Clinical trial results:
Randomized, double-blind, Phase 2 study to evaluate the efficacy and the safety of OSE-127 versus placebo in subjects with moderate to severe active ulcerative colitis who have failed or are intolerant to previous treatment(s)

Summary

EudraCT number	2020-001398-59
Trial protocol	LV BG BE HR PT
Global end of trial date	28 January 2025

Results information

Result version number	v1 (current)
This version publication date	20 February 2026
First version publication date	20 February 2026

Trial information

Trial identification

Sponsor protocol code	OSE-127-C201

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT04882007
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	OSE Immunotherapeutics
Sponsor organisation address	22, boulevard Benoni Goullin, Nantes, France, 44200
Public contact	OSE Contact, OSE Immunotherapeutics, contact@ose-immuno.com
Scientific contact	OSE Contact, OSE Immunotherapeutics, contact@ose-immuno.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	28 January 2025
Is this the analysis of the primary completion data?	Yes
Primary completion date	30 April 2024
Global end of trial reached?	Yes
Global end of trial date	28 January 2025
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To assess the efficacy of OSE-127 versus placebo on the reduction of the modified Mayo Score in moderate-to-severe UC patients who have previously failed or lost response or are intolerant to previous treatment(s)

Protection of trial subjects:

This study was conducted in compliance with Good Clinical Practice, with the Declaration of Helsinki, and with other applicable regulatory requirements. All participants were required to read and sign an informed consent form prior to participation in the study.

Background therapy:

Concomitant therapy with oral aminosalicylates and/or corticosteroids authorized, provided patient had been receiving such treatment for at least 4 weeks and with no change in dose or frequency in the 2 weeks prior to screening.

Evidence for comparator: -

Actual start date of recruitment	02 October 2020
Long term follow-up planned	Yes
Long term follow-up rationale	Safety
Long term follow-up duration	4 Months
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Poland: 47
Country: Number of subjects enrolled	Portugal: 5
Country: Number of subjects enrolled	Croatia: 11
Country: Number of subjects enrolled	Belgium: 2
Country: Number of subjects enrolled	Bulgaria: 14
Country: Number of subjects enrolled	Hungary: 4
Country: Number of subjects enrolled	Latvia: 10
Country: Number of subjects enrolled	Spain: 1
Country: Number of subjects enrolled	Belarus: 10
Country: Number of subjects enrolled	Georgia: 15
Country: Number of subjects enrolled	Serbia: 7
Country: Number of subjects enrolled	South Africa: 14
Country: Number of subjects enrolled	Russian Federation: 35
Country: Number of subjects enrolled	Ukraine: 36

Worldwide total number of subjects	211
EEA total number of subjects	94

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)	193
From 65 to 84 years	18
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

Overall, 211 patients were screened, 136 were randomized and were the safety population, and 134 formed the FAS population (2 patients excluded for Crohn’s Disease).

Period 1

Period 1 title	Induction Period
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator

Arms

Are arms mutually exclusive?	Yes
Arm title	Lusvertikimab 850 mg, Induction Period

Arm description: -

Arm type	Experimental
Investigational medicinal product name	Lusvertikimab
Investigational medicinal product code	OSE-127
Other name	
Pharmaceutical forms	Concentrate for solution for injection/infusion
Routes of administration	Intravenous use

Dosage and administration details:

Participants received Lusvertikimab 850 mg intravenous infusion at Week 0, Week 2, and Week 6

Arm title	Lusvertikimab 450 mg, Induction Period

Arm description: -

Arm type	Experimental
Investigational medicinal product name	Lusvertikimab
Investigational medicinal product code	OSE-127
Other name	
Pharmaceutical forms	Concentrate for solution for injection/infusion
Routes of administration	Intravenous use

Dosage and administration details:

Participants received Lusvertikimab 450 mg intravenous infusion at Week 0, Week 2, and Week 6

Arm title	Placebo, Induction Period

Arm description: -

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

Dosage and administration details:

Participants received Placebo intravenous infusion at Week 0, Week 2, and Week 6

Number of subjects in period 1[1]	Lusvertikimab 850 mg, Induction Period	Lusvertikimab 450 mg, Induction Period	Placebo, Induction Period
Started	50	35	49
Completed	47	32	42
Not completed	3	3	7
Adverse event, serious fatal	-	-	1
Consent withdrawn by subject	2	-	1
Physician decision	-	-	1
Adverse event, non-fatal	-	1	2
Other	-	-	1
Disease worsening	1	2	1

Notes:

[1] - The number of subjects reported to be in the baseline period are not the same as the worldwide number enrolled in the trial. It is expected that these numbers will be the same.
Justification: 211 patients were screened, 136 were randomized (safety population) and 134 formed the FAS population (2 patients excluded for Crohn's Disease).

Period 2

Period 2 title	Open-Label Extension Period
Is this the baseline period?	No
Allocation method	Not applicable
Blinding used	Not blinded

Arms

Arm title	Lusvertikimab 850 mg, Open-Label Extension Period

Arm description: -

Arm type	Experimental
Investigational medicinal product name	Lusvertikimab
Investigational medicinal product code	OSE-127
Other name	
Pharmaceutical forms	Concentrate for solution for injection/infusion
Routes of administration	Intravenous use

Dosage and administration details:

Participants received Lusvertikimab 850 mg intravenous infusion at Weeks 10, 14, 18, 22, 26, 30 and 34.

Number of subjects in period 2[2]	Lusvertikimab 850 mg, Open-Label Extension Period
Started	119
Completed	104
Not completed	15
Consent withdrawn by subject	3
Physician decision	1
Adverse event, non-fatal	2
Other	4

Disease worsening	4
Lost to follow-up	1

Notes:

[2] - 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: At Week 10, all patients from Induction period were proposed to participate in the (optional) Open-Label Extension period.

Period 3

Period 3 title	Safety Follow-up
Is this the baseline period?	No
Allocation method	Not applicable
Blinding used	Not blinded

Arms

Arm title	Safety Follow-up

Arm description:

Safety Follow-up: Week 10 to Week 22 (for patients not participating in the Open-Label Extension period) or Week 34 to Week 50 (for patients participating in the Open-Label Extension period).

Arm type	No intervention

No investigational medicinal product assigned in this arm

Number of subjects in period 3	Safety Follow-up
Started	104
Completed	94
Not completed	10
Consent withdrawn by subject	3
Other	6
Disease worsening	1

Baseline characteristics

Reporting groups	
Reporting group title	Lusvertikimab 850 mg, Induction Period
Reporting group description: -	
Reporting group title	Lusvertikimab 450 mg, Induction Period
Reporting group description: -	
Reporting group title	Placebo, Induction Period
Reporting group description: -	

Reporting group values	Lusvertikimab 850 mg, Induction Period	Lusvertikimab 450 mg, Induction Period	Placebo, Induction Period
Number of subjects	50	35	49
Age categorical Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	45	34	44
From 65-84 years	5	1	5
85 years and over	0	0	0
Age continuous Units: years			
arithmetic mean	42.5	38.8	42.7
standard deviation	± 15.1	± 10.5	± 15.9
Gender categorical Units: Subjects			
Female	23	13	21
Male	27	22	28
Modified Mayo Score (MMS)			
The Modified Mayo Score measures stool frequency, rectal bleeding and mucosal appearance at endoscopy. Each domain is graded from 0 to 3 (total score for modified Mayo Score ranges from 0 to 9).			
Units: points			
arithmetic mean	6.5	6.0	6.6
standard deviation	± 1.0	± 1.4	± 1.2

Reporting group values	Total		
Number of subjects	134		
Age categorical Units: Subjects			
In utero	0		
Preterm newborn infants (gestational age < 37 wks)	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)	123		
From 65-84 years	11		
85 years and over	0		
Age continuous			
Units: years			
arithmetic mean			
standard deviation	-		
Gender categorical			
Units: Subjects			
Female	57		
Male	77		
Modified Mayo Score (MMS)			
The Modified Mayo Score measures stool frequency, rectal bleeding and mucosal appearance at endoscopy. Each domain is graded from 0 to 3 (total score for modified Mayo Score ranges from 0 to 9).			
Units: points			
arithmetic mean			
standard deviation	-		

Subject analysis sets

Subject analysis set title	FAS
Subject analysis set type	Full analysis

Subject analysis set description:

All randomized patients with Ulcerative Colitis who received at least one dose of study treatment (2 patients excluded for Crohn’s Disease).

Reporting group values	FAS		
Number of subjects	134		
Age categorical			
Units: Subjects			
In utero	0		
Preterm newborn infants (gestational age < 37 wks)	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)	123		
From 65-84 years	11		
85 years and over	0		
Age continuous			
Units: years			
arithmetic mean	41.6		
standard deviation	± 14.4		
Gender categorical			
Units: Subjects			
Female	57		
Male	77		

Modified Mayo Score (MMS)			
The Modified Mayo Score measures stool frequency, rectal bleeding and mucosal appearance at endoscopy. Each domain is graded from 0 to 3 (total score for modified Mayo Score ranges from 0 to 9).			
Units: points			
arithmetic mean	6.4		
standard deviation	± 1.2		

End points

End points reporting groups

Reporting group title	Lusvertikimab 850 mg, Induction Period
Reporting group description: -	
Reporting group title	Lusvertikimab 450 mg, Induction Period
Reporting group description: -	
Reporting group title	Placebo, Induction Period
Reporting group description: -	
Reporting group title	Lusvertikimab 850 mg, Open-Label Extension Period
Reporting group description: -	
Reporting group title	Safety Follow-up
Reporting group description:	
Safety Follow-up: Week 10 to Week 22 (for patients not participating in the Open-Label Extension period) or Week 34 to Week 50 (for patients participating in the Open-Label Extension period).	
Subject analysis set title	FAS
Subject analysis set type	Full analysis
Subject analysis set description:	
All randomized patients with Ulcerative Colitis who received at least one dose of study treatment (2 patients excluded for Crohn’s Disease).	

Primary: Change from baseline in the modified Mayo Score (MMS) at Week 10

End point title	Change from baseline in the modified Mayo Score (MMS) at Week 10
End point description:	
End point type	Primary
End point timeframe:	
From Baseline to Week 10	

End point values	Lusvertikimab 850 mg, Induction Period	Lusvertikimab 450 mg, Induction Period	Placebo, Induction Period	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	50	35	49	
Units: points				
least squares mean (confidence interval 95%)	-2.41 (-2.99 to -1.83)	-2.68 (-3.44 to -1.91)	-1.52 (-2.14 to -0.90)	

Statistical analyses

Statistical analysis title	Treatment difference at Week 10
Comparison groups	Lusvertikimab 850 mg, Induction Period v Placebo, Induction Period

Number of subjects included in analysis	99
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.036
Method	ANCOVA
Parameter estimate	Least Square Mean Difference
Point estimate	-0.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.73
upper limit	-0.06
Variability estimate	Standard error of the mean
Dispersion value	0.426

Statistical analysis title	Treatment difference at Week 10
Comparison groups	Lusvertikimab 450 mg, Induction Period v Placebo, Induction Period
Number of subjects included in analysis	84
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.019
Method	ANCOVA
Parameter estimate	Least Square Mean Difference
Point estimate	-1.16
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.12
upper limit	-0.19
Variability estimate	Standard error of the mean
Dispersion value	0.492

Secondary: Clinical remission rate at Week 10

End point title	Clinical remission rate at Week 10
End point description:	
Clinical remission rate defined as MMS ≤ 2 points and no individual sub-score of > 1 point and a rectal bleeding at 0	
End point type	Secondary
End point timeframe:	
From Baseline to Week 10	

End point values	Lusvertikimab 850 mg, Induction Period	Lusvertikimab 450 mg, Induction Period	Placebo, Induction Period	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	50	35	49	
Units: Percentage of participants				
number (not applicable)	12.9	23.8	4.4	

Statistical analyses

Statistical analysis title	Odds Ratio
Comparison groups	Lusvertikimab 850 mg, Induction Period v Placebo, Induction Period
Number of subjects included in analysis	99
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.161
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	3.27
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.62
upper limit	17.12

Statistical analysis title	Odds Ratio
Comparison groups	Lusvertikimab 450 mg, Induction Period v Placebo, Induction Period
Number of subjects included in analysis	84
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.03
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	6.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.19
upper limit	32.29

Secondary: Endoscopic remission rate at Week 10

End point title	Endoscopic remission rate at Week 10

End point description: Endoscopic remission rate defined as an endoscopic Mayo sub-score = 0	
End point type	Secondary
End point timeframe: From Baseline to Week 10	

End point values	Lusvertikimab 850 mg, Induction Period	Lusvertikimab 450 mg, Induction Period	Placebo, Induction Period	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	50	35	49	
Units: Percentage of participants				
number (not applicable)	19.3	36.7	12.5	

Statistical analyses

Statistical analysis title	Odds Ratio
Comparison groups	Lusvertikimab 850 mg, Induction Period v Placebo, Induction Period
Number of subjects included in analysis	99
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.385
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	1.69
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.52
upper limit	5.47

Statistical analysis title	Odds Ratio
Comparison groups	Lusvertikimab 450 mg, Induction Period v Placebo, Induction Period
Number of subjects included in analysis	84
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.032
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	3.71

Confidence interval	
level	95 %
sides	2-sided
lower limit	1.12
upper limit	12.33

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Induction Period (from Week 0 to Week 10) and Open-Label Extension Period (from Week 10 to Week 34)

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	24.0

Reporting groups

Reporting group title	Lusvertikimab 850 mg Induction Period
Reporting group description: -	
Reporting group title	Lusvertikimab 450 mg Induction Period
Reporting group description: -	
Reporting group title	Placebo Induction Period
Reporting group description: -	
Reporting group title	Lusvertikimab Open-Label Extension Period

Reporting group description: -

Serious adverse events	Lusvertikimab 850 mg Induction Period	Lusvertikimab 450 mg Induction Period	Placebo Induction Period
Total subjects affected by serious adverse events			
subjects affected / exposed	3 / 51 (5.88%)	3 / 36 (8.33%)	3 / 49 (6.12%)
number of deaths (all causes)	0	0	1
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Uterine Leiomyoma			
subjects affected / exposed	1 / 51 (1.96%)	0 / 36 (0.00%)	0 / 49 (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
Benign Neoplasm			
subjects affected / exposed	0 / 51 (0.00%)	0 / 36 (0.00%)	0 / 49 (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			
Embolism Venous			
subjects affected / exposed	1 / 51 (1.96%)	0 / 36 (0.00%)	0 / 49 (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

Atheroembolism			
subjects affected / exposed	0 / 51 (0.00%)	0 / 36 (0.00%)	0 / 49 (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
General disorders and administration site conditions			
Chest Pain			
subjects affected / exposed	0 / 51 (0.00%)	0 / 36 (0.00%)	1 / 49 (2.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 51 (0.00%)	0 / 36 (0.00%)	0 / 49 (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
Gastrointestinal disorders			
Colitis Ulcerative			
subjects affected / exposed	0 / 51 (0.00%)	1 / 36 (2.78%)	1 / 49 (2.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anal Ulcer			
subjects affected / exposed	0 / 51 (0.00%)	1 / 36 (2.78%)	0 / 49 (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
Respiratory, thoracic and mediastinal disorders			
Pulmonary Embolism			
subjects affected / exposed	1 / 51 (1.96%)	0 / 36 (0.00%)	0 / 49 (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
Renal and urinary disorders			
Calculus Urinary			
subjects affected / exposed	0 / 51 (0.00%)	0 / 36 (0.00%)	0 / 49 (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			

Asymptomatic Covid-19			
subjects affected / exposed	0 / 51 (0.00%)	1 / 36 (2.78%)	0 / 49 (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
Covid-19 Pneumonia			
subjects affected / exposed	0 / 51 (0.00%)	0 / 36 (0.00%)	1 / 49 (2.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COVID-19			
subjects affected / exposed	0 / 51 (0.00%)	0 / 36 (0.00%)	0 / 49 (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
Complicated Appendicitis			
subjects affected / exposed	0 / 51 (0.00%)	0 / 36 (0.00%)	0 / 49 (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	Lusvertikimab Open-Label Extension Period		
Total subjects affected by serious adverse events			
subjects affected / exposed	10 / 120 (8.33%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Uterine Leiomyoma			
subjects affected / exposed	0 / 120 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Benign Neoplasm			
subjects affected / exposed	1 / 120 (0.83%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Vascular disorders			
Embolism Venous			

subjects affected / exposed	0 / 120 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Atheroembolism			
subjects affected / exposed	1 / 120 (0.83%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
General disorders and administration site conditions			
Chest Pain			
subjects affected / exposed	0 / 120 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	1 / 120 (0.83%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal disorders			
Colitis Ulcerative			
subjects affected / exposed	3 / 120 (2.50%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Anal Ulcer			
subjects affected / exposed	0 / 120 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Respiratory, thoracic and mediastinal disorders			
Pulmonary Embolism			
subjects affected / exposed	0 / 120 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Renal and urinary disorders			
Calculus Urinary			

subjects affected / exposed	1 / 120 (0.83%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Infections and infestations			
Asymptomatic Covid-19			
subjects affected / exposed	0 / 120 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Covid-19 Pneumonia			
subjects affected / exposed	0 / 120 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
COVID-19			
subjects affected / exposed	2 / 120 (1.67%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Complicated Appendicitis			
subjects affected / exposed	1 / 120 (0.83%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		

Frequency threshold for reporting non-serious adverse events: 2 %

Non-serious adverse events	Lusvertikimab 850 mg Induction Period	Lusvertikimab 450 mg Induction Period	Placebo Induction Period
Total subjects affected by non-serious adverse events			
subjects affected / exposed	7 / 51 (13.73%)	9 / 36 (25.00%)	12 / 49 (24.49%)
Vascular disorders			
Hypertension			
subjects affected / exposed	1 / 51 (1.96%)	0 / 36 (0.00%)	2 / 49 (4.08%)
occurrences (all)	1	0	2
Nervous system disorders			
Headache			
subjects affected / exposed	0 / 51 (0.00%)	0 / 36 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			

Lymphopenia			
subjects affected / exposed	2 / 51 (3.92%)	4 / 36 (11.11%)	1 / 49 (2.04%)
occurrences (all)	2	5	1
Anaemia			
subjects affected / exposed	0 / 51 (0.00%)	1 / 36 (2.78%)	2 / 49 (4.08%)
occurrences (all)	0	1	2
Thrombocytopenia			
subjects affected / exposed	0 / 51 (0.00%)	0 / 36 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Pyrexia			
subjects affected / exposed	0 / 51 (0.00%)	2 / 36 (5.56%)	1 / 49 (2.04%)
occurrences (all)	0	2	1
Gastrointestinal disorders			
Colitis Ulcerative			
subjects affected / exposed	2 / 51 (3.92%)	1 / 36 (2.78%)	3 / 49 (6.12%)
occurrences (all)	2	2	4
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 51 (0.00%)	0 / 36 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Covid-19			
subjects affected / exposed	0 / 51 (0.00%)	1 / 36 (2.78%)	2 / 49 (4.08%)
occurrences (all)	0	1	2
Upper Respiratory Tract Infection			
subjects affected / exposed	2 / 51 (3.92%)	0 / 36 (0.00%)	1 / 49 (2.04%)
occurrences (all)	2	0	1
Nasopharyngitis			
subjects affected / exposed	0 / 51 (0.00%)	0 / 36 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Lusvertikimab Open-Label Extension Period		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	49 / 120 (40.83%)		

Vascular disorders Hypertension subjects affected / exposed occurrences (all)	 0 / 120 (0.00%) 0		
Nervous system disorders Headache subjects affected / exposed occurrences (all)	 3 / 120 (2.50%) 5		
Blood and lymphatic system disorders Lymphopenia subjects affected / exposed occurrences (all) Anaemia subjects affected / exposed occurrences (all) Thrombocytopenia subjects affected / exposed occurrences (all)	 7 / 120 (5.83%) 9 7 / 120 (5.83%) 110 3 / 120 (2.50%) 3		
General disorders and administration site conditions Pyrexia subjects affected / exposed occurrences (all)	 0 / 120 (0.00%) 0		
Gastrointestinal disorders Colitis Ulcerative subjects affected / exposed occurrences (all)	 10 / 120 (8.33%) 12		
Musculoskeletal and connective tissue disorders Arthralgia subjects affected / exposed occurrences (all)	 3 / 120 (2.50%) 5		
Infections and infestations Covid-19 subjects affected / exposed occurrences (all) Upper Respiratory Tract Infection subjects affected / exposed occurrences (all)	 12 / 120 (10.00%) 12 0 / 120 (0.00%) 0		

Nasopharyngitis subjects affected / exposed occurrences (all)	4 / 120 (3.33%) 4		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
07 March 2022	Global protocol version 2.0 changes: - The study design was changed to discontinue the low dose arm (Lusvertikimab 450mg) based on the IDMC's recommendation from futility analysis results. - The study protocol's inclusion criteria were adapted to achieve the targeted proportion of biologics non-naïve patients in the initial randomization plan. - The revision of the sample size calculation to take into account the above 2 types of modifications.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? Yes

Date	Interruption	Restart date
01 December 2021	As per protocol, a Futility Analysis was scheduled after 50 patients (33% of the 150 planned patients) have completed the Induction Phase (availability of the primary endpoint at Week 10). To be consistent with the main purpose of a futility analysis (i.e. to unnecessarily expose patients to an investigational drug in a study that will not be able to show a treatment effect in its end), enrollment has been placed on hold starting 01 Dec 2021. Following the futility analysis, OSE accepted the IDMC recommendation to continue the study with modifications to the design (including testing one OSE-127 dose instead of 2). This recommendation automatically prolonged the enrollment hold period pending the regulatory acceptance of the protocol amendment. The induced additional delays in enrollment ended up in return in a foreseen lack of availability of vials with acceptable expiration period and had, as a consequence, the need for production of a new study medication batch, which also induced a prolongation of the enrollment hold period including for the regulatory part. Those unexpected circumstances did not affect the benefit/risk ratio nor the continuation of clinical trial activities for patients already enrolled. Enrollment resumed on 19 Sep 2022.	19 September 2022

Notes:

Limitations and caveats

None reported