Clinical trial results:
A 12 week randomized open label parallel group multicenter study to evaluate bioequivalence of 20 mg subcutaneous ofatumumab injected by pre-filled syringe or autoinjector in adult RMS patients

Summary

EudraCT number	2017-004702-17
Trial protocol	AT CZ EE LV LT ES PL BG IT
Global end of trial date	05 May 2020

Results information

Result version number	v1 (current)
This version publication date	02 October 2020
First version publication date	02 October 2020

Trial information

Trial identification

Sponsor protocol code	COMB157G2102

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT03560739
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Novartis Pharma AG
Sponsor organisation address	Postfach, Basel, Switzerland, 4002
Public contact	Clinical Disclosure Office, Novartis Pharma AG, 41 613241111, Novartis.email@novartis.com
Scientific contact	Clinical Disclosure Office, Novartis Pharma AG, 41 613241111, Novartis.email@novartis.com

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	No
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	05 May 2020
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	05 May 2020
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To demonstrate Pharmacokinetic (PK) bioequivalence of 20 mg ofatumumab injected by the pre-filled syringe (PFS) or autoinjector devices (AI)

Protection of trial subjects:

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

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	11 September 2018
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Austria: 19
Country: Number of subjects enrolled	Bulgaria: 20
Country: Number of subjects enrolled	Czech Republic: 37
Country: Number of subjects enrolled	Estonia: 13
Country: Number of subjects enrolled	Latvia: 13
Country: Number of subjects enrolled	Lithuania: 8
Country: Number of subjects enrolled	Russian Federation: 72
Country: Number of subjects enrolled	Spain: 37
Country: Number of subjects enrolled	United States: 65
Worldwide total number of subjects	284
EEA total number of subjects	147

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)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	284
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

344 participants were screened

Period 1

Period 1 title	Overall Study (overall period)
Is this the baseline period?	Yes
Allocation method	Not applicable
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	OMB 20mg AI abdomen

Arm description:

Ofatumumab 20 mg subcutaneous (s.c.) injection with autoinjector (AI) administrated on abdomen

Arm type	Experimental
Investigational medicinal product name	ofatumumab
Investigational medicinal product code	OMB157
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

ofatumumab 20 mg
subcutaneous injection
administered with
autoinjector (AI) to abdomen

Arm title	OMB 20mg PFS abdomen

Arm description:

Ofatumumab 20 mg subcutaneous (s.c.) injection with pre-filled syringes (PFS) administrated on abdomen

Arm type	Experimental
Investigational medicinal product name	ofatumumab
Investigational medicinal product code	OMB157
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

ofatumumab 20 mg
subcutaneous injection
administered with pre-filled syringe (PFS) to abdomen

Arm title	OMB 20mg AI thigh

Arm description:

Ofatumumab 20 mg subcutaneous (s.c.) injection with autoinjector (AI) administrated on thigh

Arm type	Experimental

Investigational medicinal product name	ofatumumab
Investigational medicinal product code	OMB157
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

ofatumumab 20 mg
subcutaneous injection
administered with
autoinjector (AI) to thigh

Arm title	OMB 20mg PFS thigh

Arm description:

Ofatumumab 20 mg subcutaneous (s.c.) injection with pre-filled syringes (PFS) administrated on thigh

Arm type	Experimental
Investigational medicinal product name	ofatumumab
Investigational medicinal product code	OMB157
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

ofatumumab 20 mg
subcutaneous injection
administered with
pre-filled syringe (PFS) to thigh

Number of subjects in period 1	OMB 20mg AI abdomen	OMB 20mg PFS abdomen	OMB 20mg AI thigh
Started	128	130	13
Completed	128	129	13
Not completed	0	1	0
Adverse event, non-fatal	-	1	-

Number of subjects in period 1	OMB 20mg PFS thigh
Started	13
Completed	13
Not completed	0
Adverse event, non-fatal	-

Baseline characteristics

Reporting groups	
Reporting group title	OMB 20mg AI abdomen
Reporting group description:	
Ofatumumab 20 mg subcutaneous (s.c.) injection with autoinjector (AI) administrated on abdomen	
Reporting group title	OMB 20mg PFS abdomen
Reporting group description:	
Ofatumumab 20 mg subcutaneous (s.c.) injection with pre-filled syringes (PFS) administrated on abdomen	
Reporting group title	OMB 20mg AI thigh
Reporting group description:	
Ofatumumab 20 mg subcutaneous (s.c.) injection with autoinjector (AI) administrated on thigh	
Reporting group title	OMB 20mg PFS thigh
Reporting group description:	
Ofatumumab 20 mg subcutaneous (s.c.) injection with pre-filled syringes (PFS) administrated on thigh	

Reporting group values	OMB 20mg AI abdomen	OMB 20mg PFS abdomen	OMB 20mg AI thigh
Number of subjects	128	130	13
Age Categorical Units: participants			
18 to 30 years	32	29	5
31 to 40 years	42	53	3
41 to 55 years	54	48	5
Age continuous Units: years			
arithmetic mean	37.8	37.4	35.4
standard deviation	± 9.37	± 8.66	± 8.75
Sex: Female, Male Units: participants			
Female	92	90	9
Male	36	40	4
Race/Ethnicity, Customized Units: Subjects			
American Indian or Alaska Native	1	0	0
Black or African American	2	4	0
White	125	125	13
Mixed	0	1	0

Reporting group values	OMB 20mg PFS thigh	Total	
Number of subjects	13	284	
Age Categorical Units: participants			
18 to 30 years	2	68	
31 to 40 years	10	108	
41 to 55 years	1	108	

Age continuous Units: years			
arithmetic mean	33.2		
standard deviation	± 6.18	-	
Sex: Female, Male Units: participants			
Female	8	199	
Male	5	85	
Race/Ethnicity, Customized Units: Subjects			
American Indian or Alaska Native	0	1	
Black or African American	0	6	
White	12	275	
Mixed	1	2	

End points

End points reporting groups

Reporting group title	OMB 20mg AI abdomen
Reporting group description:	
Ofatumumab 20 mg subcutaneous (s.c.) injection with autoinjector (AI) administrated on abdomen	
Reporting group title	OMB 20mg PFS abdomen
Reporting group description:	
Ofatumumab 20 mg subcutaneous (s.c.) injection with pre-filled syringes (PFS) administrated on abdomen	
Reporting group title	OMB 20mg AI thigh
Reporting group description:	
Ofatumumab 20 mg subcutaneous (s.c.) injection with autoinjector (AI) administrated on thigh	
Reporting group title	OMB 20mg PFS thigh
Reporting group description:	
Ofatumumab 20 mg subcutaneous (s.c.) injection with pre-filled syringes (PFS) administrated on thigh	

Primary: Bioequivalence of 20 mg ofatumumab injected by pre-filled syringe (PFS) vs autoinjector (AI) to abdomen as measured by AUCtau

End point title	Bioequivalence of 20 mg ofatumumab injected by pre-filled syringe (PFS) vs autoinjector (AI) to abdomen as measured by AUCtau[1]

End point description:

Bioequivalence of AUCtau) will be measured over the time period 8 to 12 dosing interval comparing the pre-filled syringe (PFS) and autoinjector (AI) devices both administered to the abdomen. Bioequivalence established if both measures meet the corresponding criterion specified by the reference-scaled average bioequivalence (RSABE) approach

End point type	Primary

End point timeframe:

Week 8 to Week 12 dosing interval

Notes:

[1] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Bioequivalence was analyzed for abdomen arms only

End point values	OMB 20mg AI abdomen	OMB 20mg PFS abdomen		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	128	128		
Units: h×µg/mL				
geometric mean (geometric coefficient of variation)	487.7 (± 103.5)	474.1 (± 79.7)		

Statistical analyses

Statistical analysis title	Criteria 1 for bioequivalence testing of AUCtau

Statistical analysis description:

For reference-scaled average bioequivalence testing, both criteria have to be met: 1) geo-mean ratio needs to fall in [0.8, 1.25]; 2) 95% upper bound of the

linearized criterion needs to be <= 0. This part is regarding criterion 1.

Comparison groups	OMB 20mg AI abdomen v OMB 20mg PFS abdomen
Number of subjects included in analysis	256
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Geo-mean ratio
Point estimate	1.03
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.8
upper limit	1.25

Statistical analysis title	Criteria 2 for bioequivalence testing of AUCtau

Statistical analysis description:

For reference-scaled average bioequivalence testing, both criteria have to be met: 1) geo-mean ratio needs to fall in [0.8, 1.25]; 2) 95% upper bound of the linearized criterion needs to be <= 0. This part is regarding criterion 2.

Comparison groups	OMB 20mg AI abdomen v OMB 20mg PFS abdomen
Number of subjects included in analysis	256
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	95% upper bound of the linearized criter
Point estimate	-0.3131
Confidence interval	
level	95 %
sides	1-sided
upper limit	0

Primary: Bioequivalence of 20 mg ofatumumab injected by pre-filled syringe (PFS) vs autoinjector (AI) to abdomen as measured by Cmax

End point title	Bioequivalence of 20 mg ofatumumab injected by pre-filled syringe (PFS) vs autoinjector (AI) to abdomen as measured by Cmax[2]

End point description:

Bioequivalence of Cmax will be measured over the time period of Week 8 to Week 12 dosing interval comparing the pre-filled syringe (PFS) and autoinjector (AI) devices both administered to the abdomen. Bioequivalence established if both measures meet the corresponding criterion specified by the reference-scaled average bioequivalence (RSABE) approach

End point type	Primary

End point timeframe:

Week 8 to Week 12 dosing interval

Notes:

[2] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Bioequivalence was analyzed for abdomen arms only

End point values	OMB 20mg AI abdomen	OMB 20mg PFS abdomen		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	128	128		
Units: µg/mL				
geometric mean (geometric coefficient of variation)	1.409 (± 89.2)	1.409 (± 67.9)		

Statistical analyses

Statistical analysis title	Criteria 1 for bioequivalence testing of of Cmax
Statistical analysis description:	
For reference-scaled average bioequivalence testing, both criteria have to be met: 1) geo-mean ratio needs to fall in [0.8, 1.25]; 2) 95% upper bound of the linearized criterion needs to be <= 0. This part is regarding criterion 1.	
Comparison groups	OMB 20mg AI abdomen v OMB 20mg PFS abdomen
Number of subjects included in analysis	256
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	geo-mean ratio
Point estimate	1
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.8
upper limit	1.25

Statistical analysis title	Criteria 2 for bioequivalence testing of Cmax
Statistical analysis description:	
For reference-scaled average bioequivalence testing, both criteria have to be met: 1) geo-mean ratio needs to fall in [0.8, 1.25]; 2) 95% upper bound of the linearized criterion needs to be <= 0. This part is regarding criterion 2.	
Comparison groups	OMB 20mg AI abdomen v OMB 20mg PFS abdomen
Number of subjects included in analysis	256
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	95% upper bound of the linearized criter
Point estimate	-0.2446
Confidence interval	
level	95 %
sides	1-sided
upper limit	0

Secondary: Pharmacokinetics of the study drug as measured by AUCtau for PFS and AI devices when administered to abdomen or thigh

End point title	Pharmacokinetics of the study drug as measured by AUCtau for

	PFS and AI devices when administered to abdomen or thigh

End point description:

Pharmacokinetics following subcutaneous administration of ofatumumab to either the abdominal region or the thigh as measured by the area under the concentration-time curve over the Week 8 to Week 12 dosing interval
(AUCtau)

End point type	Secondary

End point timeframe:

Week 8 to Week 12 dosing interval

End point values	OMB 20mg AI abdomen	OMB 20mg PFS abdomen	OMB 20mg AI thigh	OMB 20mg PFS thigh
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	128	128	13	13
Units: h×µg/mL				
geometric mean (geometric coefficient of variation)	487.7 (± 103.5)	474.1 (± 79.7)	476.0 (± 73.1)	544.1 (± 93.8)

Statistical analyses

No statistical analyses for this end point

Secondary: Pharmacokinetics of the study drug as measured by Cmax for PFS and AI devices when administered to abdomen or thigh

End point title	Pharmacokinetics of the study drug as measured by Cmax for PFS and AI devices when administered to abdomen or thigh

End point description:

Pharmacokinetics following subcutaneous administration of ofatumumab to either the abdominal region or the thigh as measured by the maximum concentration (Cmax)

End point type	Secondary

End point timeframe:

Week 8 to Week 12 dosing interval

End point values	OMB 20mg AI abdomen	OMB 20mg PFS abdomen	OMB 20mg AI thigh	OMB 20mg PFS thigh
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	128	128	13	13
Units: µg/mL				
geometric mean (geometric coefficient of variation)	1.409 (± 89.2)	1.409 (± 67.9)	1.563 (± 71.3)	1.635 (± 50.7)

Statistical analyses

No statistical analyses for this end point

Secondary: Plasma concentrations for PFS and AI devices when administered to abdomen or thigh

End point title	Plasma concentrations for PFS and AI devices when administered to abdomen or thigh

End point description:

Plasma concentrations following subcutaneous administration of ofatumumab via PFS or AI to either the abdominal region or the thigh

End point type	Secondary

End point timeframe:

Days 1, 4, 7, 14, 28, 42, 56, 57, 59, 63, 70, 77, 84

End point values	OMB 20mg AI abdomen	OMB 20mg PFS abdomen	OMB 20mg AI thigh	OMB 20mg PFS thigh
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	128	130	13	13
Units: µg/mL				
geometric mean (geometric coefficient of variation)				
Day 4 n=128,127,13,13	0.43076 (± 147.591319)	0.40075 (± 119.330376)	0.86747 (± 24.481350)	0.55704 (± 105.432315)
Day 7 n=128, 130,13,13	0.33544 (± 133.205087)	0.30511 (± 119.511321)	0.36750 (± 94.007762)	0.29662 (± 119.353006)
Day 14 n=128, 130,12,11	1.07408 (± 105.566707)	0.96359 (± 105.735963)	0.89788 (± 125.726458)	1.30586 (± 83.153962)
Day 28 Week 4 n=127, 130,13,13	0.95571 (± 113.510035)	0.95774 (± 117.852822)	1.11008 (± 66.780045)	1.41434 (± 117.959678)
Day 42 Week 6 n=128, 130,13,13	0.97327 (± 125.421064)	1.12006 (± 113.137164)	1.12006 (± 86.390639)	1.18239 (± 133.082660)
Day 56 Week 8 n=128, 130,13,13	0.28358 (± 142.760137)	0.24644 (± 133.056913)	0.23874 (± 98.041287)	0.45529 (± 143.614763)
Day 57 Week 8 n=127, 127,12,13	0.89424 (± 121.357310)	0.80986 (± 107.929658)	0.96356 (± 122.222991)	1.04905 (± 54.771002)
Day 59 Week 8 n=127, 127,13,13	1.24143 (± 103.274314)	1.23458 (± 81.737063)	1.34837 (± 82.596695)	1.52705 (± 52.253239)
Day 63 Week 9 n=126, 128,13,13	1.27031 (± 84.610014)	1.23163 (± 77.294222)	1.28263 (± 67.076249)	1.43075 (± 66.345270)
Day 70 Week 10 n=128, 127,13,13	0.78732 (± 97.440131)	0.74111 (± 82.870974)	0.67151 (± 82.769087)	0.95821 (± 83.645358)
Day 77 Week 11 n=127, 127,13,13	0.40249 (± 109.581877)	0.33720 (± 114.373887)	0.40173 (± 52.479338)	0.54085 (± 97.862609)
EOS Week 12 n=126, 118,12,13	0.20290 (± 113.812416)	0.17862 (± 102.507484)	0.17361 (± 63.899086)	0.27276 (± 98.256573)

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of patients with anti-ofatumumab antibodies

End point title	Percentage of patients with anti-ofatumumab antibodies

End point description:

Anti-drug antibodies (ADA) were assessed to evaluate the immunogenicity potential of ofatumumab. Samples for ADA assessment were taken prior to dosing at the visit. Samples were analyzed as per laboratory's SOPs by a Meso Scale Discovery (MSD) electrochemiluminescense assay. All samples confirmed to be positive for the presence of anti-ofatumumab antibodies were assessed to evaluate their ability to neutralize the ofatumumab biologic effect.

End point type	Secondary

End point timeframe:

Baseline, Week 4, 8, 12 and Overall

End point values	OMB 20mg AI abdomen	OMB 20mg PFS abdomen	OMB 20mg AI thigh	OMB 20mg PFS thigh
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	128	130	13	13
Units: percentage of participants				
number (not applicable)				
Baseline n= 128,130,13,13	0.8	3.1	0.0	7.7
Week 4 n= 128,130,13,13	0.8	0.0	0.0	0.0
Week 8 n= 124,126,13,13	0.0	0.8	0.0	0.0
Week 12 n= 125,121, 12,13	0.8	0.0	0.0	0.0
Overall n= 128,130,13,13	0.8	3.8	0.0	7.7

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information	
Timeframe for reporting adverse events: Adverse events were reported from first dose of study treatment until last administration of study treatment plus 100 days post treatment, up to maximum duration of 226 days	
Assessment type	Systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	23.0

Reporting groups	
Reporting group title	OMB 20mg AI (ABD)
Reporting group description: OMB 20mg AI (ABD)	
Reporting group title	OMB 20mg PFS (ABD)
Reporting group description: OMB 20mg PFS (ABD)	
Reporting group title	OMB 20mg AI (THI)
Reporting group description: OMB 20mg AI (THI)	
Reporting group title	OMB 20mg PFS (THI)
Reporting group description: OMB 20mg PFS (THI)	

Serious adverse events	OMB 20mg AI (ABD)	OMB 20mg PFS (ABD)	OMB 20mg AI (THI)
Total subjects affected by serious adverse events			
subjects affected / exposed	2 / 128 (1.56%)	4 / 130 (3.08%)	0 / 13 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Injury, poisoning and procedural complications			
Burns second degree			
subjects affected / exposed	1 / 128 (0.78%)	0 / 130 (0.00%)	0 / 13 (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
Ear and labyrinth disorders			
Vertigo			
subjects affected / exposed	0 / 128 (0.00%)	1 / 130 (0.77%)	0 / 13 (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
Gastrointestinal disorders			

Gastrointestinal motility disorder			
subjects affected / exposed	1 / 128 (0.78%)	0 / 130 (0.00%)	0 / 13 (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
Reproductive system and breast disorders			
Menometrorrhagia			
subjects affected / exposed	0 / 128 (0.00%)	1 / 130 (0.77%)	0 / 13 (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
Infections and infestations			
Appendicitis			
subjects affected / exposed	0 / 128 (0.00%)	1 / 130 (0.77%)	0 / 13 (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
Pneumonia			
subjects affected / exposed	0 / 128 (0.00%)	1 / 130 (0.77%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	OMB 20mg PFS (THI)		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 13 (0.00%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		
Injury, poisoning and procedural complications			
Burns second degree			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Ear and labyrinth disorders			
Vertigo			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal disorders			

Gastrointestinal motility disorder			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Reproductive system and breast disorders			
Menometrorrhagia			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Infections and infestations			
Appendicitis			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pneumonia			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

Frequency threshold for reporting non-serious adverse events: 5 %

Non-serious adverse events	OMB 20mg AI (ABD)	OMB 20mg PFS (ABD)	OMB 20mg AI (THI)
Total subjects affected by non-serious adverse events			
subjects affected / exposed	61 / 128 (47.66%)	53 / 130 (40.77%)	7 / 13 (53.85%)
Injury, poisoning and procedural complications			
Injection related reaction			
subjects affected / exposed	41 / 128 (32.03%)	29 / 130 (22.31%)	5 / 13 (38.46%)
occurrences (all)	52	39	8
Ligament sprain			
subjects affected / exposed	0 / 128 (0.00%)	0 / 130 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Nervous system disorders			
Head discomfort			
subjects affected / exposed	0 / 128 (0.00%)	0 / 130 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1

Headache			
subjects affected / exposed	13 / 128 (10.16%)	7 / 130 (5.38%)	0 / 13 (0.00%)
occurrences (all)	29	14	0
Neuralgia			
subjects affected / exposed	1 / 128 (0.78%)	0 / 130 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
Post herpetic neuralgia			
subjects affected / exposed	0 / 128 (0.00%)	0 / 130 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Blood and lymphatic system disorders			
Leukopenia			
subjects affected / exposed	3 / 128 (2.34%)	0 / 130 (0.00%)	1 / 13 (7.69%)
occurrences (all)	4	0	1
Lymphopenia			
subjects affected / exposed	1 / 128 (0.78%)	2 / 130 (1.54%)	0 / 13 (0.00%)
occurrences (all)	1	2	0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	2 / 128 (1.56%)	1 / 130 (0.77%)	0 / 13 (0.00%)
occurrences (all)	2	1	0
Fatigue			
subjects affected / exposed	3 / 128 (2.34%)	5 / 130 (3.85%)	1 / 13 (7.69%)
occurrences (all)	4	5	2
Injection site pain			
subjects affected / exposed	0 / 128 (0.00%)	0 / 130 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Injection site reaction			
subjects affected / exposed	11 / 128 (8.59%)	17 / 130 (13.08%)	0 / 13 (0.00%)
occurrences (all)	15	34	0
Pain			
subjects affected / exposed	1 / 128 (0.78%)	1 / 130 (0.77%)	0 / 13 (0.00%)
occurrences (all)	1	1	0
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	6 / 128 (4.69%)	4 / 130 (3.08%)	1 / 13 (7.69%)
occurrences (all)	6	4	1

Nausea			
subjects affected / exposed	1 / 128 (0.78%)	0 / 130 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	1 / 128 (0.78%)	2 / 130 (1.54%)	0 / 13 (0.00%)
occurrences (all)	1	2	0
Oropharyngeal pain			
subjects affected / exposed	2 / 128 (1.56%)	1 / 130 (0.77%)	0 / 13 (0.00%)
occurrences (all)	2	1	0
Rhinitis allergic			
subjects affected / exposed	1 / 128 (0.78%)	0 / 130 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
Skin and subcutaneous tissue disorders			
Pruritus			
subjects affected / exposed	0 / 128 (0.00%)	3 / 130 (2.31%)	1 / 13 (7.69%)
occurrences (all)	0	3	1
Psychiatric disorders			
Sleep disorder			
subjects affected / exposed	2 / 128 (1.56%)	1 / 130 (0.77%)	1 / 13 (7.69%)
occurrences (all)	2	1	1
Musculoskeletal and connective tissue disorders			
Muscle contracture			
subjects affected / exposed	0 / 128 (0.00%)	0 / 130 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Spinal pain			
subjects affected / exposed	0 / 128 (0.00%)	1 / 130 (0.77%)	1 / 13 (7.69%)
occurrences (all)	0	1	1
Tendonitis			
subjects affected / exposed	2 / 128 (1.56%)	0 / 130 (0.00%)	0 / 13 (0.00%)
occurrences (all)	2	0	0
Infections and infestations			
Herpes zoster			
subjects affected / exposed	0 / 128 (0.00%)	0 / 130 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Influenza			

subjects affected / exposed	1 / 128 (0.78%)	1 / 130 (0.77%)	0 / 13 (0.00%)
occurrences (all)	1	1	0
Nasopharyngitis			
subjects affected / exposed	2 / 128 (1.56%)	5 / 130 (3.85%)	0 / 13 (0.00%)
occurrences (all)	3	5	0
Oral herpes			
subjects affected / exposed	2 / 128 (1.56%)	1 / 130 (0.77%)	1 / 13 (7.69%)
occurrences (all)	2	1	1
Rhinitis			
subjects affected / exposed	3 / 128 (2.34%)	3 / 130 (2.31%)	0 / 13 (0.00%)
occurrences (all)	3	3	0
Sinusitis			
subjects affected / exposed	0 / 128 (0.00%)	1 / 130 (0.77%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
Upper respiratory tract infection			
subjects affected / exposed	1 / 128 (0.78%)	2 / 130 (1.54%)	0 / 13 (0.00%)
occurrences (all)	1	2	0

Non-serious adverse events	OMB 20mg PFS (THI)		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	7 / 13 (53.85%)		
Injury, poisoning and procedural complications			
Injection related reaction			
subjects affected / exposed	6 / 13 (46.15%)		
occurrences (all)	11		
Ligament sprain			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Nervous system disorders			
Head discomfort			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Headache			
subjects affected / exposed	1 / 13 (7.69%)		
occurrences (all)	1		
Neuralgia			

subjects affected / exposed	1 / 13 (7.69%)		
occurrences (all)	1		
Post herpetic neuralgia			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Blood and lymphatic system disorders			
Leukopenia			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Lymphopenia			
subjects affected / exposed	1 / 13 (7.69%)		
occurrences (all)	1		
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	1 / 13 (7.69%)		
occurrences (all)	1		
Fatigue			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Injection site pain			
subjects affected / exposed	1 / 13 (7.69%)		
occurrences (all)	1		
Injection site reaction			
subjects affected / exposed	1 / 13 (7.69%)		
occurrences (all)	1		
Pain			
subjects affected / exposed	1 / 13 (7.69%)		
occurrences (all)	1		
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Nausea			
subjects affected / exposed	1 / 13 (7.69%)		
occurrences (all)	1		
Respiratory, thoracic and mediastinal disorders			

Cough			
subjects affected / exposed	1 / 13 (7.69%)		
occurrences (all)	1		
Oropharyngeal pain			
subjects affected / exposed	1 / 13 (7.69%)		
occurrences (all)	1		
Rhinitis allergic			
subjects affected / exposed	1 / 13 (7.69%)		
occurrences (all)	1		
Skin and subcutaneous tissue disorders			
Pruritus			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Psychiatric disorders			
Sleep disorder			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Musculoskeletal and connective tissue disorders			
Muscle contracture			
subjects affected / exposed	1 / 13 (7.69%)		
occurrences (all)	1		
Spinal pain			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Tendonitis			
subjects affected / exposed	1 / 13 (7.69%)		
occurrences (all)	1		
Infections and infestations			
Herpes zoster			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Influenza			
subjects affected / exposed	1 / 13 (7.69%)		
occurrences (all)	1		
Nasopharyngitis			

subjects affected / exposed	1 / 13 (7.69%)		
occurrences (all)	1		
Oral herpes			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Rhinitis			
subjects affected / exposed	1 / 13 (7.69%)		
occurrences (all)	1		
Sinusitis			
subjects affected / exposed	1 / 13 (7.69%)		
occurrences (all)	1		
Upper respiratory tract infection			
subjects affected / exposed	1 / 13 (7.69%)		
occurrences (all)	1		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported