Clinical trial results:
A randomized, subject and investigator blinded, placebo-controlled and multi-center platform study, to assess efficacy and safety of different investigational drugs in patients with moderate to severe hidradenitis suppurativa

Summary

EudraCT number	2018-002757-30
Trial protocol	FR HU DK NL IS CZ BE ES
Global end of trial date	

Results information

Result version number	v1 (current)
This version publication date	11 December 2025
First version publication date	11 December 2025

Trial information

Trial identification

Sponsor protocol code	CCFZ533H12201BC

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT03827798
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Novartis Pharma AG
Sponsor organisation address	Lichtstrasse 35, Basel, Switzerland, 4056
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	Interim
Date of interim/final analysis	04 December 2024
Is this the analysis of the primary completion data?	Yes
Primary completion date	04 December 2024
Global end of trial reached?	No

Notes:

General information about the trial

Main objective of the trial:

The primary objective of this study was to assess the efficacy of the investigational treatments compared to the pooled placebo group from Cohorts A, B, C, and D, in moderate to severe inflammatory hidradenitis suppurativa (HS) patients by comparing the proportion of participants achieving clinical response defined by the simplified Hidradenitis Suppurativa Clinical Response (sHiSCR) after 16 weeks of treatment. This study has a cohort E which is ongoing and will be reported in CTIS.

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	27 February 2019
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Austria: 3
Country: Number of subjects enrolled	Belgium: 13
Country: Number of subjects enrolled	Czechia: 12
Country: Number of subjects enrolled	Denmark: 5
Country: Number of subjects enrolled	France: 50
Country: Number of subjects enrolled	Germany: 28
Country: Number of subjects enrolled	Hungary: 19
Country: Number of subjects enrolled	Iceland: 1
Country: Number of subjects enrolled	Netherlands: 14
Country: Number of subjects enrolled	Spain: 29
Country: Number of subjects enrolled	United States: 31
Worldwide total number of subjects	205
EEA total number of subjects	174

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)	205
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Participants took part in 36 investigative sites in 11 countries.

Pre-assignment

Screening details:

The study consisted of a screening period of up to 35 days.

Period 1

Period 1 title	Treatment Epoch (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Investigator, Carer, Assessor, Subject

Arms

Are arms mutually exclusive?	Yes
Arm title	Cohort A - CFZ533 600 mg

Arm description:

CFZ533 600 mg administered subcutaneous (s.c) weekly for 4 weeks, followed by bi-weekly until Week 15.

Arm type	Experimental
Investigational medicinal product name	CFZ533
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

CFZ533 600 mg administered subcutaneous (s.c) weekly for 4 weeks, followed by bi-weekly until Week 15.

Arm title	Cohort A - Placebo to CFZ533

Arm description:

Placebo administered subcutaneous (s.c) weekly for 4 weeks, followed by bi-weekly until Week 15.

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

Dosage and administration details:

Placebo administered subcutaneous (s.c) weekly for 4 weeks, followed by bi-weekly until Week 15.

Arm title	Cohort B - LYS006 20 mg

Arm description:

LYS006 20 mg administered orally twice per day until Week 16.

Arm type	Experimental

Investigational medicinal product name	LYS006
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

LYS006 20 mg administered orally twice per day until Week 16.

Arm title	Cohort B - Placebo to LYS006

Arm description:

Placebo administered orally twice per day until Week 16.

Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

Placebo administered orally twice per day until Week 16.

Arm title	Cohort C - MAS825 300 mg

Arm description:

MAS825 300 mg administered s.c. bi-weekly for 4 weeks, followed by monthly until Week 13.

Arm type	Experimental
Investigational medicinal product name	MAS825
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

MAS825 300 mg administered s.c. bi-weekly for 4 weeks, followed by monthly until Week 13.

Arm title	Cohort C - Placebo to MAS825

Arm description:

Placebo administered s.c. bi-weekly for 4 weeks, followed by monthly until Week 13.

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

Dosage and administration details:

Placebo administered s.c. bi-weekly for 4 weeks, followed by monthly until Week 13.

Arm title	Cohort D - LOU064 25 mg

Arm description:

LOU064 25 mg administered orally twice per day until Week 16.

Arm type	Experimental
Investigational medicinal product name	LOU064
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:
LOU064 25 mg administered orally twice per day until Week 16.

Arm title	Cohort D - LOU064 100 mg
Arm description: LOU064 100 mg administered orally twice per day until Week 16.	
Arm type	Experimental
Investigational medicinal product name	LOU064
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use
Dosage and administration details: LOU064 100 mg administered orally twice per day until Week 16.	
Arm title	Cohort D - Placebo to LOU064
Arm description: Placebo administered orally twice per day until Week 16.	
Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use
Dosage and administration details: Placebo administered orally twice per day until Week 16.	

Number of subjects in period 1	Cohort A - CFZ533 600 mg	Cohort A - Placebo to CFZ533	Cohort B - LYS006 20 mg
Started	29	16	27
Completed	25	12	20
Not completed	4	4	7
Physician decision	1	-	1
Consent withdrawn by subject	2	3	4
Protocol Deviation	-	-	1
Adverse event	1	1	1
Lost to follow-up	-	-	-

Number of subjects in period 1	Cohort B - Placebo to LYS006	Cohort C - MAS825 300 mg	Cohort C - Placebo to MAS825
Started	13	33	10
Completed	9	29	9
Not completed	4	4	1
Physician decision	2	1	-
Consent withdrawn by subject	1	2	1

Protocol Deviation	-	-	-
Adverse event	1	1	-
Lost to follow-up	-	-	-

Number of subjects in period 1	Cohort D - LOU064 25 mg	Cohort D - LOU064 100 mg	Cohort D - Placebo to LOU064
Started	33	33	11
Completed	29	26	8
Not completed	4	7	3
Physician decision	-	-	-
Consent withdrawn by subject	4	3	2
Protocol Deviation	-	-	-
Adverse event	-	3	-
Lost to follow-up	-	1	1

Baseline characteristics

Reporting groups	
Reporting group title	Cohort A - CFZ533 600 mg
Reporting group description:	
CFZ533 600 mg administered subcutaneous (s.c) weekly for 4 weeks, followed by bi-weekly until Week 15.	
Reporting group title	Cohort A - Placebo to CFZ533
Reporting group description:	
Placebo administered subcutaneous (s.c) weekly for 4 weeks, followed by bi-weekly until Week 15.	
Reporting group title	Cohort B - LYS006 20 mg
Reporting group description:	
LYS006 20 mg administered orally twice per day until Week 16.	
Reporting group title	Cohort B - Placebo to LYS006
Reporting group description:	
Placebo administered orally twice per day until Week 16.	
Reporting group title	Cohort C - MAS825 300 mg
Reporting group description:	
MAS825 300 mg administered s.c. bi-weekly for 4 weeks, followed by monthly until Week 13.	
Reporting group title	Cohort C - Placebo to MAS825
Reporting group description:	
Placebo administered s.c. bi-weekly for 4 weeks, followed by monthly until Week 13.	
Reporting group title	Cohort D - LOU064 25 mg
Reporting group description:	
LOU064 25 mg administered orally twice per day until Week 16.	
Reporting group title	Cohort D - LOU064 100 mg
Reporting group description:	
LOU064 100 mg administered orally twice per day until Week 16.	
Reporting group title	Cohort D - Placebo to LOU064
Reporting group description:	
Placebo administered orally twice per day until Week 16.	

Reporting group values	Cohort A - CFZ533 600 mg	Cohort A - Placebo to CFZ533	Cohort B - LYS006 20 mg
Number of subjects	29	16	27
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)	29	16	27
From 65-84 years	0	0	0
85 years and over	0	0	0

Age Continuous Units: years			
arithmetic mean	38.0	41.4	36.4
standard deviation	± 8.68	± 9.54	± 9.62
Sex: Female, Male Units: participants			
Female	16	10	17
Male	13	6	10
Race/Ethnicity, Customized Units: Subjects			
Asian	1	0	1
Black Or African American	1	1	1
Other	1	0	1
Unknown	0	0	0
White	26	15	24

Reporting group values	Cohort B - Placebo to LYS006	Cohort C - MAS825 300 mg	Cohort C - Placebo to MAS825
Number of subjects	13	33	10
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)	13	33	10
From 65-84 years	0	0	0
85 years and over	0	0	0
Age Continuous Units: years			
arithmetic mean	36.5	39.5	36.9
standard deviation	± 13.29	± 8.22	± 10.26
Sex: Female, Male Units: participants			
Female	7	19	3
Male	6	14	7
Race/Ethnicity, Customized Units: Subjects			
Asian	0	0	0
Black Or African American	0	1	0
Other	0	5	0
Unknown	0	1	0
White	13	26	10

Reporting group values	Cohort D - LOU064 25 mg	Cohort D - LOU064 100 mg	Cohort D - Placebo to LOU064
Number of subjects	33	33	11

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)	33	33	11
From 65-84 years	0	0	0
85 years and over	0	0	0
Age Continuous Units: years			
arithmetic mean	35.6	35.3	44.1
standard deviation	± 10.84	± 10.99	± 7.83
Sex: Female, Male Units: participants			
Female	18	20	3
Male	15	13	8
Race/Ethnicity, Customized Units: Subjects			
Asian	0	1	0
Black Or African American	1	1	1
Other	2	0	0
Unknown	0	0	0
White	30	31	10

Reporting group values	Total		
Number of subjects	205		
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)	205		
From 65-84 years	0		
85 years and over	0		
Age Continuous Units: years			
arithmetic mean			
standard deviation	-		
Sex: Female, Male Units: participants			
Female	113		
Male	92		

Race/Ethnicity, Customized Units: Subjects			
Asian	3		
Black Or African American	7		
Other	9		
Unknown	1		
White	185		

End points

End points reporting groups

Reporting group title	Cohort A - CFZ533 600 mg
Reporting group description: CFZ533 600 mg administered subcutaneous (s.c) weekly for 4 weeks, followed by bi-weekly until Week 15.	
Reporting group title	Cohort A - Placebo to CFZ533
Reporting group description: Placebo administered subcutaneous (s.c) weekly for 4 weeks, followed by bi-weekly until Week 15.	
Reporting group title	Cohort B - LYS006 20 mg
Reporting group description: LYS006 20 mg administered orally twice per day until Week 16.	
Reporting group title	Cohort B - Placebo to LYS006
Reporting group description: Placebo administered orally twice per day until Week 16.	
Reporting group title	Cohort C - MAS825 300 mg
Reporting group description: MAS825 300 mg administered s.c. bi-weekly for 4 weeks, followed by monthly until Week 13.	
Reporting group title	Cohort C - Placebo to MAS825
Reporting group description: Placebo administered s.c. bi-weekly for 4 weeks, followed by monthly until Week 13.	
Reporting group title	Cohort D - LOU064 25 mg
Reporting group description: LOU064 25 mg administered orally twice per day until Week 16.	
Reporting group title	Cohort D - LOU064 100 mg
Reporting group description: LOU064 100 mg administered orally twice per day until Week 16.	
Reporting group title	Cohort D - Placebo to LOU064
Reporting group description: Placebo administered orally twice per day until Week 16.	
Subject analysis set title	Pooled Placebo (Cohorts A, B and C)
Subject analysis set type	Full analysis
Subject analysis set description: Placebo to CFZ533, LYS006 and MAS825.	
Subject analysis set title	Pooled Placebo (Cohorts A, B, C and D)
Subject analysis set type	Full analysis
Subject analysis set description: Placebo to CFZ533, LYS006, MAS825 and LOU064.	

Primary: Percentage of participants achieving Clinical Response measured by simplified Hidradenitis Suppurativa (sHiSCR)

End point title	Percentage of participants achieving Clinical Response measured by simplified Hidradenitis Suppurativa (sHiSCR)[1]

End point description:

sHiSCR was defined as at least a 50 percent (%) reduction in abscess and inflammatory nodule (AN) counts, and no increase in draining fistula count related to baseline. The primary variable was modeled with the binomial distribution. A neutral non-informative Beta (1/3, 1/3) distribution was used as the prior for the response rate for all treatment groups. Based on the priors and the observed primary outcome, posterior distributions for the response rate for the investigational treatment and pooled placebo groups were computed respectively. At the time of the statistical comparison for cohorts A, B, and C, the placebo data for cohorts D and E were incomplete and therefore excluded. Similarly, during the comparison for cohort D, the placebo data for cohort E was still pending and was not included.

End point type	Primary

End point timeframe:

Baseline, Week 16

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: The end point is specific for the arms presented.

End point values	Cohort A - CFZ533 600 mg	Cohort B - LYS006 20 mg	Cohort C - MAS825 300 mg	Cohort D - LOU064 25 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	29	25	32	33
Units: percentage of participants				
number (not applicable)	58.62	32.00	46.88	72.73

End point values	Cohort D - LOU064 100 mg	Pooled Placebo (Cohorts A, B and C)	Pooled Placebo (Cohorts A, B, C and D)	
Subject group type	Reporting group	Subject analysis set	Subject analysis set	
Number of subjects analysed	33	39	49	
Units: percentage of participants				
number (not applicable)	48.48	35.9	34.69	

Statistical analyses

Statistical analysis title	Clinical Response
Comparison groups	Cohort A - CFZ533 600 mg v Pooled Placebo (Cohorts A, B and C)
Number of subjects included in analysis	68
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Posterior estimate treatment difference
Point estimate	22.1
Confidence interval	
level	90 %
sides	2-sided
lower limit	2.5
upper limit	41

Statistical analysis title	Clinical Response
Comparison groups	Cohort B - LYS006 20 mg v Pooled Placebo (Cohorts A, B and C)

Number of subjects included in analysis	64
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Posterior estimate treatment difference
Point estimate	-3.3
Confidence interval	
level	90 %
sides	2-sided
lower limit	-21.9
upper limit	15.9

Statistical analysis title	Clinical Response
Comparison groups	Cohort C - MAS825 300 mg v Pooled Placebo (Cohorts A, B and C)
Number of subjects included in analysis	71
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Posterior estimate treatment difference
Point estimate	12.2
Confidence interval	
level	90 %
sides	2-sided
lower limit	-7.5
upper limit	31.6

Statistical analysis title	Clinical Response
Comparison groups	Cohort D - LOU064 25 mg v Pooled Placebo (Cohorts A, B, C and D)
Number of subjects included in analysis	82
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Posterior estimate treatment difference
Point estimate	37.2
Confidence interval	
level	90 %
sides	2-sided
lower limit	19.7
upper limit	53

Statistical analysis title	Clinical Response
Comparison groups	Cohort D - LOU064 100 mg v Pooled Placebo (Cohorts A, B, C and D)

Number of subjects included in analysis	82
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Posterior estimate treatment difference
Point estimate	13.9
Confidence interval	
level	90 %
sides	2-sided
lower limit	-4.2
upper limit	31.9

Adverse events

Adverse events information	
Timeframe for reporting adverse events: Cohorts A, B and C: 28 weeks including 12 weeks follow up period. Cohort D: 20 weeks including 4 weeks follow up period.	
Assessment type	Systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	27.1

Reporting groups	
Reporting group title	Cohort A-CFZ533 600 mg
Reporting group description: CFZ533 600 mg	
Reporting group title	Cohort C-MAS825 300 mg
Reporting group description: MAS825 300 mg	
Reporting group title	Cohort B-LYS006 20 mg
Reporting group description: LYS006 20 mg	
Reporting group title	Cohort D-LOU064 25 mg
Reporting group description: LOU064 25 mg	
Reporting group title	Cohort D-LOU064 100 mg
Reporting group description: LOU064 100 mg	
Reporting group title	Pooled Placebo
Reporting group description: Pooled Placebo (Cohorts A, B, C and D)	
Reporting group title	Total
Reporting group description: Total	

Serious adverse events	Cohort A-CFZ533 600 mg	Cohort C-MAS825 300 mg	Cohort B-LYS006 20 mg
Total subjects affected by serious adverse events			
subjects affected / exposed	4 / 29 (13.79%)	1 / 33 (3.03%)	2 / 27 (7.41%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Investigations			
Blood creatine phosphokinase increased			
subjects affected / exposed	0 / 29 (0.00%)	0 / 33 (0.00%)	1 / 27 (3.70%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Vascular disorders			
Hypertensive crisis			
subjects affected / exposed	0 / 29 (0.00%)	0 / 33 (0.00%)	0 / 27 (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			
Pancreatitis acute			
subjects affected / exposed	0 / 29 (0.00%)	0 / 33 (0.00%)	0 / 27 (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	1 / 29 (3.45%)	0 / 33 (0.00%)	0 / 27 (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
Testicular torsion			
subjects affected / exposed	1 / 29 (3.45%)	0 / 33 (0.00%)	0 / 27 (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			
Alcohol withdrawal syndrome			
subjects affected / exposed	0 / 29 (0.00%)	0 / 33 (0.00%)	1 / 27 (3.70%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Depression			
subjects affected / exposed	0 / 29 (0.00%)	1 / 33 (3.03%)	0 / 27 (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			
Abscess limb			
subjects affected / exposed	1 / 29 (3.45%)	0 / 33 (0.00%)	0 / 27 (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
Genital abscess			

subjects affected / exposed	1 / 29 (3.45%)	0 / 33 (0.00%)	0 / 27 (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
Testicular abscess			
subjects affected / exposed	0 / 29 (0.00%)	0 / 33 (0.00%)	0 / 27 (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	Cohort D-LOU064 25 mg	Cohort D-LOU064 100 mg	Pooled Placebo
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 33 (3.03%)	1 / 33 (3.03%)	1 / 50 (2.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Investigations			
Blood creatine phosphokinase increased			
subjects affected / exposed	0 / 33 (0.00%)	0 / 33 (0.00%)	0 / 50 (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			
Hypertensive crisis			
subjects affected / exposed	0 / 33 (0.00%)	1 / 33 (3.03%)	0 / 50 (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
Gastrointestinal disorders			
Pancreatitis acute			
subjects affected / exposed	1 / 33 (3.03%)	0 / 33 (0.00%)	0 / 50 (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			
Ovarian cyst			
subjects affected / exposed	0 / 33 (0.00%)	0 / 33 (0.00%)	0 / 50 (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
Testicular torsion			

subjects affected / exposed	0 / 33 (0.00%)	0 / 33 (0.00%)	0 / 50 (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			
Alcohol withdrawal syndrome			
subjects affected / exposed	0 / 33 (0.00%)	0 / 33 (0.00%)	0 / 50 (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
Depression			
subjects affected / exposed	0 / 33 (0.00%)	0 / 33 (0.00%)	0 / 50 (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			
Abscess limb			
subjects affected / exposed	0 / 33 (0.00%)	0 / 33 (0.00%)	0 / 50 (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
Genital abscess			
subjects affected / exposed	0 / 33 (0.00%)	0 / 33 (0.00%)	0 / 50 (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
Testicular abscess			
subjects affected / exposed	0 / 33 (0.00%)	0 / 33 (0.00%)	1 / 50 (2.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Total		
Total subjects affected by serious adverse events			
subjects affected / exposed	10 / 205 (4.88%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		
Investigations			
Blood creatine phosphokinase increased			

subjects affected / exposed	1 / 205 (0.49%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Vascular disorders			
Hypertensive crisis			
subjects affected / exposed	1 / 205 (0.49%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal disorders			
Pancreatitis acute			
subjects affected / exposed	1 / 205 (0.49%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Reproductive system and breast disorders			
Ovarian cyst			
subjects affected / exposed	1 / 205 (0.49%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Testicular torsion			
subjects affected / exposed	1 / 205 (0.49%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Psychiatric disorders			
Alcohol withdrawal syndrome			
subjects affected / exposed	1 / 205 (0.49%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Depression			
subjects affected / exposed	1 / 205 (0.49%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Infections and infestations			
Abscess limb			

subjects affected / exposed	1 / 205 (0.49%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Genital abscess			
subjects affected / exposed	1 / 205 (0.49%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Testicular abscess			
subjects affected / exposed	1 / 205 (0.49%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		

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

Non-serious adverse events	Cohort A-CFZ533 600 mg	Cohort C-MAS825 300 mg	Cohort B-LYS006 20 mg
Total subjects affected by non-serious adverse events			
subjects affected / exposed	23 / 29 (79.31%)	22 / 33 (66.67%)	19 / 27 (70.37%)
Investigations			
Blood creatine phosphokinase increased			
subjects affected / exposed	0 / 29 (0.00%)	0 / 33 (0.00%)	0 / 27 (0.00%)
occurrences (all)	0	0	0
Bacterial test positive			
subjects affected / exposed	2 / 29 (6.90%)	1 / 33 (3.03%)	1 / 27 (3.70%)
occurrences (all)	2	1	1
Blood glucose increased			
subjects affected / exposed	0 / 29 (0.00%)	0 / 33 (0.00%)	0 / 27 (0.00%)
occurrences (all)	0	0	0
Blood urine present			
subjects affected / exposed	2 / 29 (6.90%)	1 / 33 (3.03%)	0 / 27 (0.00%)
occurrences (all)	2	1	0
Nitrite urine present			
subjects affected / exposed	2 / 29 (6.90%)	0 / 33 (0.00%)	0 / 27 (0.00%)
occurrences (all)	3	0	0
Crystal urine present			

subjects affected / exposed	0 / 29 (0.00%)	0 / 33 (0.00%)	1 / 27 (3.70%)
occurrences (all)	0	0	1
C-reactive protein increased			
subjects affected / exposed	0 / 29 (0.00%)	2 / 33 (6.06%)	0 / 27 (0.00%)
occurrences (all)	0	2	0
Urine albumin/creatinine ratio increased			
subjects affected / exposed	2 / 29 (6.90%)	1 / 33 (3.03%)	3 / 27 (11.11%)
occurrences (all)	3	2	3
Vascular disorders			
Hypertension			
subjects affected / exposed	1 / 29 (3.45%)	1 / 33 (3.03%)	1 / 27 (3.70%)
occurrences (all)	1	1	1
Nervous system disorders			
Headache			
subjects affected / exposed	2 / 29 (6.90%)	5 / 33 (15.15%)	4 / 27 (14.81%)
occurrences (all)	4	7	4
Dizziness			
subjects affected / exposed	1 / 29 (3.45%)	0 / 33 (0.00%)	2 / 27 (7.41%)
occurrences (all)	1	0	3
General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	1 / 29 (3.45%)	3 / 33 (9.09%)	4 / 27 (14.81%)
occurrences (all)	1	3	4
Asthenia			
subjects affected / exposed	3 / 29 (10.34%)	2 / 33 (6.06%)	0 / 27 (0.00%)
occurrences (all)	3	2	0
Pyrexia			
subjects affected / exposed	1 / 29 (3.45%)	1 / 33 (3.03%)	3 / 27 (11.11%)
occurrences (all)	1	2	3
Blood and lymphatic system disorders			
Increased tendency to bruise			
subjects affected / exposed	0 / 29 (0.00%)	0 / 33 (0.00%)	0 / 27 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Diarrhoea			

subjects affected / exposed	1 / 29 (3.45%)	2 / 33 (6.06%)	1 / 27 (3.70%)
occurrences (all)	1	2	1
Constipation			
subjects affected / exposed	0 / 29 (0.00%)	0 / 33 (0.00%)	0 / 27 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	1 / 29 (3.45%)	0 / 33 (0.00%)	1 / 27 (3.70%)
occurrences (all)	1	0	1
Flatulence			
subjects affected / exposed	0 / 29 (0.00%)	0 / 33 (0.00%)	2 / 27 (7.41%)
occurrences (all)	0	0	2
Abdominal pain			
subjects affected / exposed	2 / 29 (6.90%)	0 / 33 (0.00%)	0 / 27 (0.00%)
occurrences (all)	2	0	0
Respiratory, thoracic and mediastinal disorders			
Oropharyngeal pain			
subjects affected / exposed	1 / 29 (3.45%)	1 / 33 (3.03%)	2 / 27 (7.41%)
occurrences (all)	1	1	2
Skin and subcutaneous tissue disorders			
Pruritus			
subjects affected / exposed	1 / 29 (3.45%)	0 / 33 (0.00%)	0 / 27 (0.00%)
occurrences (all)	1	0	0
Pain of skin			
subjects affected / exposed	0 / 29 (0.00%)	0 / 33 (0.00%)	0 / 27 (0.00%)
occurrences (all)	0	0	0
Hidradenitis			
subjects affected / exposed	0 / 29 (0.00%)	5 / 33 (15.15%)	2 / 27 (7.41%)
occurrences (all)	0	6	3
Erythema			
subjects affected / exposed	1 / 29 (3.45%)	1 / 33 (3.03%)	0 / 27 (0.00%)
occurrences (all)	1	1	0
Renal and urinary disorders			
Proteinuria			
subjects affected / exposed	1 / 29 (3.45%)	0 / 33 (0.00%)	1 / 27 (3.70%)
occurrences (all)	1	0	1
Psychiatric disorders			

Depression			
subjects affected / exposed	0 / 29 (0.00%)	2 / 33 (6.06%)	1 / 27 (3.70%)
occurrences (all)	0	2	1
Musculoskeletal and connective tissue disorders			
Pain in extremity			
subjects affected / exposed	2 / 29 (6.90%)	1 / 33 (3.03%)	1 / 27 (3.70%)
occurrences (all)	2	1	1
Myalgia			
subjects affected / exposed	2 / 29 (6.90%)	0 / 33 (0.00%)	0 / 27 (0.00%)
occurrences (all)	2	0	0
Back pain			
subjects affected / exposed	2 / 29 (6.90%)	1 / 33 (3.03%)	1 / 27 (3.70%)
occurrences (all)	2	1	2
Arthralgia			
subjects affected / exposed	3 / 29 (10.34%)	0 / 33 (0.00%)	1 / 27 (3.70%)
occurrences (all)	3	0	1
Infections and infestations			
Nasopharyngitis			
subjects affected / exposed	1 / 29 (3.45%)	3 / 33 (9.09%)	4 / 27 (14.81%)
occurrences (all)	2	3	4
Influenza			
subjects affected / exposed	0 / 29 (0.00%)	0 / 33 (0.00%)	0 / 27 (0.00%)
occurrences (all)	0	0	0
Ear infection			
subjects affected / exposed	0 / 29 (0.00%)	0 / 33 (0.00%)	2 / 27 (7.41%)
occurrences (all)	0	0	2
COVID-19			
subjects affected / exposed	3 / 29 (10.34%)	8 / 33 (24.24%)	1 / 27 (3.70%)
occurrences (all)	3	8	1
Bacteriuria			
subjects affected / exposed	0 / 29 (0.00%)	1 / 33 (3.03%)	0 / 27 (0.00%)
occurrences (all)	0	1	0
Sinusitis			
subjects affected / exposed	2 / 29 (6.90%)	3 / 33 (9.09%)	0 / 27 (0.00%)
occurrences (all)	2	3	0
Upper respiratory tract infection			

subjects affected / exposed	1 / 29 (3.45%)	0 / 33 (0.00%)	0 / 27 (0.00%)
occurrences (all)	1	0	0
Tonsillitis			
subjects affected / exposed	0 / 29 (0.00%)	0 / 33 (0.00%)	0 / 27 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Cohort D-LOU064 25 mg	Cohort D-LOU064 100 mg	Pooled Placebo
Total subjects affected by non-serious adverse events			
subjects affected / exposed	26 / 33 (78.79%)	15 / 33 (45.45%)	33 / 50 (66.00%)
Investigations			
Blood creatine phosphokinase increased			
subjects affected / exposed	2 / 33 (6.06%)	0 / 33 (0.00%)	1 / 50 (2.00%)
occurrences (all)	2	0	1
Bacterial test positive			
subjects affected / exposed	0 / 33 (0.00%)	0 / 33 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
Blood glucose increased			
subjects affected / exposed	2 / 33 (6.06%)	0 / 33 (0.00%)	0 / 50 (0.00%)
occurrences (all)	2	0	0
Blood urine present			
subjects affected / exposed	2 / 33 (6.06%)	0 / 33 (0.00%)	0 / 50 (0.00%)
occurrences (all)	2	0	0
Nitrite urine present			
subjects affected / exposed	0 / 33 (0.00%)	0 / 33 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
Crystal urine present			
subjects affected / exposed	0 / 33 (0.00%)	1 / 33 (3.03%)	5 / 50 (10.00%)
occurrences (all)	0	1	6
C-reactive protein increased			
subjects affected / exposed	2 / 33 (6.06%)	0 / 33 (0.00%)	3 / 50 (6.00%)
occurrences (all)	2	0	4
Urine albumin/creatinine ratio increased			
subjects affected / exposed	1 / 33 (3.03%)	1 / 33 (3.03%)	2 / 50 (4.00%)
occurrences (all)	1	1	2
Vascular disorders			

Hypertension			
subjects affected / exposed	2 / 33 (6.06%)	0 / 33 (0.00%)	4 / 50 (8.00%)
occurrences (all)	3	0	4
Nervous system disorders			
Headache			
subjects affected / exposed	4 / 33 (12.12%)	0 / 33 (0.00%)	6 / 50 (12.00%)
occurrences (all)	9	0	8
Dizziness			
subjects affected / exposed	2 / 33 (6.06%)	1 / 33 (3.03%)	1 / 50 (2.00%)
occurrences (all)	2	1	1
General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	3 / 33 (9.09%)	1 / 33 (3.03%)	4 / 50 (8.00%)
occurrences (all)	3	1	4
Asthenia			
subjects affected / exposed	2 / 33 (6.06%)	0 / 33 (0.00%)	3 / 50 (6.00%)
occurrences (all)	2	0	3
Pyrexia			
subjects affected / exposed	2 / 33 (6.06%)	0 / 33 (0.00%)	2 / 50 (4.00%)
occurrences (all)	2	0	2
Blood and lymphatic system disorders			
Increased tendency to bruise			
subjects affected / exposed	0 / 33 (0.00%)	2 / 33 (6.06%)	0 / 50 (0.00%)
occurrences (all)	0	2	0
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	2 / 33 (6.06%)	3 / 33 (9.09%)	5 / 50 (10.00%)
occurrences (all)	2	3	5
Constipation			
subjects affected / exposed	1 / 33 (3.03%)	2 / 33 (6.06%)	1 / 50 (2.00%)
occurrences (all)	1	2	1
Nausea			
subjects affected / exposed	2 / 33 (6.06%)	0 / 33 (0.00%)	2 / 50 (4.00%)
occurrences (all)	2	0	3
Flatulence			

subjects affected / exposed	0 / 33 (0.00%)	0 / 33 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
Abdominal pain			
subjects affected / exposed	1 / 33 (3.03%)	1 / 33 (3.03%)	2 / 50 (4.00%)
occurrences (all)	1	1	2
Respiratory, thoracic and mediastinal disorders			
Oropharyngeal pain			
subjects affected / exposed	2 / 33 (6.06%)	1 / 33 (3.03%)	0 / 50 (0.00%)
occurrences (all)	2	1	0
Skin and subcutaneous tissue disorders			
Pruritus			
subjects affected / exposed	2 / 33 (6.06%)	1 / 33 (3.03%)	2 / 50 (4.00%)
occurrences (all)	2	1	2
Pain of skin			
subjects affected / exposed	2 / 33 (6.06%)	1 / 33 (3.03%)	0 / 50 (0.00%)
occurrences (all)	2	1	0
Hidradenitis			
subjects affected / exposed	1 / 33 (3.03%)	0 / 33 (0.00%)	5 / 50 (10.00%)
occurrences (all)	1	0	5
Erythema			
subjects affected / exposed	2 / 33 (6.06%)	0 / 33 (0.00%)	0 / 50 (0.00%)
occurrences (all)	2	0	0
Renal and urinary disorders			
Proteinuria			
subjects affected / exposed	2 / 33 (6.06%)	0 / 33 (0.00%)	2 / 50 (4.00%)
occurrences (all)	2	0	2
Psychiatric disorders			
Depression			
subjects affected / exposed	0 / 33 (0.00%)	0 / 33 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Pain in extremity			
subjects affected / exposed	1 / 33 (3.03%)	0 / 33 (0.00%)	1 / 50 (2.00%)
occurrences (all)	1	0	1
Myalgia			

subjects affected / exposed	0 / 33 (0.00%)	0 / 33 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
Back pain			
subjects affected / exposed	0 / 33 (0.00%)	0 / 33 (0.00%)	1 / 50 (2.00%)
occurrences (all)	0	0	1
Arthralgia			
subjects affected / exposed	1 / 33 (3.03%)	0 / 33 (0.00%)	2 / 50 (4.00%)
occurrences (all)	1	0	4
Infections and infestations			
Nasopharyngitis			
subjects affected / exposed	7 / 33 (21.21%)	2 / 33 (6.06%)	1 / 50 (2.00%)
occurrences (all)	7	2	1
Influenza			
subjects affected / exposed	1 / 33 (3.03%)	0 / 33 (0.00%)	3 / 50 (6.00%)
occurrences (all)	1	0	3
Ear infection			
subjects affected / exposed	2 / 33 (6.06%)	0 / 33 (0.00%)	0 / 50 (0.00%)
occurrences (all)	2	0	0
COVID-19			
subjects affected / exposed	2 / 33 (6.06%)	2 / 33 (6.06%)	3 / 50 (6.00%)
occurrences (all)	2	2	3
Bacteriuria			
subjects affected / exposed	2 / 33 (6.06%)	0 / 33 (0.00%)	0 / 50 (0.00%)
occurrences (all)	2	0	0
Sinusitis			
subjects affected / exposed	0 / 33 (0.00%)	0 / 33 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			
subjects affected / exposed	2 / 33 (6.06%)	1 / 33 (3.03%)	2 / 50 (4.00%)
occurrences (all)	2	2	2
Tonsillitis			
subjects affected / exposed	2 / 33 (6.06%)	0 / 33 (0.00%)	0 / 50 (0.00%)
occurrences (all)	2	0	0

Non-serious adverse events	Total		
Total subjects affected by non-serious adverse events			

subjects affected / exposed	138 / 205 (67.32%)		
Investigations			
Blood creatine phosphokinase increased			
subjects affected / exposed	3 / 205 (1.46%)		
occurrences (all)	3		
Bacterial test positive			
subjects affected / exposed	4 / 205 (1.95%)		
occurrences (all)	4		
Blood glucose increased			
subjects affected / exposed	2 / 205 (0.98%)		
occurrences (all)	2		
Blood urine present			
subjects affected / exposed	5 / 205 (2.44%)		
occurrences (all)	5		
Nitrite urine present			
subjects affected / exposed	2 / 205 (0.98%)		
occurrences (all)	3		
Crystal urine present			
subjects affected / exposed	7 / 205 (3.41%)		
occurrences (all)	8		
C-reactive protein increased			
subjects affected / exposed	7 / 205 (3.41%)		
occurrences (all)	8		
Urine albumin/creatinine ratio increased			
subjects affected / exposed	10 / 205 (4.88%)		
occurrences (all)	12		
Vascular disorders			
Hypertension			
subjects affected / exposed	9 / 205 (4.39%)		
occurrences (all)	10		
Nervous system disorders			
Headache			
subjects affected / exposed	21 / 205 (10.24%)		
occurrences (all)	32		
Dizziness			

subjects affected / exposed	7 / 205 (3.41%)		
occurrences (all)	8		
General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	16 / 205 (7.80%)		
occurrences (all)	16		
Asthenia			
subjects affected / exposed	10 / 205 (4.88%)		
occurrences (all)	10		
Pyrexia			
subjects affected / exposed	9 / 205 (4.39%)		
occurrences (all)	10		
Blood and lymphatic system disorders			
Increased tendency to bruise			
subjects affected / exposed	2 / 205 (0.98%)		
occurrences (all)	2		
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	14 / 205 (6.83%)		
occurrences (all)	14		
Constipation			
subjects affected / exposed	4 / 205 (1.95%)		
occurrences (all)	4		
Nausea			
subjects affected / exposed	6 / 205 (2.93%)		
occurrences (all)	7		
Flatulence			
subjects affected / exposed	2 / 205 (0.98%)		
occurrences (all)	2		
Abdominal pain			
subjects affected / exposed	6 / 205 (2.93%)		
occurrences (all)	6		
Respiratory, thoracic and mediastinal disorders			
Oropharyngeal pain			
subjects affected / exposed	7 / 205 (3.41%)		
occurrences (all)	7		

Skin and subcutaneous tissue disorders			
Pruritus			
subjects affected / exposed	6 / 205 (2.93%)		
occurrences (all)	6		
Pain of skin			
subjects affected / exposed	3 / 205 (1.46%)		
occurrences (all)	3		
Hidradenitis			
subjects affected / exposed	13 / 205 (6.34%)		
occurrences (all)	15		
Erythema			
subjects affected / exposed	4 / 205 (1.95%)		
occurrences (all)	4		
Renal and urinary disorders			
Proteinuria			
subjects affected / exposed	6 / 205 (2.93%)		
occurrences (all)	6		
Psychiatric disorders			
Depression			
subjects affected / exposed	3 / 205 (1.46%)		
occurrences (all)	3		
Musculoskeletal and connective tissue disorders			
Pain in extremity			
subjects affected / exposed	6 / 205 (2.93%)		
occurrences (all)	6		
Myalgia			
subjects affected / exposed	2 / 205 (0.98%)		
occurrences (all)	2		
Back pain			
subjects affected / exposed	5 / 205 (2.44%)		
occurrences (all)	6		
Arthralgia			
subjects affected / exposed	7 / 205 (3.41%)		
occurrences (all)	9		
Infections and infestations			

Nasopharyngitis			
subjects affected / exposed	18 / 205 (8.78%)		
occurrences (all)	19		
Influenza			
subjects affected / exposed	4 / 205 (1.95%)		
occurrences (all)	4		
Ear infection			
subjects affected / exposed	4 / 205 (1.95%)		
occurrences (all)	4		
COVID-19			
subjects affected / exposed	19 / 205 (9.27%)		
occurrences (all)	19		
Bacteriuria			
subjects affected / exposed	3 / 205 (1.46%)		
occurrences (all)	3		
Sinusitis			
subjects affected / exposed	5 / 205 (2.44%)		
occurrences (all)	5		
Upper respiratory tract infection			
subjects affected / exposed	6 / 205 (2.93%)		
occurrences (all)	7		
Tonsillitis			
subjects affected / exposed	2 / 205 (0.98%)		
occurrences (all)	2		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
24 July 2019	The main purpose of this amendment was to remove the requirement for male contraception in the LYS006 cohort given that completed preclinical safety studies with LYS006 showed there was no teratogenic or genotoxic potential observed with LYS006
19 June 2020	The main purpose of this amendment was to address requests from Health Authorities and Ethics Committees, as well as to correct some inconsistencies in the protocol discovered during implementation.
26 February 2021	The main purpose of this amendment was to introduce an additional cohort (Cohort C) into this platform study.
03 December 2021	The main purpose of this amendment was to introduce an additional cohort (Cohort D) into this platform study.
03 February 2022	The purpose of this amendment was to add a blood sample for coagulation parameters to Cohort D, for safety monitoring reasons.
03 June 2022	The purpose of this amendment was to address comments raised by the Health Authority.
14 March 2023	The main purpose of this amendment was to introduce an additional cohort (Cohort E) into this platform study.
12 July 2023	The main purpose of this amendment was to update the dosage form for Cohort E.
29 November 2023	The main purpose of this amendment was to revise the exclusion criteria specific to Cohort E.
24 May 2024	The main purpose of this amendment was to introduce the Auxiliary Medicinal Products (AxMP) definition and related safety reporting rules, to comply with EU Clinical Trial Regulation 536/2014 (EU CTR).

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? Yes

Date	Interruption	Restart date
24 May 2023	Novartis filed a study Temporary Halt in May 2023 to maintain the study active as Cohort D was about to be completed and the submission of Cohort E-related protocol amendment (Amendment No. 8) was in process of preparation.	09 January 2024

Notes:

Limitations and caveats

None reported