed	0 / 198 (0.00%)	0 / 195 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	0 / 198 (0.00%)	0 / 195 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Dermatitis			
subjects affected / exposed	0 / 198 (0.00%)	0 / 195 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Acne			
subjects affected / exposed	0 / 198 (0.00%)	1 / 195 (0.51%)	0 / 80 (0.00%)
occurrences (all)	0	1	0
Dermatitis allergic			
subjects affected / exposed	0 / 198 (0.00%)	0 / 195 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Scar			
subjects affected / exposed	0 / 198 (0.00%)	0 / 195 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0

Alopecia			
subjects affected / exposed	0 / 198 (0.00%)	0 / 195 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Dermatitis atopic			
subjects affected / exposed	0 / 198 (0.00%)	0 / 195 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Dermatitis contact			
subjects affected / exposed	0 / 198 (0.00%)	0 / 195 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Drug eruption			
subjects affected / exposed	0 / 198 (0.00%)	0 / 195 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Hangnail			
subjects affected / exposed	0 / 198 (0.00%)	0 / 195 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Ingrowing nail			
subjects affected / exposed	0 / 198 (0.00%)	0 / 195 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Photosensitivity reaction			
subjects affected / exposed	0 / 198 (0.00%)	0 / 195 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Rash			
subjects affected / exposed	1 / 198 (0.51%)	0 / 195 (0.00%)	0 / 80 (0.00%)
occurrences (all)	1	0	0
Urticaria			
subjects affected / exposed	0 / 198 (0.00%)	0 / 195 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 198 (0.00%)	0 / 195 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Back pain			
subjects affected / exposed	0 / 198 (0.00%)	0 / 195 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Arthropathy			

subjects affected / exposed	0 / 198 (0.00%)	0 / 195 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Costochondritis			
subjects affected / exposed	0 / 198 (0.00%)	0 / 195 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Muscle contracture			
subjects affected / exposed	0 / 198 (0.00%)	0 / 195 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Myalgia			
subjects affected / exposed	0 / 198 (0.00%)	0 / 195 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Neck pain			
subjects affected / exposed	0 / 198 (0.00%)	0 / 195 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Pain in extremity			
subjects affected / exposed	0 / 198 (0.00%)	0 / 195 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Tendonitis			
subjects affected / exposed	0 / 198 (0.00%)	0 / 195 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Torticollis			
subjects affected / exposed	0 / 198 (0.00%)	0 / 195 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Rheumatoid arthritis			
subjects affected / exposed	0 / 198 (0.00%)	0 / 195 (0.00%)	1 / 80 (1.25%)
occurrences (all)	0	0	1
Infections and infestations			
Upper respiratory tract infection			
subjects affected / exposed	0 / 198 (0.00%)	0 / 195 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Pharyngitis			
subjects affected / exposed	0 / 198 (0.00%)	0 / 195 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Tonsillitis			
subjects affected / exposed	0 / 198 (0.00%)	0 / 195 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0

Gastroenteritis			
subjects affected / exposed	0 / 198 (0.00%)	0 / 195 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	0 / 198 (0.00%)	0 / 195 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Bronchitis			
subjects affected / exposed	0 / 198 (0.00%)	0 / 195 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Respiratory tract infection			
subjects affected / exposed	0 / 198 (0.00%)	0 / 195 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Rhinitis			
subjects affected / exposed	0 / 198 (0.00%)	0 / 195 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Viral infection			
subjects affected / exposed	0 / 198 (0.00%)	0 / 195 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Ear infection			
subjects affected / exposed	0 / 198 (0.00%)	0 / 195 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Influenza			
subjects affected / exposed	0 / 198 (0.00%)	0 / 195 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Laryngitis			
subjects affected / exposed	0 / 198 (0.00%)	0 / 195 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Lower respiratory tract infection			
subjects affected / exposed	0 / 198 (0.00%)	0 / 195 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Urinary tract infection			
subjects affected / exposed	0 / 198 (0.00%)	0 / 195 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Acute tonsillitis			
subjects affected / exposed	0 / 198 (0.00%)	0 / 195 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0

H1N1 influenza			
subjects affected / exposed	0 / 198 (0.00%)	0 / 195 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Mumps			
subjects affected / exposed	0 / 198 (0.00%)	0 / 195 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Otitis media			
subjects affected / exposed	0 / 198 (0.00%)	0 / 195 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Respiratory tract infection viral			
subjects affected / exposed	0 / 198 (0.00%)	0 / 195 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Sinusitis			
subjects affected / exposed	0 / 198 (0.00%)	0 / 195 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Acarodermatitis			
subjects affected / exposed	0 / 198 (0.00%)	0 / 195 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Cellulitis			
subjects affected / exposed	0 / 198 (0.00%)	0 / 195 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Gastritis viral			
subjects affected / exposed	0 / 198 (0.00%)	0 / 195 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis viral			
subjects affected / exposed	1 / 198 (0.51%)	0 / 195 (0.00%)	0 / 80 (0.00%)
occurrences (all)	1	0	0
Herpes simplex			
subjects affected / exposed	0 / 198 (0.00%)	0 / 195 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Impetigo			
subjects affected / exposed	0 / 198 (0.00%)	0 / 195 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Pertussis			
subjects affected / exposed	0 / 198 (0.00%)	0 / 195 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0

Pneumonia			
subjects affected / exposed	0 / 198 (0.00%)	0 / 195 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Pulpitis dental			
subjects affected / exposed	0 / 198 (0.00%)	0 / 195 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Pyelonephritis			
subjects affected / exposed	0 / 198 (0.00%)	0 / 195 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Subcutaneous abscess			
subjects affected / exposed	0 / 198 (0.00%)	0 / 195 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Viral upper respiratory tract infection			
subjects affected / exposed	0 / 198 (0.00%)	0 / 195 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	0 / 198 (0.00%)	0 / 195 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	rLP2086 120 mcg-Stage 2	rLP2086 200 mcg-Stage 2	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	1 / 170 (0.59%)	0 / 151 (0.00%)	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Fibroma			
subjects affected / exposed	0 / 170 (0.00%)	0 / 151 (0.00%)	
occurrences (all)	0	0	
General disorders and administration site conditions			
Influenza like illness			
subjects affected / exposed	0 / 170 (0.00%)	0 / 151 (0.00%)	
occurrences (all)	0	0	
Injection site pain			
subjects affected / exposed	0 / 170 (0.00%)	0 / 151 (0.00%)	
occurrences (all)	0	0	
Pyrexia			

subjects affected / exposed	0 / 170 (0.00%)	0 / 151 (0.00%)	
occurrences (all)	0	0	
Injection site swelling			
subjects affected / exposed	0 / 170 (0.00%)	0 / 151 (0.00%)	
occurrences (all)	0	0	
Chest pain			
subjects affected / exposed	0 / 170 (0.00%)	0 / 151 (0.00%)	
occurrences (all)	0	0	
Hypothermia			
subjects affected / exposed	0 / 170 (0.00%)	0 / 151 (0.00%)	
occurrences (all)	0	0	
Injection site dermatitis			
subjects affected / exposed	0 / 170 (0.00%)	0 / 151 (0.00%)	
occurrences (all)	0	0	
Injection site erythema			
subjects affected / exposed	0 / 170 (0.00%)	0 / 151 (0.00%)	
occurrences (all)	0	0	
Injection site haematoma			
subjects affected / exposed	0 / 170 (0.00%)	0 / 151 (0.00%)	
occurrences (all)	0	0	
Injection site pallor			
subjects affected / exposed	0 / 170 (0.00%)	0 / 151 (0.00%)	
occurrences (all)	0	0	
Injection site paraesthesia			
subjects affected / exposed	0 / 170 (0.00%)	0 / 151 (0.00%)	
occurrences (all)	0	0	
Injection site pruritus			
subjects affected / exposed	0 / 170 (0.00%)	0 / 151 (0.00%)	
occurrences (all)	0	0	
Vaccination site pallor			
subjects affected / exposed	0 / 170 (0.00%)	0 / 151 (0.00%)	
occurrences (all)	0	0	
Vessel puncture site haematoma			
subjects affected / exposed	0 / 170 (0.00%)	0 / 151 (0.00%)	
occurrences (all)	0	0	
Immune system disorders			

Allergy to animal			
subjects affected / exposed	0 / 170 (0.00%)	0 / 151 (0.00%)	
occurrences (all)	0	0	
Allergy to chemicals			
subjects affected / exposed	0 / 170 (0.00%)	0 / 151 (0.00%)	
occurrences (all)	0	0	
Seasonal allergy			
subjects affected / exposed	0 / 170 (0.00%)	0 / 151 (0.00%)	
occurrences (all)	0	0	
Reproductive system and breast disorders			
Dysmenorrhoea			
subjects affected / exposed	0 / 170 (0.00%)	0 / 151 (0.00%)	
occurrences (all)	0	0	
Penile discharge			
subjects affected / exposed	0 / 170 (0.00%)	0 / 151 (0.00%)	
occurrences (all)	0	0	
Respiratory, thoracic and mediastinal disorders			
Oropharyngeal pain			
subjects affected / exposed	0 / 170 (0.00%)	0 / 151 (0.00%)	
occurrences (all)	0	0	
Rhinorrhoea			
subjects affected / exposed	0 / 170 (0.00%)	0 / 151 (0.00%)	
occurrences (all)	0	0	
Cough			
subjects affected / exposed	0 / 170 (0.00%)	0 / 151 (0.00%)	
occurrences (all)	0	0	
Asthma			
subjects affected / exposed	0 / 170 (0.00%)	0 / 151 (0.00%)	
occurrences (all)	0	0	
Rhinitis allergic			
subjects affected / exposed	0 / 170 (0.00%)	0 / 151 (0.00%)	
occurrences (all)	0	0	
Asthma exercise induced			
subjects affected / exposed	0 / 170 (0.00%)	0 / 151 (0.00%)	
occurrences (all)	0	0	
Epistaxis			

subjects affected / exposed	0 / 170 (0.00%)	0 / 151 (0.00%)	
occurrences (all)	0	0	
Psychiatric disorders			
Abnormal behaviour			
subjects affected / exposed	0 / 170 (0.00%)	0 / 151 (0.00%)	
occurrences (all)	0	0	
Investigations			
Blood iron decreased			
subjects affected / exposed	0 / 170 (0.00%)	0 / 151 (0.00%)	
occurrences (all)	0	0	
Electrocardiogram QT prolonged			
subjects affected / exposed	0 / 170 (0.00%)	0 / 151 (0.00%)	
occurrences (all)	0	0	
Injury, poisoning and procedural complications			
Contusion			
subjects affected / exposed	0 / 170 (0.00%)	0 / 151 (0.00%)	
occurrences (all)	0	0	
Thermal burn			
subjects affected / exposed	0 / 170 (0.00%)	0 / 151 (0.00%)	
occurrences (all)	0	0	
Skin laceration			
subjects affected / exposed	0 / 170 (0.00%)	0 / 151 (0.00%)	
occurrences (all)	0	0	
Arthropod bite			
subjects affected / exposed	0 / 170 (0.00%)	0 / 151 (0.00%)	
occurrences (all)	0	0	
Concussion			
subjects affected / exposed	0 / 170 (0.00%)	0 / 151 (0.00%)	
occurrences (all)	0	0	
Foot fracture			
subjects affected / exposed	0 / 170 (0.00%)	0 / 151 (0.00%)	
occurrences (all)	0	0	
Joint sprain			
subjects affected / exposed	0 / 170 (0.00%)	0 / 151 (0.00%)	
occurrences (all)	0	0	
Procedural pain			

subjects affected / exposed	0 / 170 (0.00%)	0 / 151 (0.00%)	
occurrences (all)	0	0	
Radius fracture			
subjects affected / exposed	0 / 170 (0.00%)	0 / 151 (0.00%)	
occurrences (all)	0	0	
Road traffic accident			
subjects affected / exposed	0 / 170 (0.00%)	0 / 151 (0.00%)	
occurrences (all)	0	0	
Soft tissue injury			
subjects affected / exposed	0 / 170 (0.00%)	0 / 151 (0.00%)	
occurrences (all)	0	0	
Whiplash injury			
subjects affected / exposed	0 / 170 (0.00%)	0 / 151 (0.00%)	
occurrences (all)	0	0	
Wrist fracture			
subjects affected / exposed	0 / 170 (0.00%)	0 / 151 (0.00%)	
occurrences (all)	0	0	
Ankle fracture			
subjects affected / exposed	0 / 170 (0.00%)	0 / 151 (0.00%)	
occurrences (all)	0	0	
Back injury			
subjects affected / exposed	0 / 170 (0.00%)	0 / 151 (0.00%)	
occurrences (all)	0	0	
Chemical burn of skin			
subjects affected / exposed	0 / 170 (0.00%)	0 / 151 (0.00%)	
occurrences (all)	0	0	
Chest injury			
subjects affected / exposed	0 / 170 (0.00%)	0 / 151 (0.00%)	
occurrences (all)	0	0	
Foreign body			
subjects affected / exposed	0 / 170 (0.00%)	0 / 151 (0.00%)	
occurrences (all)	0	0	
Head injury			
subjects affected / exposed	0 / 170 (0.00%)	0 / 151 (0.00%)	
occurrences (all)	0	0	
Ligament injury			

subjects affected / exposed	0 / 170 (0.00%)	0 / 151 (0.00%)	
occurrences (all)	0	0	
Poisoning			
subjects affected / exposed	0 / 170 (0.00%)	0 / 151 (0.00%)	
occurrences (all)	0	0	
Post concussion syndrome			
subjects affected / exposed	0 / 170 (0.00%)	0 / 151 (0.00%)	
occurrences (all)	0	0	
Post procedural haematoma			
subjects affected / exposed	0 / 170 (0.00%)	0 / 151 (0.00%)	
occurrences (all)	0	0	
Skeletal injury			
subjects affected / exposed	0 / 170 (0.00%)	0 / 151 (0.00%)	
occurrences (all)	0	0	
Ulna fracture			
subjects affected / exposed	0 / 170 (0.00%)	0 / 151 (0.00%)	
occurrences (all)	0	0	
Hand fracture			
subjects affected / exposed	0 / 170 (0.00%)	0 / 151 (0.00%)	
occurrences (all)	0	0	
Limb injury			
subjects affected / exposed	0 / 170 (0.00%)	0 / 151 (0.00%)	
occurrences (all)	0	0	
Upper limb fracture			
subjects affected / exposed	0 / 170 (0.00%)	0 / 151 (0.00%)	
occurrences (all)	0	0	
Congenital, familial and genetic disorders			
Factor V Leiden mutation			
subjects affected / exposed	1 / 170 (0.59%)	0 / 151 (0.00%)	
occurrences (all)	1	0	
Cardiac disorders			
Palpitations			
subjects affected / exposed	0 / 170 (0.00%)	0 / 151 (0.00%)	
occurrences (all)	0	0	
Nervous system disorders			

Headache			
subjects affected / exposed	0 / 170 (0.00%)	0 / 151 (0.00%)	
occurrences (all)	0	0	
Syncope			
subjects affected / exposed	0 / 170 (0.00%)	0 / 151 (0.00%)	
occurrences (all)	0	0	
Migraine			
subjects affected / exposed	0 / 170 (0.00%)	0 / 151 (0.00%)	
occurrences (all)	0	0	
Burning sensation mucosal			
subjects affected / exposed	0 / 170 (0.00%)	0 / 151 (0.00%)	
occurrences (all)	0	0	
Presyncope			
subjects affected / exposed	0 / 170 (0.00%)	0 / 151 (0.00%)	
occurrences (all)	0	0	
Tremor			
subjects affected / exposed	0 / 170 (0.00%)	0 / 151 (0.00%)	
occurrences (all)	0	0	
Blood and lymphatic system disorders			
Lymphadenopathy			
subjects affected / exposed	0 / 170 (0.00%)	0 / 151 (0.00%)	
occurrences (all)	0	0	
Ear and labyrinth disorders			
Ear pain			
subjects affected / exposed	0 / 170 (0.00%)	0 / 151 (0.00%)	
occurrences (all)	0	0	
Vertigo			
subjects affected / exposed	0 / 170 (0.00%)	0 / 151 (0.00%)	
occurrences (all)	0	0	
Eye disorders			
Conjunctivitis			
subjects affected / exposed	0 / 170 (0.00%)	0 / 151 (0.00%)	
occurrences (all)	0	0	
Eye inflammation			
subjects affected / exposed	0 / 170 (0.00%)	0 / 151 (0.00%)	
occurrences (all)	0	0	
Eyelid cyst			

subjects affected / exposed	0 / 170 (0.00%)	0 / 151 (0.00%)	
occurrences (all)	0	0	
Photophobia			
subjects affected / exposed	0 / 170 (0.00%)	0 / 151 (0.00%)	
occurrences (all)	0	0	
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	0 / 170 (0.00%)	0 / 151 (0.00%)	
occurrences (all)	0	0	
Diarrhoea			
subjects affected / exposed	0 / 170 (0.00%)	0 / 151 (0.00%)	
occurrences (all)	0	0	
Dyspepsia			
subjects affected / exposed	0 / 170 (0.00%)	0 / 151 (0.00%)	
occurrences (all)	0	0	
Glossodynia			
subjects affected / exposed	0 / 170 (0.00%)	0 / 151 (0.00%)	
occurrences (all)	0	0	
Dental caries			
subjects affected / exposed	0 / 170 (0.00%)	0 / 151 (0.00%)	
occurrences (all)	0	0	
Food poisoning			
subjects affected / exposed	0 / 170 (0.00%)	0 / 151 (0.00%)	
occurrences (all)	0	0	
Gingivitis			
subjects affected / exposed	0 / 170 (0.00%)	0 / 151 (0.00%)	
occurrences (all)	0	0	
Inguinal hernia			
subjects affected / exposed	0 / 170 (0.00%)	0 / 151 (0.00%)	
occurrences (all)	0	0	
Irritable bowel syndrome			
subjects affected / exposed	0 / 170 (0.00%)	0 / 151 (0.00%)	
occurrences (all)	0	0	
Mouth ulceration			
subjects affected / exposed	0 / 170 (0.00%)	0 / 151 (0.00%)	
occurrences (all)	0	0	

Tooth impacted			
subjects affected / exposed	0 / 170 (0.00%)	0 / 151 (0.00%)	
occurrences (all)	0	0	
Toothache			
subjects affected / exposed	0 / 170 (0.00%)	0 / 151 (0.00%)	
occurrences (all)	0	0	
Vomiting			
subjects affected / exposed	0 / 170 (0.00%)	0 / 151 (0.00%)	
occurrences (all)	0	0	
Skin and subcutaneous tissue disorders			
Dermatitis			
subjects affected / exposed	0 / 170 (0.00%)	0 / 151 (0.00%)	
occurrences (all)	0	0	
Acne			
subjects affected / exposed	0 / 170 (0.00%)	0 / 151 (0.00%)	
occurrences (all)	0	0	
Dermatitis allergic			
subjects affected / exposed	0 / 170 (0.00%)	0 / 151 (0.00%)	
occurrences (all)	0	0	
Scar			
subjects affected / exposed	0 / 170 (0.00%)	0 / 151 (0.00%)	
occurrences (all)	0	0	
Alopecia			
subjects affected / exposed	0 / 170 (0.00%)	0 / 151 (0.00%)	
occurrences (all)	0	0	
Dermatitis atopic			
subjects affected / exposed	0 / 170 (0.00%)	0 / 151 (0.00%)	
occurrences (all)	0	0	
Dermatitis contact			
subjects affected / exposed	0 / 170 (0.00%)	0 / 151 (0.00%)	
occurrences (all)	0	0	
Drug eruption			
subjects affected / exposed	0 / 170 (0.00%)	0 / 151 (0.00%)	
occurrences (all)	0	0	
Hangnail			

subjects affected / exposed	0 / 170 (0.00%)	0 / 151 (0.00%)	
occurrences (all)	0	0	
Ingrowing nail			
subjects affected / exposed	0 / 170 (0.00%)	0 / 151 (0.00%)	
occurrences (all)	0	0	
Photosensitivity reaction			
subjects affected / exposed	0 / 170 (0.00%)	0 / 151 (0.00%)	
occurrences (all)	0	0	
Rash			
subjects affected / exposed	0 / 170 (0.00%)	0 / 151 (0.00%)	
occurrences (all)	0	0	
Urticaria			
subjects affected / exposed	0 / 170 (0.00%)	0 / 151 (0.00%)	
occurrences (all)	0	0	
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 170 (0.00%)	0 / 151 (0.00%)	
occurrences (all)	0	0	
Back pain			
subjects affected / exposed	0 / 170 (0.00%)	0 / 151 (0.00%)	
occurrences (all)	0	0	
Arthropathy			
subjects affected / exposed	0 / 170 (0.00%)	0 / 151 (0.00%)	
occurrences (all)	0	0	
Costochondritis			
subjects affected / exposed	0 / 170 (0.00%)	0 / 151 (0.00%)	
occurrences (all)	0	0	
Muscle contracture			
subjects affected / exposed	0 / 170 (0.00%)	0 / 151 (0.00%)	
occurrences (all)	0	0	
Myalgia			
subjects affected / exposed	0 / 170 (0.00%)	0 / 151 (0.00%)	
occurrences (all)	0	0	
Neck pain			

subjects affected / exposed	0 / 170 (0.00%)	0 / 151 (0.00%)	
occurrences (all)	0	0	
Pain in extremity			
subjects affected / exposed	0 / 170 (0.00%)	0 / 151 (0.00%)	
occurrences (all)	0	0	
Tendonitis			
subjects affected / exposed	0 / 170 (0.00%)	0 / 151 (0.00%)	
occurrences (all)	0	0	
Torticollis			
subjects affected / exposed	0 / 170 (0.00%)	0 / 151 (0.00%)	
occurrences (all)	0	0	
Rheumatoid arthritis			
subjects affected / exposed	0 / 170 (0.00%)	0 / 151 (0.00%)	
occurrences (all)	0	0	
Infections and infestations			
Upper respiratory tract infection			
subjects affected / exposed	0 / 170 (0.00%)	0 / 151 (0.00%)	
occurrences (all)	0	0	
Pharyngitis			
subjects affected / exposed	0 / 170 (0.00%)	0 / 151 (0.00%)	
occurrences (all)	0	0	
Tonsillitis			
subjects affected / exposed	0 / 170 (0.00%)	0 / 151 (0.00%)	
occurrences (all)	0	0	
Gastroenteritis			
subjects affected / exposed	0 / 170 (0.00%)	0 / 151 (0.00%)	
occurrences (all)	0	0	
Nasopharyngitis			
subjects affected / exposed	0 / 170 (0.00%)	0 / 151 (0.00%)	
occurrences (all)	0	0	
Bronchitis			
subjects affected / exposed	0 / 170 (0.00%)	0 / 151 (0.00%)	
occurrences (all)	0	0	
Respiratory tract infection			
subjects affected / exposed	0 / 170 (0.00%)	0 / 151 (0.00%)	
occurrences (all)	0	0	

Rhinitis			
subjects affected / exposed	0 / 170 (0.00%)	0 / 151 (0.00%)	
occurrences (all)	0	0	
Viral infection			
subjects affected / exposed	0 / 170 (0.00%)	0 / 151 (0.00%)	
occurrences (all)	0	0	
Ear infection			
subjects affected / exposed	0 / 170 (0.00%)	0 / 151 (0.00%)	
occurrences (all)	0	0	
Influenza			
subjects affected / exposed	0 / 170 (0.00%)	0 / 151 (0.00%)	
occurrences (all)	0	0	
Laryngitis			
subjects affected / exposed	0 / 170 (0.00%)	0 / 151 (0.00%)	
occurrences (all)	0	0	
Lower respiratory tract infection			
subjects affected / exposed	0 / 170 (0.00%)	0 / 151 (0.00%)	
occurrences (all)	0	0	
Urinary tract infection			
subjects affected / exposed	0 / 170 (0.00%)	0 / 151 (0.00%)	
occurrences (all)	0	0	
Acute tonsillitis			
subjects affected / exposed	0 / 170 (0.00%)	0 / 151 (0.00%)	
occurrences (all)	0	0	
H1N1 influenza			
subjects affected / exposed	0 / 170 (0.00%)	0 / 151 (0.00%)	
occurrences (all)	0	0	
Mumps			
subjects affected / exposed	0 / 170 (0.00%)	0 / 151 (0.00%)	
occurrences (all)	0	0	
Otitis media			
subjects affected / exposed	0 / 170 (0.00%)	0 / 151 (0.00%)	
occurrences (all)	0	0	
Respiratory tract infection viral			
subjects affected / exposed	0 / 170 (0.00%)	0 / 151 (0.00%)	
occurrences (all)	0	0	

Sinusitis			
subjects affected / exposed	0 / 170 (0.00%)	0 / 151 (0.00%)	
occurrences (all)	0	0	
Acarodermatitis			
subjects affected / exposed	0 / 170 (0.00%)	0 / 151 (0.00%)	
occurrences (all)	0	0	
Cellulitis			
subjects affected / exposed	0 / 170 (0.00%)	0 / 151 (0.00%)	
occurrences (all)	0	0	
Gastritis viral			
subjects affected / exposed	0 / 170 (0.00%)	0 / 151 (0.00%)	
occurrences (all)	0	0	
Gastroenteritis viral			
subjects affected / exposed	0 / 170 (0.00%)	0 / 151 (0.00%)	
occurrences (all)	0	0	
Herpes simplex			
subjects affected / exposed	0 / 170 (0.00%)	0 / 151 (0.00%)	
occurrences (all)	0	0	
Impetigo			
subjects affected / exposed	0 / 170 (0.00%)	0 / 151 (0.00%)	
occurrences (all)	0	0	
Pertussis			
subjects affected / exposed	0 / 170 (0.00%)	0 / 151 (0.00%)	
occurrences (all)	0	0	
Pneumonia			
subjects affected / exposed	0 / 170 (0.00%)	0 / 151 (0.00%)	
occurrences (all)	0	0	
Pulpitis dental			
subjects affected / exposed	0 / 170 (0.00%)	0 / 151 (0.00%)	
occurrences (all)	0	0	
Pyelonephritis			
subjects affected / exposed	0 / 170 (0.00%)	0 / 151 (0.00%)	
occurrences (all)	0	0	
Subcutaneous abscess			
subjects affected / exposed	0 / 170 (0.00%)	0 / 151 (0.00%)	
occurrences (all)	0	0	

Viral upper respiratory tract infection subjects affected / exposed occurrences (all)	0 / 170 (0.00%) 0	0 / 151 (0.00%) 0	
Metabolism and nutrition disorders Decreased appetite subjects affected / exposed occurrences (all)	0 / 170 (0.00%) 0	0 / 151 (0.00%) 0	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
05 November 2008	1- The stopping rules for moderate systemic reactions and chills of any severity were removed.
16 September 2009	1- Pregnancy testing at each visit of stage 2 was added. 2- Study visit procedures were updated to reflect that investigators should inquire about autoimmune diseases at the 6-month safety follow-up of stage 1 and at each visit throughout stage 2.
16 November 2009	1- The window for the third vaccination was broadened to 9 months. The vaccination schedule was changed to 0, 2, and 6 to 9 months. 2- The window for the immunogenicity blood collection 24 months postdose 3 and following was broadened from 2 to 3 months.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? Yes

Date	Interruption	Restart date
22 October 2009	A serious adverse event (SAE) characterized by severe headache and vomiting occurred in a subject during stage 1 of the study. This event was considered possibly related to study vaccine and triggered a protocol-defined study pause.	-

Notes:

Limitations and caveats

None reported