Clinical trial results:
A phase II, randomised, double-blind, parallel-group, placebo-controlled trial to assess the ongoing pregnancy rate with OXO-001 (200 mg, 300 mg) or placebo at 10 weeks following fresh single blastocyst transfer resulting from donor oocyte IVF/ICSI

Summary

EudraCT number	2021-000001-25
Trial protocol	PL ES CZ
Global end of trial date	31 October 2023

Results information

Result version number	v1 (current)
This version publication date	28 November 2024
First version publication date	28 November 2024

Trial information

Trial identification

Sponsor protocol code	OXO-001-201

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT05076032
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	OXOLIFE
Sponsor organisation address	C/ Riu de l'Or 12, Baixos 2a, Barcelona, Spain, 08034
Public contact	CEO, Oxolife S.L., +34 609771937, info@oxolife.com
Scientific contact	CEO, Oxolife S.L., +34 609771937, info@oxolife.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	15 November 2023
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	31 October 2023
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

Assess the efficacy of oral OXO-001 (200 mg and 300 mg) versus placebo taken once-daily to increase the ongoing pregnancy rate (defined as the rate of intrauterine pregnancy with foetal heartbeat) at 10 weeks post embryo transfer (ET)

Protection of trial subjects:

This study was conducted in full compliance with the protocol, adhering to the ethical principles outlined in the Declaration of Helsinki, the International Council for Harmonization (ICH) Harmonized Tripartite Guideline for Good Clinical Practice (GCP), the European Union Clinical Trial Directive, and all relevant local laws and regulations.
Prior to the initiation of the study at any site, written approval of the protocol, Informed Consent Form (ICF), and all materials provided to potential participants were obtained ffrom Ethics Committee (IEC) and Competent Authorities (CA).

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	01 September 2021
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	Poland: 24
Country: Number of subjects enrolled	Spain: 241
Country: Number of subjects enrolled	Czechia: 114
Worldwide total number of subjects	379
EEA total number of subjects	379

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)	379
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

A total of 408 subjects were screened over a 9-month competitive recruitment period at 28 sites across three European countries: 15 sites in Spain, 9 in the Czech Republic, and 4 in Poland.

Pre-assignment

Screening details:

408 subjects were screened of which 379 were randomized. Out of this 379 randomized, 368 subjects received treatment and 307 underwent ET as ET eligibilty criteria. 305 subjects complete the trial as intended. One subject in OXO-001-200mg group underwent ET although ET eligibility criteria were not fulfilled and was excluded from the full analysis

Period 1

Period 1 title	overall trial (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator, Monitor, Data analyst

Blinding implementation details:

All tablets (OXO-001 100 mg, OXO-001 150 mg and placebo) were identical in size, colour, taste and appearance. The packaging and labelling did not allow for any distinction between test and reference drug.
No person involved in conducting the trial had access to the randomisation code before the blind was officially broken.

Arms

Are arms mutually exclusive?	Yes
Arm title	OXO-001 200 mg

Arm description:

Subjects randomised exposed to OXO-001-200 mg were included in this group.

Arm type	Experimental
Investigational medicinal product name	OXO-001
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Two tablets once daily early in the morning, Treatment started 26 to 62 days prior to ET and was continued for 5 weeks after ET

Arm title	OXO-001 300 mg

Arm description:

Subjects randomised and exposed to OXO-001-300 mg were included in this group

Arm type	Experimental
Investigational medicinal product name	OXO-001
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Two tablets once daily early in the morning, Treatment started 26 to 62 days prior to ET and was continued for 5 weeks after ET

Arm title	Placebo

Arm description:

Subjects randomised and exposed to placebo were included in this group

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

Dosage and administration details:

Two tablets once daily early in the morning, Treatment started 26 to 62 days prior to ET and was continued for 5 weeks after ET

Number of subjects in period 1	OXO-001 200 mg	OXO-001 300 mg	Placebo
Started	126	126	127
Completed	97	106	102
Not completed	29	20	25
Consent withdrawn by subject	6	5	3
at sponsor request	1	-	-
Ineligibility/not fulfilling ET criteria	8	7	6
Adverse event, non-fatal	4	2	5
At the discretion of the investigator	-	-	2
Pregnancy	3	1	1
lost of follow up	-	-	1
other	5	5	5
Protocol deviation	2	-	2

Baseline characteristics

Reporting groups	
Reporting group title	OXO-001 200 mg
Reporting group description:	
Subjects randomised exposed to OXO-001-200 mg were included in this group.	
Reporting group title	OXO-001 300 mg
Reporting group description:	
Subjects randomised and exposed to OXO-001-300 mg were included in this group	
Reporting group title	Placebo
Reporting group description:	
Subjects randomised and exposed to placebo were included in this group	

Reporting group values	OXO-001 200 mg	OXO-001 300 mg	Placebo
Number of subjects	126	126	127
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)	126	126	127
From 65-84 years	0	0	0
85 years and over	0	0	0
Age continuous Units: years			
arithmetic mean	39.5	39.7	40.7
standard deviation	± 4.36	± 4.42	± 3.46
Gender categorical Units: Subjects			
Female	126	126	127
Male	0	0	0

Reporting group values	Total		
Number of subjects	379		
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)	379		

From 65-84 years	0		
85 years and over	0		

Age continuous			
Units: years			
arithmetic mean			
standard deviation	-		
Gender categorical			
Units: Subjects			
Female	379		
Male	0		

Subject analysis sets

Subject analysis set title	Modified Full Analysis set (m-FAS) analysis set
Subject analysis set type	Modified intention-to-treat

Subject analysis set description:

The m-FAS analysis set was defined as all randomised and exposed subjects that fulfil elegibility ET criteria .

Subject analysis set title	Modified Full analysis set up to 40 years
Subject analysis set type	Modified intention-to-treat

Subject analysis set description:

The m-FAS analysis up to 40 years set was defined as subjects up to 40 years randomised,exposed and that fulfil elegibility ET criteria .

Subject analysis set title	Safety analysis set
Subject analysis set type	Safety analysis

Subject analysis set description:

The safety analysis set was defined as all randomised and exposed subjects

Reporting group values	Modified Full Analysis set (m-FAS) analysis set	Modified Full analysis set up to 40 years	Safety analysis set
Number of subjects	307	145	368
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)	307	145	368
From 65-84 years	0	0	0
85 years and over	0	0	0
Age continuous			
Units: years			
arithmetic mean	40	36.7	40.0
standard deviation	± 4.10	± 3.72	± 4.13
Gender categorical			
Units: Subjects			
Female	307	145	368

Male	0	0	0

End points

End points reporting groups

Reporting group title	OXO-001 200 mg
Reporting group description:	
Subjects randomised exposed to OXO-001-200 mg were included in this group.	
Reporting group title	OXO-001 300 mg
Reporting group description:	
Subjects randomised and exposed to OXO-001-300 mg were included in this group	
Reporting group title	Placebo
Reporting group description:	
Subjects randomised and exposed to placebo were included in this group	
Subject analysis set title	Modified Full Analysis set (m-FAS) analysis set
Subject analysis set type	Modified intention-to-treat
Subject analysis set description:	
The m-FAS analysis set was defined as all randomised and exposed subjects that fulfil elegibility ET criteria .	
Subject analysis set title	Modified Full analysis set up to 40 years
Subject analysis set type	Modified intention-to-treat
Subject analysis set description:	
The m-FAS analysis up to 40 years set was defined as subjects up to 40 years randomised,exposed and that fulfil elegibility ET criteria .	
Subject analysis set title	Safety analysis set
Subject analysis set type	Safety analysis
Subject analysis set description:	
The safety analysis set was defined as all randomised and exposed subjects	

Primary: Ongoing pregnancy rate (OPR)

End point title	Ongoing pregnancy rate (OPR)
End point description:	
Ongoing pregnancy rate was defined as confirmed intrauterine pregnancy with confirmed heartbeat 10 weeks post ET. Data are presented for the modified full analysis (m-FAS) set.	
End point type	Primary
End point timeframe:	
10 weeks post Embrio Transfer (ET)	

End point values	OXO-001 200 mg	OXO-001 300 mg	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	97	106	104	
Units: percent				
number (not applicable)	44.33	47.17	46.15	

Statistical analyses

Statistical analysis title	Percentage OPR 10 weeks post -ET

Statistical analysis description:

The analysis of the primary endpoint was performed using a logistic regression model with treatment group, age group (< 35, 35-37, 38-40, 41-42, ≥ 43), pooled site (Site 1 subgroup) and blastocyst quality (3, 4, 5-6) as factors, with a two-sided type I error of 0.05. The treatment effect was characterised by (adjusted) odds ratio of each dose group relative to placebo with associated two-sided 95% confidence intervals (CIs).

Comparison groups	OXO-001 200 mg v Placebo
Number of subjects included in analysis	201
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Odds ratio (OR)
Point estimate	0.99
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.54
upper limit	1.81

Statistical analysis title	Percentage OPR 10 weeks post -ET

Statistical analysis description:

The analysis of the primary endpoint was performed using a logistic regression model with treatment group, age group (< 35, 35-37, 38-40, 41-42, ≥ 43), pooled site (Site 1 subgroup) and blastocyst quality (3, 4, 5-6) as factors, with a two-sided type I error of 0.05. The treatment effect was characterised by (adjusted) odds ratio of each dose group relative to placebo with associated two-sided 95% confidence intervals (CIs).

Comparison groups	OXO-001 300 mg v Placebo
Number of subjects included in analysis	210
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Odds ratio (OR)
Point estimate	0.97
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.54
upper limit	1.74

Primary: OPR women up to 40 years

End point title	OPR women up to 40 years

End point description:

Confirmed intrauterine pregnancy with confirmed heartbeat 10 weeks post ET for women up to 4o years

End point type	Primary

End point timeframe:

10 weeks post Embrio Transfer (ET)

End point values	OXO-001 200 mg	OXO-001 300 mg	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	49	54	42	
Units: percent				
number (not applicable)	44.90	46.30	35.71	

Statistical analyses

Statistical analysis title	Percentage OPR 10 weeks post -ET
Statistical analysis description: Ongoing Pregnancy Rate (OPR) 10 weeks post ET (m-FAS)	
Comparison groups	Placebo v OXO-001 200 mg
Number of subjects included in analysis	91
Analysis specification	Post-hoc
Analysis type	superiority
Parameter estimate	Odds ratio (OR)
Point estimate	1.44
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.6
upper limit	3.5

Statistical analysis title	Percentage OPR 10 weeks post -ET
Statistical analysis description: Ongoing Pregnancy Rate (OPR) 10 weeks post ET (m-FAS)	
Comparison groups	Placebo v OXO-001 300 mg
Number of subjects included in analysis	96
Analysis specification	Post-hoc
Analysis type	superiority
Parameter estimate	Odds ratio (OR)
Point estimate	1.38
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.58
upper limit	3.32

Secondary: Biochemical Pergnancy Rate (BPR)

End point title	Biochemical Pergnancy Rate (BPR)

End point description: Positive blood pregnancy test 10 to 15 days post ET (m-FAS)	
End point type	Secondary
End point timeframe: 10 to 15 days post ET	

End point values	OXO-001 200 mg	OXO-001 300 mg	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	97	106	104	
Units: percent				
number (not applicable)	65.98	72.64	61.54	

Statistical analyses

Statistical analysis title	Percentage BPR 10 to 15 days post ET
Statistical analysis description: Percentage of women with positive blood pregnancy test 10 to 15 days post ET (m-FAS)	
Comparison groups	OXO-001 200 mg v Placebo
Number of subjects included in analysis	201
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Odds ratio (OR)
Point estimate	1.42
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.76
upper limit	2.65

Statistical analysis title	Percentage BPR 10 to 15 days post ET
Statistical analysis description: Percentage of women with positive blood pregnancy test 10 to 15 days post ET (m-FAS)	
Comparison groups	Placebo v OXO-001 300 mg
Number of subjects included in analysis	210
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Odds ratio (OR)
Point estimate	1.63
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.87
upper limit	3.04

Secondary: CLinical Pregnancy rate (CPR)	
End point title	CLinical Pregnancy rate (CPR)
End point description:	
Percentage of women with clinical pregnancy (defined as pregnancy withfoetal heartbeat) at 6 weeks post ET (m-FAS)	
End point type	Secondary
End point timeframe:	
6 weeks post ET	

End point values	OXO-001 200 mg	OXO-001 300 mg	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	97	106	104	
Units: percent				
number (not applicable)	49.48	50.94	46.15	

Statistical analyses

Statistical analysis title	Percentage CPR 6 weeks post -ET
Statistical analysis description:	
Percentage of women with clinical pregnancy (defined as pregnancy withfoetal heartbeat) at 6 weeks post ET (m-FAS)	
Comparison groups	OXO-001 200 mg v Placebo
Number of subjects included in analysis	201
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Odds ratio (OR)
Point estimate	1.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.7
upper limit	2.38

Statistical analysis title	Percentage CPR 6 weeks post -ET
Statistical analysis description:	
Percentage of women with clinical pregnancy (defined as pregnancy withfoetal heartbeat) at 6 weeks post ET (m-FAS)	
Comparison groups	Placebo v OXO-001 300 mg

Number of subjects included in analysis	210
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Odds ratio (OR)
Point estimate	1.15
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.63
upper limit	2.07

Secondary: BIochemical pregnancy rate women up to 40 years .

End point title	BIochemical pregnancy rate women up to 40 years .
End point description:	
Positive blood pregnancy test 10 to 15 days post ET women up to 40 years	
End point type	Secondary
End point timeframe:	
10 to 15 days post ET	

End point values	OXO-001 200 mg	OXO-001 300 mg	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	49	54	42	
Units: percent				
number (not applicable)	67.35	75.93	52.38	

Statistical analyses

Statistical analysis title	Percentage BQR 10 to 15 days post ET
Statistical analysis description:	
Percentage of women with positive blood pregnancy test 10 to 15 days post ET	
Comparison groups	OXO-001 200 mg v Placebo
Number of subjects included in analysis	91
Analysis specification	Post-hoc
Analysis type	superiority
Parameter estimate	Odds ratio (OR)
Point estimate	2.08
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.83
upper limit	5.2

Statistical analysis title	Percentage BQR 10 to 15 days post ET
Statistical analysis description:	
Percentage of women with positive blood pregnancy test 10 to 15 days post ET	
Comparison groups	Placebo v OXO-001 300 mg
Number of subjects included in analysis	96
Analysis specification	Post-hoc
Analysis type	superiority
P-value	= 0.022
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	3.03
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.17
upper limit	7.85

Secondary: CPR women up to 40 years	
End point title	CPR women up to 40 years
End point description:	
Percentage of women with clinical pregnancy (defined as pregnancy withfoetal heartbeat) at 6 weeks post ET.	
End point type	Secondary
End point timeframe:	
6 weeks post Embrio Transfer (ET)	

End point values	OXO-001 200 mg	OXO-001 300 mg	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	49	54	42	
Units: percent				
number (not applicable)	46.94	50.00	35.71	

Statistical analyses

Statistical analysis title	Percentage CPR 6 weeks post -ET
Statistical analysis description:	
Percentage of women with clinical pregnancy (defined as pregnancy withfoetal heartbeat) at 6 weeks post ET.	
Comparison groups	Placebo v OXO-001 200 mg

Number of subjects included in analysis	91
Analysis specification	Post-hoc
Analysis type	superiority
Parameter estimate	Odds ratio (OR)
Point estimate	1.56
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.64
upper limit	3.79

Statistical analysis title	Percentage CPR 6 weeks post -ET

Statistical analysis description:

Percentage of women with clinical pregnancy (defined as pregnancy withfoetal heartbeat) at 6 weeks post ET.

Comparison groups	Placebo v OXO-001 300 mg
Number of subjects included in analysis	96
Analysis specification	Post-hoc
Analysis type	superiority
Parameter estimate	Odds ratio (OR)
Point estimate	1.62
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.68
upper limit	3.88

Adverse events

Adverse events information

Timeframe for reporting adverse events:

The period of observation for the collection of AEs extends from the time when the subject gives informed consent until 10 weeks post ET

Adverse event reporting additional description:

In addition, the following AEs and SAEs should be reported after completion of Visit 8:
- AEs which could affect foetal outcome or AEs suspected related to IP,
- SAEs related to pregnancy,
- Any congenital anomalies or SAEs experienced by the foetus (until birth), neonate (from birth up to 28 days) or infant (until 6 months after birth)

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	24

Reporting groups

Reporting group title	OXO-001 200 mg

Reporting group description:

Subjects randomised exposed to OXO-001-200 mg were included in this group.

Reporting group title	OXO-001 300 mg

Reporting group description:

Subjects randomised and exposed to OXO-001-300 mg were included in this group

Reporting group title	Placebo

Reporting group description:

Subjects randomised and exposed to placebo were included in this group

Serious adverse events	OXO-001 200 mg	OXO-001 300 mg	Placebo
Total subjects affected by serious adverse events			
subjects affected / exposed	9 / 121 (7.44%)	9 / 125 (7.20%)	8 / 122 (6.56%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Brain neoplasm benign			
subjects affected / exposed	0 / 121 (0.00%)	1 / 125 (0.80%)	0 / 122 (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
Breast cancer			
subjects affected / exposed	0 / 121 (0.00%)	0 / 125 (0.00%)	1 / 122 (0.82%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Congenital, familial and genetic disorders			

Atrial septal defect			
subjects affected / exposed	0 / 121 (0.00%)	1 / 125 (0.80%)	0 / 122 (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
Beckwith-Wiedemann syndrome			
subjects affected / exposed	0 / 121 (0.00%)	1 / 125 (0.80%)	0 / 122 (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
Congenital hydrocephalus			
subjects affected / exposed	1 / 121 (0.83%)	0 / 125 (0.00%)	0 / 122 (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
Congenital inguinal hernia			
subjects affected / exposed	0 / 121 (0.00%)	1 / 125 (0.80%)	0 / 122 (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
Congenital naevus			
subjects affected / exposed	1 / 121 (0.83%)	0 / 125 (0.00%)	0 / 122 (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
Congenital torticollis			
subjects affected / exposed	0 / 121 (0.00%)	0 / 125 (0.00%)	1 / 122 (0.82%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Craniofacial deformity			
subjects affected / exposed	0 / 121 (0.00%)	1 / 125 (0.80%)	0 / 122 (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
Developmental hip dysplasia			
subjects affected / exposed	1 / 121 (0.83%)	0 / 125 (0.00%)	0 / 122 (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
Duodenal atresia			

subjects affected / exposed	0 / 121 (0.00%)	0 / 125 (0.00%)	1 / 122 (0.82%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dysmorphism			
subjects affected / exposed	0 / 121 (0.00%)	1 / 125 (0.80%)	0 / 122 (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
Infantile genetic agranulocytosis			
subjects affected / exposed	1 / 121 (0.83%)	0 / 125 (0.00%)	0 / 122 (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
Klinefelter's syndrome			
subjects affected / exposed	0 / 121 (0.00%)	1 / 125 (0.80%)	0 / 122 (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
Patent ductus arteriosus			
subjects affected / exposed	0 / 121 (0.00%)	1 / 125 (0.80%)	0 / 122 (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
Syndactyly			
subjects affected / exposed	0 / 121 (0.00%)	1 / 125 (0.80%)	0 / 122 (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
Surgical and medical procedures			
Abortion induced			
subjects affected / exposed	0 / 121 (0.00%)	2 / 125 (1.60%)	0 / 122 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pregnancy, puerperium and perinatal conditions			
Pre-eclampsia			
subjects affected / exposed	3 / 121 (2.48%)	2 / 125 (1.60%)	3 / 122 (2.46%)
occurrences causally related to treatment / all	0 / 3	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Abortion spontaneous			
subjects affected / exposed	0 / 121 (0.00%)	0 / 125 (0.00%)	2 / 122 (1.64%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Premature baby			
subjects affected / exposed	2 / 121 (1.65%)	0 / 125 (0.00%)	0 / 122 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
abnormal cord insertion			
subjects affected / exposed	0 / 121 (0.00%)	1 / 125 (0.80%)	0 / 122 (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
Ectopic pregnancy			
subjects affected / exposed	1 / 121 (0.83%)	0 / 125 (0.00%)	0 / 122 (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
Foetal growth restriction			
subjects affected / exposed	0 / 121 (0.00%)	1 / 125 (0.80%)	0 / 122 (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
Pregnancy of unknown location			
subjects affected / exposed	1 / 121 (0.83%)	0 / 125 (0.00%)	0 / 122 (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
Blood and lymphatic system disorders			
Placental transfusion syndrome			
subjects affected / exposed	0 / 121 (0.00%)	1 / 125 (0.80%)	0 / 122 (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
Ear and labyrinth disorders			
Hypoacusis			
subjects affected / exposed	1 / 121 (0.83%)	0 / 125 (0.00%)	0 / 122 (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

Gastrointestinal disorders			
Intestinal obstruction			
subjects affected / exposed	1 / 121 (0.83%)	0 / 125 (0.00%)	0 / 122 (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
Respiratory, thoracic and mediastinal disorders			
Neonatal respiratory depression			
subjects affected / exposed	0 / 121 (0.00%)	0 / 125 (0.00%)	1 / 122 (0.82%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endocrine disorders			
Adrenal haemorrhage			
subjects affected / exposed	0 / 121 (0.00%)	0 / 125 (0.00%)	1 / 122 (0.82%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Bronchiolitis			
subjects affected / exposed	0 / 121 (0.00%)	1 / 125 (0.80%)	0 / 122 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis			
subjects affected / exposed	1 / 121 (0.83%)	0 / 125 (0.00%)	0 / 122 (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
Staphylococcal sepsis			
subjects affected / exposed	0 / 121 (0.00%)	0 / 125 (0.00%)	1 / 122 (0.82%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

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

Non-serious adverse events	OXO-001 200 mg	OXO-001 300 mg	Placebo
Total subjects affected by non-serious adverse events			
subjects affected / exposed	71 / 121 (58.68%)	78 / 125 (62.40%)	62 / 122 (50.82%)

Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Benign breast neoplasm			
subjects affected / exposed	0 / 121 (0.00%)	0 / 125 (0.00%)	1 / 122 (0.82%)
occurrences (all)	0	0	1
Vascular disorders			
Hot flush			
subjects affected / exposed	0 / 121 (0.00%)	0 / 125 (0.00%)	1 / 122 (0.82%)
occurrences (all)	0	0	1
Hypertension			
subjects affected / exposed	0 / 121 (0.00%)	0 / 125 (0.00%)	1 / 122 (0.82%)
occurrences (all)	0	0	1
Phlebitis			
subjects affected / exposed	0 / 121 (0.00%)	1 / 125 (0.80%)	0 / 122 (0.00%)
occurrences (all)	0	1	0
Thrombosis			
subjects affected / exposed	0 / 121 (0.00%)	0 / 125 (0.00%)	1 / 122 (0.82%)
occurrences (all)	0	0	1
Surgical and medical procedures			
Abortion induced			
subjects affected / exposed	0 / 121 (0.00%)	1 / 125 (0.80%)	0 / 122 (0.00%)
occurrences (all)	0	1	0
Pregnancy, puerperium and perinatal conditions			
Abortion spontaneous			
subjects affected / exposed	9 / 121 (7.44%)	14 / 125 (11.20%)	12 / 122 (9.84%)
occurrences (all)	9	14	12
Abortion missed			
subjects affected / exposed	4 / 121 (3.31%)	3 / 125 (2.40%)	4 / 122 (3.28%)
occurrences (all)	4	3	4
Subchorionic haematoma			
subjects affected / exposed	2 / 121 (1.65%)	2 / 125 (1.60%)	3 / 122 (2.46%)
occurrences (all)	2	2	3
Biochemical pregnancy			
subjects affected / exposed	3 / 121 (2.48%)	1 / 125 (0.80%)	1 / 122 (0.82%)
occurrences (all)	3	1	1
Gestational diabetes			

subjects affected / exposed	1 / 121 (0.83%)	3 / 125 (2.40%)	1 / 122 (0.82%)
occurrences (all)	1	3	1
Haemorrage in pregnancy			
subjects affected / exposed	2 / 121 (1.65%)	2 / 125 (1.60%)	0 / 122 (0.00%)
occurrences (all)	4	2	0
Abortion threatened			
subjects affected / exposed	1 / 121 (0.83%)	2 / 125 (1.60%)	0 / 122 (0.00%)
occurrences (all)	2	2	0
Gestational hypertension			
subjects affected / exposed	0 / 121 (0.00%)	0 / 125 (0.00%)	3 / 122 (2.46%)
occurrences (all)	0	0	3
Anembryonic gestation			
subjects affected / exposed	1 / 121 (0.83%)	1 / 125 (0.80%)	0 / 122 (0.00%)
occurrences (all)	1	1	0
Morning sickness			
subjects affected / exposed	2 / 121 (1.65%)	0 / 125 (0.00%)	0 / 122 (0.00%)
occurrences (all)	2	0	0
Abortion spontaneous incomplete			
subjects affected / exposed	1 / 121 (0.83%)	0 / 125 (0.00%)	0 / 122 (0.00%)
occurrences (all)	1	0	0
Foetal hypokinesia			
subjects affected / exposed	0 / 121 (0.00%)	0 / 125 (0.00%)	1 / 122 (0.82%)
occurrences (all)	0	0	1
Jaundice neonatal			
subjects affected / exposed	0 / 121 (0.00%)	0 / 125 (0.00%)	1 / 122 (0.82%)
occurrences (all)	0	0	1
Placenta accreta			
subjects affected / exposed	0 / 121 (0.00%)	1 / 125 (0.80%)	0 / 122 (0.00%)
occurrences (all)	0	1	0
Uterine atony			
subjects affected / exposed	0 / 121 (0.00%)	1 / 125 (0.80%)	0 / 122 (0.00%)
occurrences (all)	0	1	0
Vanishing twin syndrome			
subjects affected / exposed	0 / 121 (0.00%)	1 / 125 (0.80%)	0 / 122 (0.00%)
occurrences (all)	0	1	0
General disorders and administration			

site conditions			
Asthenia			
subjects affected / exposed	2 / 121 (1.65%)	0 / 125 (0.00%)	1 / 122 (0.82%)
occurrences (all)	2	0	1
Fatigue			
subjects affected / exposed	1 / 121 (0.83%)	0 / 125 (0.00%)	1 / 122 (0.82%)
occurrences (all)	1	0	1
Illness			
subjects affected / exposed	2 / 121 (1.65%)	0 / 125 (0.00%)	0 / 122 (0.00%)
occurrences (all)	2	0	0
Chest discomfort			
subjects affected / exposed	0 / 121 (0.00%)	0 / 125 (0.00%)	1 / 122 (0.82%)
occurrences (all)	0	0	1
Chest pain			
subjects affected / exposed	0 / 121 (0.00%)	1 / 125 (0.80%)	0 / 122 (0.00%)
occurrences (all)	0	1	0
Chills			
subjects affected / exposed	0 / 121 (0.00%)	0 / 125 (0.00%)	1 / 122 (0.82%)
occurrences (all)	0	0	1
Pain			
subjects affected / exposed	0 / 121 (0.00%)	0 / 125 (0.00%)	1 / 122 (0.82%)
occurrences (all)	0	0	1
Pyrexia			
subjects affected / exposed	0 / 121 (0.00%)	0 / 125 (0.00%)	1 / 122 (0.82%)
occurrences (all)	0	0	1
Immune system disorders			
Seasonal allergy			
subjects affected / exposed	1 / 121 (0.83%)	0 / 125 (0.00%)	1 / 122 (0.82%)
occurrences (all)	1	0	1
Drug hypersensitivity			
subjects affected / exposed	0 / 121 (0.00%)	1 / 125 (0.80%)	0 / 122 (0.00%)
occurrences (all)	0	1	0
Reproductive system and breast disorders			
Vaginal haemorrhage			
subjects affected / exposed	12 / 121 (9.92%)	11 / 125 (8.80%)	13 / 122 (10.66%)
occurrences (all)	15	16	16

Dysmenorrhoea			
subjects affected / exposed	2 / 121 (1.65%)	4 / 125 (3.20%)	1 / 122 (0.82%)
occurrences (all)	2	4	1
Ovarian cyst			
subjects affected / exposed	0 / 121 (0.00%)	3 / 125 (2.40%)	1 / 122 (0.82%)
occurrences (all)	0	3	1
Pelvic pain			
subjects affected / exposed	1 / 121 (0.83%)	2 / 125 (1.60%)	1 / 122 (0.82%)
occurrences (all)	1	2	1
Intermenstrual bleeding			
subjects affected / exposed	1 / 121 (0.83%)	1 / 125 (0.80%)	0 / 122 (0.00%)
occurrences (all)	1	2	0
Uterine haemorrhage			
subjects affected / exposed	1 / 121 (0.83%)	0 / 125 (0.00%)	1 / 122 (0.82%)
occurrences (all)	1	0	1
Uterine polyp			
subjects affected / exposed	1 / 121 (0.83%)	0 / 125 (0.00%)	1 / 122 (0.82%)
occurrences (all)	1	0	1
Vulvovaginal pruritus			
subjects affected / exposed	0 / 121 (0.00%)	1 / 125 (0.80%)	1 / 122 (0.82%)
occurrences (all)	0	1	1
Adenomyosis			
subjects affected / exposed	1 / 121 (0.83%)	0 / 125 (0.00%)	0 / 122 (0.00%)
occurrences (all)	1	0	0
Adnexa uteri pain			
subjects affected / exposed	1 / 121 (0.83%)	0 / 125 (0.00%)	0 / 122 (0.00%)
occurrences (all)	1	0	0
Breast discomfort			
subjects affected / exposed	0 / 121 (0.00%)	1 / 125 (0.80%)	0 / 122 (0.00%)
occurrences (all)	0	1	0
Breast pain			
subjects affected / exposed	1 / 121 (0.83%)	0 / 125 (0.00%)	0 / 122 (0.00%)
occurrences (all)	1	0	0
Cervical dysplasia			
subjects affected / exposed	1 / 121 (0.83%)	0 / 125 (0.00%)	0 / 122 (0.00%)
occurrences (all)	1	0	0

Endometrial disorder			
subjects affected / exposed	0 / 121 (0.00%)	1 / 125 (0.80%)	0 / 122 (0.00%)
occurrences (all)	0	1	0
Hydrometra			
subjects affected / exposed	1 / 121 (0.83%)	0 / 125 (0.00%)	0 / 122 (0.00%)
occurrences (all)	1	0	0
Ovarian oedema			
subjects affected / exposed	0 / 121 (0.00%)	1 / 125 (0.80%)	0 / 122 (0.00%)
occurrences (all)	0	1	0
Pruritus genital			
subjects affected / exposed	0 / 121 (0.00%)	1 / 125 (0.80%)	0 / 122 (0.00%)
occurrences (all)	0	1	0
Uterine haematoma			
subjects affected / exposed	0 / 121 (0.00%)	0 / 125 (0.00%)	1 / 122 (0.82%)
occurrences (all)	0	0	1
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	1 / 121 (0.83%)	1 / 125 (0.80%)	0 / 122 (0.00%)
occurrences (all)	2	1	0
Oropharyngeal pain			
subjects affected / exposed	0 / 121 (0.00%)	0 / 125 (0.00%)	2 / 122 (1.64%)
occurrences (all)	0	0	2
Dyspnoea			
subjects affected / exposed	0 / 121 (0.00%)	0 / 125 (0.00%)	1 / 122 (0.82%)
occurrences (all)	0	0	1
Nasal congestion			
subjects affected / exposed	0 / 121 (0.00%)	0 / 125 (0.00%)	1 / 122 (0.82%)
occurrences (all)	0	0	1
Psychiatric disorders			
Anxiety			
subjects affected / exposed	1 / 121 (0.83%)	0 / 125 (0.00%)	0 / 122 (0.00%)
occurrences (all)	1	0	0
Insomnia			
subjects affected / exposed	0 / 121 (0.00%)	1 / 125 (0.80%)	0 / 122 (0.00%)
occurrences (all)	0	1	0
Nervousness			

subjects affected / exposed	0 / 121 (0.00%)	0 / 125 (0.00%)	1 / 122 (0.82%)
occurrences (all)	0	0	1
Stress			
subjects affected / exposed	0 / 121 (0.00%)	1 / 125 (0.80%)	0 / 122 (0.00%)
occurrences (all)	0	1	0
Investigations			
SARS-CoV-2 test positive			
subjects affected / exposed	5 / 121 (4.13%)	2 / 125 (1.60%)	1 / 122 (0.82%)
occurrences (all)	5	2	1
Blood triglycerides increased			
subjects affected / exposed	1 / 121 (0.83%)	3 / 125 (2.40%)	2 / 122 (1.64%)
occurrences (all)	1	3	2
Vitamin D decreased			
subjects affected / exposed	0 / 121 (0.00%)	2 / 125 (1.60%)	0 / 122 (0.00%)
occurrences (all)	0	2	0
Alanine aminotransferase increased			
subjects affected / exposed	0 / 121 (0.00%)	0 / 125 (0.00%)	1 / 122 (0.82%)
occurrences (all)	0	0	1
Amniotic fluid volume increased			
subjects affected / exposed	0 / 121 (0.00%)	1 / 125 (0.80%)	0 / 122 (0.00%)
occurrences (all)	0	1	0
Blood pressure systolic increased			
subjects affected / exposed	0 / 121 (0.00%)	0 / 125 (0.00%)	1 / 122 (0.82%)
occurrences (all)	0	0	1
Liver function test increased			
subjects affected / exposed	1 / 121 (0.83%)	0 / 125 (0.00%)	0 / 122 (0.00%)
occurrences (all)	1	0	0
lymphocyte morpholgy abnormal			
subjects affected / exposed	1 / 121 (0.83%)	0 / 125 (0.00%)	0 / 122 (0.00%)
occurrences (all)	1	0	0
Injury, poisoning and procedural complications			
Post vaccination syndrome			
subjects affected / exposed	2 / 121 (1.65%)	0 / 125 (0.00%)	0 / 122 (0.00%)
occurrences (all)	2	0	0
Ear injury			

subjects affected / exposed	1 / 121 (0.83%)	0 / 125 (0.00%)	0 / 122 (0.00%)
occurrences (all)	1	0	0
Nervous system disorders			
Headache			
subjects affected / exposed	17 / 121 (14.05%)	19 / 125 (15.20%)	12 / 122 (9.84%)
occurrences (all)	27	25	16
Dizziness			
subjects affected / exposed	1 / 121 (0.83%)	3 / 125 (2.40%)	4 / 122 (3.28%)
occurrences (all)	1	3	7
Somnolence			
subjects affected / exposed	1 / 121 (0.83%)	1 / 125 (0.80%)	1 / 122 (0.82%)
occurrences (all)	2	1	1
Migraine			
subjects affected / exposed	2 / 121 (1.65%)	0 / 125 (0.00%)	0 / 122 (0.00%)
occurrences (all)	2	0	0
Sciatica			
subjects affected / exposed	0 / 121 (0.00%)	0 / 125 (0.00%)	1 / 122 (0.82%)
occurrences (all)	0	0	1
Syncope			
subjects affected / exposed	0 / 121 (0.00%)	0 / 125 (0.00%)	1 / 122 (0.82%)
occurrences (all)	0	0	1
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 121 (0.00%)	0 / 125 (0.00%)	1 / 122 (0.82%)
occurrences (all)	0	0	1
Eye disorders			
Eye inflammation			
subjects affected / exposed	1 / 121 (0.83%)	0 / 125 (0.00%)	0 / 122 (0.00%)
occurrences (all)	1	0	0
Strabismus			
subjects affected / exposed	1 / 121 (0.83%)	0 / 125 (0.00%)	0 / 122 (0.00%)
occurrences (all)	1	0	0
Gastrointestinal disorders			
Nausea			
subjects affected / exposed	9 / 121 (7.44%)	11 / 125 (8.80%)	11 / 122 (9.02%)
occurrences (all)	9	11	11
Vomiting			

subjects affected / exposed	4 / 121 (3.31%)	5 / 125 (4.00%)	4 / 122 (3.28%)
occurrences (all)	5	6	4
Diarrhoea			
subjects affected / exposed	1 / 121 (0.83%)	6 / 125 (4.80%)	1 / 122 (0.82%)
occurrences (all)	1	7	1
Dyspepsia			
subjects affected / exposed	0 / 121 (0.00%)	2 / 125 (1.60%)	1 / 122 (0.82%)
occurrences (all)	0	2	1
Abdominal pain			
subjects affected / exposed	0 / 121 (0.00%)	1 / 125 (0.80%)	1 / 122 (0.82%)
occurrences (all)	0	1	1
Abdominal pain lower			
subjects affected / exposed	1 / 121 (0.83%)	1 / 125 (0.80%)	0 / 122 (0.00%)
occurrences (all)	1	1	0
Constipation			
subjects affected / exposed	1 / 121 (0.83%)	1 / 125 (0.80%)	0 / 122 (0.00%)
occurrences (all)	1	1	0
Flatulence			
subjects affected / exposed	1 / 121 (0.83%)	1 / 125 (0.80%)	0 / 122 (0.00%)
occurrences (all)	1	1	0
Gastrooesophageal reflux disease			
subjects affected / exposed	1 / 121 (0.83%)	1 / 125 (0.80%)	0 / 122 (0.00%)
occurrences (all)	1	1	0
Abdominal discomfort			
subjects affected / exposed	1 / 121 (0.83%)	0 / 125 (0.00%)	0 / 122 (0.00%)
occurrences (all)	1	0	0
Abdominal distension			
subjects affected / exposed	0 / 121 (0.00%)	0 / 125 (0.00%)	1 / 122 (0.82%)
occurrences (all)	0	0	1
Abdominal pain upper			
subjects affected / exposed	0 / 121 (0.00%)	0 / 125 (0.00%)	1 / 122 (0.82%)
occurrences (all)	0	0	1
Epigastric discomfort			
subjects affected / exposed	0 / 121 (0.00%)	0 / 125 (0.00%)	1 / 122 (0.82%)
occurrences (all)	0	0	1
Gastritis			

subjects affected / exposed	0 / 121 (0.00%)	1 / 125 (0.80%)	0 / 122 (0.00%)
occurrences (all)	0	1	0
Haemorrhoids			
subjects affected / exposed	0 / 121 (0.00%)	0 / 125 (0.00%)	1 / 122 (0.82%)
occurrences (all)	0	0	1
Rectal haemorrhage			
subjects affected / exposed	1 / 121 (0.83%)	0 / 125 (0.00%)	0 / 122 (0.00%)
occurrences (all)	1	0	0
toothache			
subjects affected / exposed	1 / 121 (0.83%)	0 / 125 (0.00%)	0 / 122 (0.00%)
occurrences (all)	1	0	0
Hepatobiliary disorders			
Cholestasis			
subjects affected / exposed	0 / 121 (0.00%)	0 / 125 (0.00%)	1 / 122 (0.82%)
occurrences (all)	0	0	1
Hepatic mass			
subjects affected / exposed	0 / 121 (0.00%)	1 / 125 (0.80%)	0 / 122 (0.00%)
occurrences (all)	0	1	0
Hyperbilirubinaemia			
subjects affected / exposed	0 / 121 (0.00%)	0 / 125 (0.00%)	1 / 122 (0.82%)
occurrences (all)	0	0	1
Skin and subcutaneous tissue disorders			
Rash			
subjects affected / exposed	2 / 121 (1.65%)	0 / 125 (0.00%)	0 / 122 (0.00%)
occurrences (all)	2	0	0
Rash erythematous			
subjects affected / exposed	0 / 121 (0.00%)	2 / 125 (1.60%)	0 / 122 (0.00%)
occurrences (all)	0	2	0
Chloasma			
subjects affected / exposed	0 / 121 (0.00%)	0 / 125 (0.00%)	1 / 122 (0.82%)
occurrences (all)	0	0	1
Dry skin			
subjects affected / exposed	1 / 121 (0.83%)	0 / 125 (0.00%)	0 / 122 (0.00%)
occurrences (all)	1	0	0
Eczema			

subjects affected / exposed	1 / 121 (0.83%)	0 / 125 (0.00%)	0 / 122 (0.00%)
occurrences (all)	1	0	0
Pruritus			
subjects affected / exposed	1 / 121 (0.83%)	0 / 125 (0.00%)	0 / 122 (0.00%)
occurrences (all)	1	0	0
Rash pruritic			
subjects affected / exposed	0 / 121 (0.00%)	0 / 125 (0.00%)	1 / 122 (0.82%)
occurrences (all)	0	0	1
Urticaria			
subjects affected / exposed	0 / 121 (0.00%)	1 / 125 (0.80%)	0 / 122 (0.00%)
occurrences (all)	0	1	0
Renal and urinary disorders			
Renal colic			
subjects affected / exposed	1 / 121 (0.83%)	0 / 125 (0.00%)	1 / 122 (0.82%)
occurrences (all)	1	0	1
Oliguria			
subjects affected / exposed	1 / 121 (0.83%)	0 / 125 (0.00%)	0 / 122 (0.00%)
occurrences (all)	1	0	0
Polyuria			
subjects affected / exposed	0 / 121 (0.00%)	0 / 125 (0.00%)	1 / 122 (0.82%)
occurrences (all)	0	0	1
Endocrine disorders			
Hypothyroidism			
subjects affected / exposed	0 / 121 (0.00%)	1 / 125 (0.80%)	0 / 122 (0.00%)
occurrences (all)	0	1	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 121 (0.00%)	1 / 125 (0.80%)	0 / 122 (0.00%)
occurrences (all)	0	1	0
Back pain			
subjects affected / exposed	0 / 121 (0.00%)	0 / 125 (0.00%)	1 / 122 (0.82%)
occurrences (all)	0	0	1
Flank pain			
subjects affected / exposed	1 / 121 (0.83%)	0 / 125 (0.00%)	0 / 122 (0.00%)
occurrences (all)	1	0	0
Myalgia			

subjects affected / exposed	0 / 121 (0.00%)	0 / 125 (0.00%)	1 / 122 (0.82%)
occurrences (all)	0	0	1
Neck pain			
subjects affected / exposed	1 / 121 (0.83%)	0 / 125 (0.00%)	0 / 122 (0.00%)
occurrences (all)	3	0	0
Infections and infestations			
COVID-19			
subjects affected / exposed	11 / 121 (9.09%)	8 / 125 (6.40%)	8 / 122 (6.56%)
occurrences (all)	11	8	8
Nasopharyngitis			
subjects affected / exposed	2 / 121 (1.65%)	2 / 125 (1.60%)	2 / 122 (1.64%)
occurrences (all)	2	2	2
Furuncle			
subjects affected / exposed	1 / 121 (0.83%)	1 / 125 (0.80%)	0 / 122 (0.00%)
occurrences (all)	1	1	0
Influenza			
subjects affected / exposed	1 / 121 (0.83%)	2 / 125 (1.60%)	0 / 122 (0.00%)
occurrences (all)	1	2	0
Gastroenteritis			
subjects affected / exposed	0 / 121 (0.00%)	1 / 125 (0.80%)	1 / 122 (0.82%)
occurrences (all)	0	1	1
Pharyngitis			
subjects affected / exposed	1 / 121 (0.83%)	1 / 125 (0.80%)	0 / 122 (0.00%)
occurrences (all)	1	1	0
Cystitis			
subjects affected / exposed	0 / 121 (0.00%)	0 / 125 (0.00%)	1 / 122 (0.82%)
occurrences (all)	0	0	1
eyelid infection			
subjects affected / exposed	1 / 121 (0.83%)	0 / 125 (0.00%)	0 / 122 (0.00%)
occurrences (all)	1	0	0
Fungal infection			
subjects affected / exposed	0 / 121 (0.00%)	1 / 125 (0.80%)	0 / 122 (0.00%)
occurrences (all)	0	1	0
Gastroenteritis viral			
subjects affected / exposed	0 / 121 (0.00%)	0 / 125 (0.00%)	1 / 122 (0.82%)
occurrences (all)	0	0	1

gastrointestinal bacterial overgrowth			
subjects affected / exposed	1 / 121 (0.83%)	0 / 125 (0.00%)	0 / 122 (0.00%)
occurrences (all)	1	0	0
Herpes virus infection			
subjects affected / exposed	0 / 121 (0.00%)	1 / 125 (0.80%)	0 / 122 (0.00%)
occurrences (all)	0	1	0
Herpes zoster			
subjects affected / exposed	1 / 121 (0.83%)	0 / 125 (0.00%)	0 / 122 (0.00%)
occurrences (all)	1	0	0
Pulpitis dental			
subjects affected / exposed	1 / 121 (0.83%)	0 / 125 (0.00%)	0 / 122 (0.00%)
occurrences (all)	1	0	0
Sinusitis			
subjects affected / exposed	0 / 121 (0.00%)	0 / 125 (0.00%)	1 / 122 (0.82%)
occurrences (all)	0	0	1
Tonsillitis			
subjects affected / exposed	1 / 121 (0.83%)	0 / 125 (0.00%)	0 / 122 (0.00%)
occurrences (all)	1	0	0
Urinary tract infection			
subjects affected / exposed	0 / 121 (0.00%)	0 / 125 (0.00%)	1 / 122 (0.82%)
occurrences (all)	0	0	1
Vaginal infection			
subjects affected / exposed	0 / 121 (0.00%)	0 / 125 (0.00%)	1 / 122 (0.82%)
occurrences (all)	0	0	1
Vulvovaginal candidiasis			
subjects affected / exposed	0 / 121 (0.00%)	1 / 125 (0.80%)	0 / 122 (0.00%)
occurrences (all)	0	1	0
Vulvovaginal mycotic infection			
subjects affected / exposed	0 / 121 (0.00%)	1 / 125 (0.80%)	0 / 122 (0.00%)
occurrences (all)	0	1	0
Metabolism and nutrition disorders			
Fluid retention			
subjects affected / exposed	1 / 121 (0.83%)	0 / 125 (0.00%)	0 / 122 (0.00%)
occurrences (all)	1	0	0

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