Clinical trial results:
A Randomized, Double-blind, Placebo-controlled, Multicenter Study to Assess the Safety and Efficacy of Inclacumab in Participants With Sickle Cell Disease Experiencing Vaso-occlusive Crises

Summary

EudraCT number	2020-005286-13
Trial protocol	FR DE IT
Global end of trial date	06 June 2024

Results information

Result version number	v1 (current)
This version publication date	15 November 2025
First version publication date	15 November 2025

Trial information

Trial identification

Sponsor protocol code	C5361001

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT04935879
WHO universal trial number (UTN)	-
Other trial identifiers	Other Study ID: GBT2104-131

Notes:

Sponsors

Sponsor organisation name	Pfizer Inc.
Sponsor organisation address	66 Hudson Boulevard East, New York, United States, NY 10001
Public contact	PfizerClinicalTrials.gov Call Center, Pfizer Inc., 001 8007181021, ClinicalTrials.gov_Inquiries@pfizer.com
Scientific contact	Pfizer ClinicalTrials.gov Call Center, Pfizer Inc., 001 8007181021, ClinicalTrials.gov_Inquiries@pfizer.com

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	Yes
EMA paediatric investigation plan number(s)	EMEA-003219-PIP01-22
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	06 August 2025
Is this the analysis of the primary completion data?	Yes
Primary completion date	06 June 2024
Global end of trial reached?	Yes
Global end of trial date	06 June 2024
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The primary objective of this study was to evaluate the safety and efficacy of treatment every 12-week with inclacumab to reduce the incidence of Vaso-occlusive Crises (VOCs) in participants with sickle cell disease (SCD).

Protection of trial subjects:

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

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	04 October 2021
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	Brazil: 25
Country: Number of subjects enrolled	Colombia: 15
Country: Number of subjects enrolled	Egypt: 19
Country: Number of subjects enrolled	France: 4
Country: Number of subjects enrolled	Kenya: 56
Country: Number of subjects enrolled	Lebanon: 8
Country: Number of subjects enrolled	Nigeria: 60
Country: Number of subjects enrolled	Oman: 4
Country: Number of subjects enrolled	Saudi Arabia: 3
Country: Number of subjects enrolled	Tanzania, United Republic of: 11
Country: Number of subjects enrolled	Türkiye: 10
Country: Number of subjects enrolled	United States: 26
Worldwide total number of subjects	241
EEA total number of subjects	4

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)	39
Adults (18-64 years)	202
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Adult and adolescent participants with sickle cell disease (SCD) were enrolled across 12 countries.

Pre-assignment

Screening details:

A total of 241 participants were enrolled and randomized in this study.

Period 1

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

Blinding implementation details:

Double blind method was used.

Arms

Are arms mutually exclusive?	Yes
Arm title	Inclacumab

Arm description:

Participants with SCD were randomized to receive inclacumab at a dose of 30 mg/kg IV on Day 1 and Q12W on Weeks 12, 24 and 36.Participants were followed up till Week 48 and was part of "48-Week Treatment Period". Participants at Week 48 had a choice to either enter an OLE study (under a separate protocol) to receive inclacumab or were followed up for another 12 weeks i.e. Week 60.

Arm type	Experimental
Investigational medicinal product name	Inclacumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Participants received inclacumab at a dose of 30 mg/kg, IV, Q12W on Day 1 on Weeks 12, 24 and 36. Participants were followed up till Week 48 and was part of "48-Week Treatment Period".

Arm title	Placebo

Arm description:

Participants with SCD were randomized to receive placebo matched to inclacumab IV on Day 1 and Q12W on Weeks 12, 24 and 36. Participants were followed up till Week 48 and was part of "48-Week Treatment Period". Participants at Week 48 had a choice to either enter an OLE study (under a separate protocol) to receive inclacumab or were followed up for another 12 weeks i.e. Week 60.

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

Dosage and administration details:

Participants received placebo IV, Q12W on Day 1 on Weeks 12, 24 and 36. Participants were followed up till Week 48 and was part of "48-Week Treatment Period".

Number of subjects in period 1	Inclacumab	Placebo
Started	119	122
Treated	118	121
Completed	103	108
Not completed	16	14
Consent withdrawn by subject	8	6
Adverse event, non-fatal	2	1
Pregnancy	2	3
Unspecified	3	3
Lost to follow-up	1	1

Baseline characteristics

Reporting groups	
Reporting group title	Inclacumab
Reporting group description:	
Participants with SCD were randomized to receive inclacumab at a dose of 30 mg/kg IV on Day 1 and Q12W on Weeks 12, 24 and 36.Participants were followed up till Week 48 and was part of "48-Week Treatment Period". Participants at Week 48 had a choice to either enter an OLE study (under a separate protocol) to receive inclacumab or were followed up for another 12 weeks i.e. Week 60.	
Reporting group title	Placebo
Reporting group description:	
Participants with SCD were randomized to receive placebo matched to inclacumab IV on Day 1 and Q12W on Weeks 12, 24 and 36. Participants were followed up till Week 48 and was part of "48-Week Treatment Period". Participants at Week 48 had a choice to either enter an OLE study (under a separate protocol) to receive inclacumab or were followed up for another 12 weeks i.e. Week 60.	

Reporting group values	Inclacumab	Placebo	Total
Number of subjects	119	122	241
Age Categorical Units: Subjects			
Age continuous Units: years			
arithmetic mean	25.0	24.6	
standard deviation	± 7.14	± 8.34	-
Gender categorical Units: Subjects			
Male	55	59	114
Female	64	63	127
Ethnicity Units: Subjects			
Hispanic or Latino	18	19	37
Not Hispanic or Latino	92	102	194
Unknown or Not Reported	9	1	10
Race/Ethnicity, Customized Units: Subjects			
Race African	63	58	121
Race American Indian or Alaska Native	3	2	5
Race Arab	1	2	3
Race Black or African American	16	24	40
Race Middle Eastern	1	0	1
Race White	7	10	17
Race Other	2	1	3
Race Multiracial	22	25	47
Race Not Reported	4	0	4
Age categorical Units: Subjects			
>= 16 to less than (<) 18 years	12	27	39
>= 18 to 65 years	107	95	202

End points

End points reporting groups

Reporting group title	Inclacumab

Reporting group description:

Participants with SCD were randomized to receive inclacumab at a dose of 30 mg/kg IV on Day 1 and Q12W on Weeks 12, 24 and 36.Participants were followed up till Week 48 and was part of "48-Week Treatment Period". Participants at Week 48 had a choice to either enter an OLE study (under a separate protocol) to receive inclacumab or were followed up for another 12 weeks i.e. Week 60.

Reporting group title	Placebo

Reporting group description:

Participants with SCD were randomized to receive placebo matched to inclacumab IV on Day 1 and Q12W on Weeks 12, 24 and 36. Participants were followed up till Week 48 and was part of "48-Week Treatment Period". Participants at Week 48 had a choice to either enter an OLE study (under a separate protocol) to receive inclacumab or were followed up for another 12 weeks i.e. Week 60.

Primary: Rate of Vaso-occlusive Crises (VOCs) [Adjudicated] Through Week 48

End point title	Rate of Vaso-occlusive Crises (VOCs) [Adjudicated] Through Week 48

End point description:

Rate of VOCs during the 48-week treatment period. A VOC was defined as an acute episode of pain that: had no medically determined cause other than a vaso-occlusive event; resulted in a visit to a medical facility (hospitalization, emergency department, urgent care center, outpatient clinic, or infusion center), or resulted in a remote contact with a healthcare provider and required parenteral narcotic agents, parenteral nonsteroidal anti-inflammatory drugs (NSAIDs), or an increase in treatment with oral narcotics. The rate of VOC was defined as number of VOC events per 48 weeks and presented in this endpoint. The intent-to treat (ITT) population included all randomized participants.

End point type	Primary

End point timeframe:

Randomization (Day 1) up to Week 48

End point values	Inclacumab	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	119	122		
Units: Events per 48 weeks				
number (confidence interval 95%)	1.49 (1.22 to 1.83)	1.58 (1.30 to 1.93)		

Statistical analyses

Statistical analysis title	Inclacumab vs placebo

Statistical analysis description:

Adjusted rates are based on estimate from a negative binomial model with the independent variable of treatment group (inclacumab, placebo) and adjusted for baseline hydroxyurea (HU) use (yes, no), number of VOCs in 12 months prior to screening visit (2-4, 5-10), and geographic region (North America, sub-Saharan Africa, Europe/rest of world).

Comparison groups	Inclacumab v Placebo

Number of subjects included in analysis	241
Analysis specification	Pre-specified
Analysis type	superiority[1]
P-value	= 0.6967
Method	Negative binomial regression model
Parameter estimate	Rate ratio
Point estimate	0.95
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.71
upper limit	1.25

Notes:

[1] - Rate ratio = Ratio of rate of VOC for inclacumab group to placebo group.

Secondary: Time to First VOC Through Week 48

End point title	Time to First VOC Through Week 48

End point description:

A VOC was defined as an acute episode of pain that: had no medically determined cause other than a vaso-occlusive event; resulted in a visit to a medical facility (hospitalization, emergency department, urgent care center, outpatient clinic, or infusion center), or resulted in a remote contact with a healthcare provider and required parenteral narcotic agents, parenteral NSAIDs, or an increase in treatment with oral narcotics. Time to first VOC was the time between randomization date and onset date of first VOC event during 48 weeks. Kaplan-Meier method was used for estimation. The ITT population included all randomized participants.

End point type	Secondary

End point timeframe:

Randomization (Day 1) up to Week 48

End point values	Inclacumab	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	119	122		
Units: Weeks				
median (confidence interval 95%)	28.7 (15.7 to 43.1)	21.6 (17.3 to 28.7)		

Statistical analyses

Statistical analysis title	Inclacumab vs placebo

Statistical analysis description:

Analysis was stratified by baseline HU use (yes, no), number of VOCs in 12 months prior to screening visit (2-4, 5-10), and geographic region (North America, sub-Saharan Africa, Europe/rest of world).

Comparison groups	Inclacumab v Placebo

Number of subjects included in analysis	241
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.4298
Method	Logrank
Parameter estimate	Hazard ratio (HR)
Point estimate	0.88
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.63
upper limit	1.22

Secondary: Time to Second VOC Through Week 48

End point title	Time to Second VOC Through Week 48

End point description:

A VOC was defined as an acute episode of pain that: had no medically determined cause other than a vaso-occlusive event; resulted in a visit to a medical facility (hospitalization, emergency department, urgent care center, outpatient clinic, or infusion center), or resulted in a remote contact with a healthcare provider and required parenteral narcotic agents, parenteral NSAIDs, or an increase in treatment with oral narcotics. Time to second VOC was the time between randomization date and onset date of second VOC event during 48 weeks. Kaplan-Meier method was used for estimation. The ITT population included all randomized participants. 99999 signifies: Median, upper and lower limit of 95% confidence interval (CI) was not estimated due to insufficient number of participants with events.

End point type	Secondary

End point timeframe:

Randomization (Day 1) up to Week 48

End point values	Inclacumab	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	119	122		
Units: Weeks				
median (confidence interval 95%)	99999 (99999 to 99999)	99999 (99999 to 99999)		

Statistical analyses

No statistical analyses for this end point

Secondary: Rate of VOCs Required Admission to a Healthcare Facility and Treatment With Parenteral Pain Medication [Adjudicated] Through Week 48

End point title	Rate of VOCs Required Admission to a Healthcare Facility and Treatment With Parenteral Pain Medication [Adjudicated] Through Week 48

End point description:

A VOC that required admission to a healthcare facility and treatment with parenteral pain medication where admission included: a hospital admission or an admission to an emergency room, observation

unit, or infusion center for >= 12 hours, or 2 visits to an emergency room, observation unit, or infusion center over a 72-hour period. The rate of VOC was defined as number of VOC events per 48 weeks; rate of VOCs which required admission to a healthcare facility and treatment with parenteral pain medication is presented in this endpoint. The ITT population included all randomized participants.

End point type	Secondary

End point timeframe:

Randomization (Day 1) up to Week 48

End point values	Inclacumab	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	119	122		
Units: Events per 48 weeks				
number (confidence interval 95%)	0.85 (0.65 to 1.10)	0.83 (0.64 to 1.08)		

Statistical analyses

Statistical analysis title	Inclacumab vs placebo

Statistical analysis description:

Adjusted rates are based on estimate from a negative binomial model with the independent variable of treatment group (inclacumab, placebo) and adjusted for baseline HU use (yes, no), number of VOCs in the 12 months prior to screening visit (2-4, 5-10), and geographic region (North America, sub-Saharan Africa, Europe/rest of the world).

Comparison groups	Inclacumab v Placebo
Number of subjects included in analysis	241
Analysis specification	Pre-specified
Analysis type	superiority[2]
P-value	= 0.9246
Method	Negative binomial regression model
Parameter estimate	Rate Ratio
Point estimate	1.02
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.71
upper limit	1.47

Notes:

[2] - Rate ratio = Ratio of rate of VOC for inclacumab group to placebo group.

Secondary: Percentage of Participants With no VOCs Through Week 48

End point title	Percentage of Participants With no VOCs Through Week 48

End point description:

A VOC was defined as an acute episode of pain that: had no medically determined cause other than a vaso-occlusive event; resulted in a visit to a medical facility (hospitalization, emergency department, urgent care center, outpatient clinic, or infusion center), or resulted in a remote contact with a healthcare provider and required parenteral narcotic agents, parenteral NSAIDs, or an increase in treatment with oral narcotics. Participants without an observed VOC who discontinued the study prior to the end of the 48-week treatment period were assumed to had experienced at least one VOC. The ITT population included all randomized participants.

End point type	Secondary

End point timeframe:

Randomization (Day 1) up to Week 48

End point values	Inclacumab	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	119	122		
Units: Percentage of participants				
number (confidence interval 95%)	36.0 (27.1 to 45.0)	25.7 (17.7 to 33.7)		

Statistical analyses

Statistical analysis title	Inclacumab vs placebo

Statistical analysis description:

Cochran-Mantel-Haenszel (CMH) test stratified by baseline HU use (yes, no), number of VOCs in the 12 months prior to study entry (2-4, 5-10), and geographic region (North America, sub-Saharan Africa, Europe/rest of world).

Comparison groups	Inclacumab v Placebo
Number of subjects included in analysis	241
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0912
Method	Cochran-Mantel-Haenszel
Parameter estimate	Difference in Percentage
Point estimate	10.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.6
upper limit	22.2

Secondary: Rate of Inpatient Hospitalization Days for a VOC Through Week 48

End point title	Rate of Inpatient Hospitalization Days for a VOC Through Week 48

End point description:

A VOC was defined as an acute episode of pain that: had no medically determined cause other than a vaso-occlusive event; resulted in a visit to a medical facility hospitalization. For each VOC event requiring inpatient hospitalization (regardless of treatment received) during the 48-week, the number of days hospitalized were determined based on the hospital admission and discharge dates. The rate of inpatient hospitalization days was defined as number of inpatient hospitalization days for a VOC per 48 weeks and presented in this endpoint. The ITT population included all randomized participants.

End point type	Secondary

End point timeframe:

Randomization (Day 1) up to Week 48

End point values	Inclacumab	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	119	122		
Units: Hospitalization days per 48 weeks				
number (confidence interval 95%)	4.96 (3.05 to 8.07)	5.37 (3.34 to 8.62)		

Statistical analyses

Statistical analysis title	Inclacumab vs placebo

Statistical analysis description:

Adjusted rates are based on estimate from a negative binomial model with the independent variable of treatment group (inclacumab, placebo) and adjusted for baseline HU use (yes, no), number of VOCs in 12 months prior to screening visit (2-4, 5-10), and geographic region (North America, sub-Saharan Africa, Europe/rest of world).

Comparison groups	Inclacumab v Placebo
Number of subjects included in analysis	241
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.8263 [3]
Method	Negative binomial regression model
Parameter estimate	Rate ratio
Point estimate	0.92
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.46
upper limit	1.87

Notes:

[3] - Rate ratio = Ratio of rate of VOC for inclacumab group to placebo group.

Secondary: Number of Participants With Treatment Emergent Adverse Events (TEAEs)

End point title	Number of Participants With Treatment Emergent Adverse Events (TEAEs)

End point description:

An AE was defined as any untoward medical occurrence in a participant administered a pharmaceutical product during the course of a clinical investigation. An AE can therefore be any unfavorable and unintended sign, symptom, or disease temporally associated with the use of an investigational product, whether or not thought to be related to the investigational product. A TEAE was defined as an AE with an onset after the initiation of dosing for the first dose of study drug. A serious adverse events (SAE) or serious suspected adverse reaction is an AE or suspected adverse reaction that, at any dose, in the view of the either the investigator or sponsor, results in any of the following outcomes: death, life-threatening AE, inpatient hospitalization or prolongation of existing hospitalization and congenital anomaly/birth defect. AEs included both serious and all non-SAEs. Safety population included randomized participants who received treatment with study drug.

End point type	Secondary

End point timeframe:

Day 1 up to Week 60 (12 week of follow-up post Week 48)

End point values	Inclacumab	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	118	121		
Units: Participants	87	97		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Day 1 up to Week 60 (12 week of follow-up post Week 48)

Adverse event reporting additional description:

Same event may appear as both non-SAE and SAE, but what is presented are distinct events. An event may be categorized as serious in 1 participant and non-serious in other participant, or a participant may have experienced both SAE and non-SAE. The safety population included randomized participants who received treatment with study drug.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	v28.0

Reporting groups

Reporting group title	Placebo

Reporting group description:

Participants with SCD were randomized to receive placebo matched to inclacumab IV on Day 1 and Q12W on Weeks 12, 24 and 36. Participants were followed up till Week 48 and was part of "48-Week Treatment Period". Participants at Week 48 had a choice to either enter an OLE study (under a separate protocol) to receive inclacumab or were followed up for another 12 weeks i.e. Week 60.

Reporting group title	Inclacumab

Reporting group description:

Participants with SCD were randomized to receive inclacumab at a dose of 30 mg/kg IV on Day 1 and Q12W on Weeks 12, 24 and 36.Participants were followed up till Week 48 and was part of "48-Week Treatment Period". Participants at Week 48 had a choice to either enter an OLE study (under a separate protocol) to receive inclacumab or were followed up for another 12 weeks i.e. Week 60.

Serious adverse events	Placebo	Inclacumab	
Total subjects affected by serious adverse events			
subjects affected / exposed	27 / 121 (22.31%)	23 / 118 (19.49%)	
number of deaths (all causes)	2	3	
number of deaths resulting from adverse events	2	3	
Vascular disorders			
Deep vein thrombosis			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 121 (0.83%)	0 / 118 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pregnancy, puerperium and perinatal conditions			
Abortion spontaneous			
alternative assessment type: Non-systematic			

subjects affected / exposed	0 / 121 (0.00%)	1 / 118 (0.85%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
General disorders and administration site conditions			
Pyrexia			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 121 (0.00%)	1 / 118 (0.85%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Multiple organ dysfunction syndrome			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 121 (0.00%)	1 / 118 (0.85%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Respiratory, thoracic and mediastinal disorders			
Pulmonary embolism			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 121 (0.00%)	2 / 118 (1.69%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary arterial hypertension			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 121 (0.83%)	0 / 118 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Psychiatric disorders			
Disorientation			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 121 (0.83%)	0 / 118 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Injury, poisoning and procedural complications			

Infusion related reaction			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 121 (0.00%)	1 / 118 (0.85%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Joint injury			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 121 (0.00%)	1 / 118 (0.85%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac disorders			
Cardio-respiratory arrest			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 121 (0.00%)	1 / 118 (0.85%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Nervous system disorders			
Migraine			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 121 (0.00%)	1 / 118 (0.85%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sciatica			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 121 (0.00%)	1 / 118 (0.85%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	8 / 121 (6.61%)	3 / 118 (2.54%)	
occurrences causally related to treatment / all	1 / 8	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemolysis			

subjects affected / exposed	1 / 121 (0.83%)	1 / 118 (0.85%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
Haemolytic anaemia			
subjects affected / exposed	0 / 121 (0.00%)	1 / 118 (0.85%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Polycythaemia			
subjects affected / exposed	1 / 121 (0.83%)	0 / 118 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sickle cell anaemia with crisis			
subjects affected / exposed	0 / 121 (0.00%)	1 / 118 (0.85%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Iron deficiency anaemia			
subjects affected / exposed	0 / 121 (0.00%)	1 / 118 (0.85%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
Umbilical hernia			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 121 (0.83%)	0 / 118 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colitis ischaemic			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 121 (0.83%)	0 / 118 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin and subcutaneous tissue disorders			
Skin ulcer			
alternative assessment type: Non-systematic			

subjects affected / exposed	0 / 121 (0.00%)	1 / 118 (0.85%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal and urinary disorders			
Urethral stenosis			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 121 (0.00%)	1 / 118 (0.85%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nephrolithiasis			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 121 (0.83%)	0 / 118 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
Pneumonia			
alternative assessment type: Non-systematic			
subjects affected / exposed	5 / 121 (4.13%)	5 / 118 (4.24%)	
occurrences causally related to treatment / all	0 / 6	0 / 7	
deaths causally related to treatment / all	0 / 1	0 / 0	
Bacterial infection			
alternative assessment type: Non-systematic			
subjects affected / exposed	3 / 121 (2.48%)	2 / 118 (1.69%)	
occurrences causally related to treatment / all	0 / 5	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary tract infection			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 121 (0.83%)	2 / 118 (1.69%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Malaria			
alternative assessment type: Non-systematic			

subjects affected / exposed	7 / 121 (5.79%)	5 / 118 (4.24%)	
occurrences causally related to treatment / all	0 / 8	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atypical pneumonia			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 121 (0.00%)	1 / 118 (0.85%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Escherichia bacteraemia			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 121 (0.00%)	1 / 118 (0.85%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Catheter site infection			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 121 (0.00%)	1 / 118 (0.85%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
COVID-19			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 121 (0.00%)	1 / 118 (0.85%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory tract infection			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 121 (0.00%)	1 / 118 (0.85%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tonsillitis			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 121 (0.83%)	0 / 118 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Lower respiratory tract infection			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 121 (0.83%)	0 / 118 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastroenteritis			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 121 (0.83%)	0 / 118 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cystitis			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 121 (0.83%)	0 / 118 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Septic shock			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 121 (0.00%)	1 / 118 (0.85%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory tract infection viral			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 121 (0.00%)	1 / 118 (0.85%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Upper respiratory tract infection			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 121 (0.83%)	0 / 118 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolism and nutrition disorders			
Hyperkalaemia			
alternative assessment type: Non-systematic			

subjects affected / exposed	0 / 121 (0.00%)	1 / 118 (0.85%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	

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

Non-serious adverse events	Placebo	Inclacumab	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	90 / 121 (74.38%)	83 / 118 (70.34%)	
Vascular disorders			
Hyperaemia			
subjects affected / exposed	0 / 121 (0.00%)	1 / 118 (0.85%)	
occurrences (all)	0	1	
Phlebitis			
subjects affected / exposed	0 / 121 (0.00%)	1 / 118 (0.85%)	
occurrences (all)	0	1	
Hypotension			
subjects affected / exposed	1 / 121 (0.83%)	3 / 118 (2.54%)	
occurrences (all)	1	5	
Flushing			
subjects affected / exposed	0 / 121 (0.00%)	1 / 118 (0.85%)	
occurrences (all)	0	1	
Haematoma			
subjects affected / exposed	0 / 121 (0.00%)	1 / 118 (0.85%)	
occurrences (all)	0	2	
Hypertension			
subjects affected / exposed	1 / 121 (0.83%)	0 / 118 (0.00%)	
occurrences (all)	1	0	
General disorders and administration site conditions			
Pain			
subjects affected / exposed	5 / 121 (4.13%)	6 / 118 (5.08%)	
occurrences (all)	7	8	
Pyrexia			
subjects affected / exposed	4 / 121 (3.31%)	7 / 118 (5.93%)	
occurrences (all)	4	7	
Non-cardiac chest pain			

subjects affected / exposed	1 / 121 (0.83%)	4 / 118 (3.39%)	
occurrences (all)	1	4	
Asthenia			
subjects affected / exposed	1 / 121 (0.83%)	2 / 118 (1.69%)	
occurrences (all)	1	2	
Chest pain			
subjects affected / exposed	0 / 121 (0.00%)	2 / 118 (1.69%)	
occurrences (all)	0	2	
Chest discomfort			
subjects affected / exposed	0 / 121 (0.00%)	1 / 118 (0.85%)	
occurrences (all)	0	1	
Gait disturbance			
subjects affected / exposed	0 / 121 (0.00%)	1 / 118 (0.85%)	
occurrences (all)	0	1	
Influenza like illness			
subjects affected / exposed	1 / 121 (0.83%)	1 / 118 (0.85%)	
occurrences (all)	1	1	
Malaise			
subjects affected / exposed	0 / 121 (0.00%)	1 / 118 (0.85%)	
occurrences (all)	0	1	
Oedema peripheral			
subjects affected / exposed	0 / 121 (0.00%)	1 / 118 (0.85%)	
occurrences (all)	0	2	
Injury associated with device			
subjects affected / exposed	1 / 121 (0.83%)	0 / 118 (0.00%)	
occurrences (all)	1	0	
Peripheral swelling			
subjects affected / exposed	1 / 121 (0.83%)	0 / 118 (0.00%)	
occurrences (all)	1	0	
Sluggishness			
subjects affected / exposed	1 / 121 (0.83%)	0 / 118 (0.00%)	
occurrences (all)	1	0	
Swelling			
subjects affected / exposed	1 / 121 (0.83%)	0 / 118 (0.00%)	
occurrences (all)	1	0	
Fatigue			

subjects affected / exposed	2 / 121 (1.65%)	3 / 118 (2.54%)	
occurrences (all)	2	3	
Immune system disorders			
Seasonal allergy			
subjects affected / exposed	0 / 121 (0.00%)	2 / 118 (1.69%)	
occurrences (all)	0	2	
Hypersensitivity			
subjects affected / exposed	1 / 121 (0.83%)	1 / 118 (0.85%)	
occurrences (all)	1	1	
Reproductive system and breast disorders			
Priapism			
subjects affected / exposed	2 / 121 (1.65%)	2 / 118 (1.69%)	
occurrences (all)	2	2	
Penile swelling			
subjects affected / exposed	0 / 121 (0.00%)	1 / 118 (0.85%)	
occurrences (all)	0	1	
Vaginal haemorrhage			
subjects affected / exposed	0 / 121 (0.00%)	2 / 118 (1.69%)	
occurrences (all)	0	2	
Erectile dysfunction			
subjects affected / exposed	0 / 121 (0.00%)	1 / 118 (0.85%)	
occurrences (all)	0	1	
Heavy menstrual bleeding			
subjects affected / exposed	0 / 121 (0.00%)	1 / 118 (0.85%)	
occurrences (all)	0	1	
Dysmenorrhoea			
subjects affected / exposed	1 / 121 (0.83%)	0 / 118 (0.00%)	
occurrences (all)	1	0	
Vaginal discharge			
subjects affected / exposed	0 / 121 (0.00%)	1 / 118 (0.85%)	
occurrences (all)	0	1	
Respiratory, thoracic and mediastinal disorders			
Nasal congestion			
subjects affected / exposed	1 / 121 (0.83%)	1 / 118 (0.85%)	
occurrences (all)	1	1	
Hypoxia			

subjects affected / exposed	0 / 121 (0.00%)	1 / 118 (0.85%)	
occurrences (all)	0	1	
Epistaxis			
subjects affected / exposed	1 / 121 (0.83%)	1 / 118 (0.85%)	
occurrences (all)	1	1	
Asthma			
subjects affected / exposed	0 / 121 (0.00%)	1 / 118 (0.85%)	
occurrences (all)	0	1	
Rhinorrhoea			
subjects affected / exposed	0 / 121 (0.00%)	2 / 118 (1.69%)	
occurrences (all)	0	2	
Oropharyngeal pain			
subjects affected / exposed	6 / 121 (4.96%)	3 / 118 (2.54%)	
occurrences (all)	7	3	
Dyspnoea			
subjects affected / exposed	0 / 121 (0.00%)	3 / 118 (2.54%)	
occurrences (all)	0	3	
Cough			
subjects affected / exposed	3 / 121 (2.48%)	3 / 118 (2.54%)	
occurrences (all)	3	3	
Painful respiration			
subjects affected / exposed	0 / 121 (0.00%)	1 / 118 (0.85%)	
occurrences (all)	0	1	
Tachypnoea			
subjects affected / exposed	0 / 121 (0.00%)	1 / 118 (0.85%)	
occurrences (all)	0	1	
Sinus disorder			
subjects affected / exposed	0 / 121 (0.00%)	1 / 118 (0.85%)	
occurrences (all)	0	1	
Rhinitis allergic			
subjects affected / exposed	0 / 121 (0.00%)	1 / 118 (0.85%)	
occurrences (all)	0	1	
Pulmonary embolism			
subjects affected / exposed	0 / 121 (0.00%)	1 / 118 (0.85%)	
occurrences (all)	0	1	
Pleural effusion			

subjects affected / exposed	1 / 121 (0.83%)	0 / 118 (0.00%)	
occurrences (all)	1	0	
Tonsillar hypertrophy			
subjects affected / exposed	1 / 121 (0.83%)	0 / 118 (0.00%)	
occurrences (all)	2	0	
Psychiatric disorders			
Anxiety			
subjects affected / exposed	0 / 121 (0.00%)	3 / 118 (2.54%)	
occurrences (all)	0	4	
Adjustment disorder with depressed mood			
subjects affected / exposed	1 / 121 (0.83%)	0 / 118 (0.00%)	
occurrences (all)	1	0	
Insomnia			
subjects affected / exposed	0 / 121 (0.00%)	1 / 118 (0.85%)	
occurrences (all)	0	1	
Depression			
subjects affected / exposed	2 / 121 (1.65%)	1 / 118 (0.85%)	
occurrences (all)	2	1	
Investigations			
C-reactive protein increased			
subjects affected / exposed	3 / 121 (2.48%)	3 / 118 (2.54%)	
occurrences (all)	3	4	
Blood lactate dehydrogenase increased			
subjects affected / exposed	1 / 121 (0.83%)	2 / 118 (1.69%)	
occurrences (all)	1	2	
Fibrin D dimer increased			
subjects affected / exposed	0 / 121 (0.00%)	2 / 118 (1.69%)	
occurrences (all)	0	2	
Platelet count decreased			
subjects affected / exposed	0 / 121 (0.00%)	2 / 118 (1.69%)	
occurrences (all)	0	2	
Alanine aminotransferase increased			
subjects affected / exposed	1 / 121 (0.83%)	1 / 118 (0.85%)	
occurrences (all)	1	1	
Aspartate aminotransferase increased			

subjects affected / exposed	1 / 121 (0.83%)	1 / 118 (0.85%)	
occurrences (all)	1	1	
Blood bilirubin increased			
subjects affected / exposed	2 / 121 (1.65%)	1 / 118 (0.85%)	
occurrences (all)	2	1	
Blood creatine phosphokinase increased			
subjects affected / exposed	0 / 121 (0.00%)	1 / 118 (0.85%)	
occurrences (all)	0	1	
Blood creatinine increased			
subjects affected / exposed	0 / 121 (0.00%)	1 / 118 (0.85%)	
occurrences (all)	0	1	
Blood fibrinogen decreased			
subjects affected / exposed	0 / 121 (0.00%)	1 / 118 (0.85%)	
occurrences (all)	0	1	
Blood glucose increased			
subjects affected / exposed	0 / 121 (0.00%)	1 / 118 (0.85%)	
occurrences (all)	0	1	
Blood potassium increased			
subjects affected / exposed	0 / 121 (0.00%)	1 / 118 (0.85%)	
occurrences (all)	0	1	
C-reactive protein			
subjects affected / exposed	0 / 121 (0.00%)	1 / 118 (0.85%)	
occurrences (all)	0	1	
Coagulation test abnormal			
subjects affected / exposed	0 / 121 (0.00%)	1 / 118 (0.85%)	
occurrences (all)	0	1	
Activated partial thromboplastin time prolonged			
subjects affected / exposed	1 / 121 (0.83%)	0 / 118 (0.00%)	
occurrences (all)	1	0	
Oxygen saturation decreased			
subjects affected / exposed	1 / 121 (0.83%)	0 / 118 (0.00%)	
occurrences (all)	1	0	
Weight decreased			

subjects affected / exposed	0 / 121 (0.00%)	1 / 118 (0.85%)	
occurrences (all)	0	1	
Serum ferritin increased			
subjects affected / exposed	1 / 121 (0.83%)	1 / 118 (0.85%)	
occurrences (all)	1	1	
Reticulocyte percentage increased			
subjects affected / exposed	0 / 121 (0.00%)	1 / 118 (0.85%)	
occurrences (all)	0	1	
Reticulocyte count increased			
subjects affected / exposed	1 / 121 (0.83%)	1 / 118 (0.85%)	
occurrences (all)	1	1	
Prothrombin time shortened			
subjects affected / exposed	0 / 121 (0.00%)	1 / 118 (0.85%)	
occurrences (all)	0	1	
Protein total decreased			
subjects affected / exposed	0 / 121 (0.00%)	1 / 118 (0.85%)	
occurrences (all)	0	1	
Platelet count increased			
subjects affected / exposed	0 / 121 (0.00%)	1 / 118 (0.85%)	
occurrences (all)	0	1	
Neutrophil count abnormal			
subjects affected / exposed	0 / 121 (0.00%)	1 / 118 (0.85%)	
occurrences (all)	0	1	
Hepatic enzyme increased			
subjects affected / exposed	0 / 121 (0.00%)	1 / 118 (0.85%)	
occurrences (all)	0	1	
Blood iron decreased			
subjects affected / exposed	1 / 121 (0.83%)	0 / 118 (0.00%)	
occurrences (all)	1	0	
Haemoglobin decreased			
subjects affected / exposed	1 / 121 (0.83%)	0 / 118 (0.00%)	
occurrences (all)	1	0	
International normalised ratio increased			
subjects affected / exposed	1 / 121 (0.83%)	0 / 118 (0.00%)	
occurrences (all)	1	0	

Neutrophil count increased			
subjects affected / exposed	1 / 121 (0.83%)	0 / 118 (0.00%)	
occurrences (all)	1	0	
White blood cell count increased			
subjects affected / exposed	1 / 121 (0.83%)	1 / 118 (0.85%)	
occurrences (all)	1	1	
SARS-CoV-2 test positive			
subjects affected / exposed	3 / 121 (2.48%)	0 / 118 (0.00%)	
occurrences (all)	4	0	
Prothrombin time prolonged			
subjects affected / exposed	1 / 121 (0.83%)	0 / 118 (0.00%)	
occurrences (all)	1	0	
Injury, poisoning and procedural complications			
Fall			
subjects affected / exposed	2 / 121 (1.65%)	0 / 118 (0.00%)	
occurrences (all)	2	0	
Contusion			
subjects affected / exposed	0 / 121 (0.00%)	1 / 118 (0.85%)	
occurrences (all)	0	1	
Infusion related reaction			
subjects affected / exposed	0 / 121 (0.00%)	1 / 118 (0.85%)	
occurrences (all)	0	1	
Ligament sprain			
subjects affected / exposed	0 / 121 (0.00%)	1 / 118 (0.85%)	
occurrences (all)	0	1	
Limb injury			
subjects affected / exposed	0 / 121 (0.00%)	1 / 118 (0.85%)	
occurrences (all)	0	1	
Muscle strain			
subjects affected / exposed	0 / 121 (0.00%)	1 / 118 (0.85%)	
occurrences (all)	0	1	
Road traffic accident			
subjects affected / exposed	0 / 121 (0.00%)	1 / 118 (0.85%)	
occurrences (all)	0	1	
Concussion			

subjects affected / exposed	1 / 121 (0.83%)	0 / 118 (0.00%)	
occurrences (all)	1	0	
Joint injury			
subjects affected / exposed	1 / 121 (0.83%)	0 / 118 (0.00%)	
occurrences (all)	1	0	
Muscle injury			
subjects affected / exposed	1 / 121 (0.83%)	0 / 118 (0.00%)	
occurrences (all)	1	0	
Vascular access site pruritus			
subjects affected / exposed	1 / 121 (0.83%)	0 / 118 (0.00%)	
occurrences (all)	2	0	
Cardiac disorders			
Tachycardia			
subjects affected / exposed	0 / 121 (0.00%)	2 / 118 (1.69%)	
occurrences (all)	0	2	
Cor pulmonale acute			
subjects affected / exposed	0 / 121 (0.00%)	1 / 118 (0.85%)	
occurrences (all)	0	1	
Cardiomegaly			
subjects affected / exposed	1 / 121 (0.83%)	0 / 118 (0.00%)	
occurrences (all)	1	0	
Tricuspid valve incompetence			
subjects affected / exposed	1 / 121 (0.83%)	0 / 118 (0.00%)	
occurrences (all)	1	0	
Palpitations			
subjects affected / exposed	0 / 121 (0.00%)	1 / 118 (0.85%)	
occurrences (all)	0	1	
Nervous system disorders			
Migraine			
subjects affected / exposed	1 / 121 (0.83%)	2 / 118 (1.69%)	
occurrences (all)	1	2	
Headache			
subjects affected / exposed	21 / 121 (17.36%)	16 / 118 (13.56%)	
occurrences (all)	31	22	
Subarachnoid haemorrhage			

subjects affected / exposed	1 / 121 (0.83%)	0 / 118 (0.00%)	
occurrences (all)	1	0	
Hypoaesthesia			
subjects affected / exposed	1 / 121 (0.83%)	0 / 118 (0.00%)	
occurrences (all)	1	0	
Epilepsy			
subjects affected / exposed	1 / 121 (0.83%)	0 / 118 (0.00%)	
occurrences (all)	1	0	
Syncope			
subjects affected / exposed	1 / 121 (0.83%)	1 / 118 (0.85%)	
occurrences (all)	1	1	
Psychogenic seizure			
subjects affected / exposed	0 / 121 (0.00%)	1 / 118 (0.85%)	
occurrences (all)	0	1	
Dizziness			
subjects affected / exposed	3 / 121 (2.48%)	1 / 118 (0.85%)	
occurrences (all)	3	1	
Amputation stump pain			
subjects affected / exposed	0 / 121 (0.00%)	1 / 118 (0.85%)	
occurrences (all)	0	1	
Amnesia			
subjects affected / exposed	0 / 121 (0.00%)	1 / 118 (0.85%)	
occurrences (all)	0	1	
Ageusia			
subjects affected / exposed	0 / 121 (0.00%)	1 / 118 (0.85%)	
occurrences (all)	0	1	
Somnolence			
subjects affected / exposed	1 / 121 (0.83%)	0 / 118 (0.00%)	
occurrences (all)	1	0	
Paraesthesia			
subjects affected / exposed	1 / 121 (0.83%)	1 / 118 (0.85%)	
occurrences (all)	1	1	
Blood and lymphatic system disorders			
Sickle cell anaemia with crisis			
subjects affected / exposed	21 / 121 (17.36%)	21 / 118 (17.80%)	
occurrences (all)	33	36	

Anaemia			
subjects affected / exposed	9 / 121 (7.44%)	5 / 118 (4.24%)	
occurrences (all)	10	8	
Thrombocytopenia			
subjects affected / exposed	0 / 121 (0.00%)	4 / 118 (3.39%)	
occurrences (all)	0	5	
Neutropenia			
subjects affected / exposed	0 / 121 (0.00%)	3 / 118 (2.54%)	
occurrences (all)	0	4	
Leukocytosis			
subjects affected / exposed	2 / 121 (1.65%)	1 / 118 (0.85%)	
occurrences (all)	2	1	
Neutrophilia			
subjects affected / exposed	0 / 121 (0.00%)	1 / 118 (0.85%)	
occurrences (all)	0	1	
Thrombocytosis			
subjects affected / exposed	0 / 121 (0.00%)	1 / 118 (0.85%)	
occurrences (all)	0	1	
Lymphadenitis			
subjects affected / exposed	1 / 121 (0.83%)	0 / 118 (0.00%)	
occurrences (all)	1	0	
Haemolysis			
subjects affected / exposed	0 / 121 (0.00%)	1 / 118 (0.85%)	
occurrences (all)	0	1	
Ear and labyrinth disorders			
Ear pain			
subjects affected / exposed	0 / 121 (0.00%)	1 / 118 (0.85%)	
occurrences (all)	0	1	
Vertigo			
subjects affected / exposed	1 / 121 (0.83%)	1 / 118 (0.85%)	
occurrences (all)	1	1	
Eye disorders			
Conjunctivitis allergic			
subjects affected / exposed	0 / 121 (0.00%)	1 / 118 (0.85%)	
occurrences (all)	0	1	
Pterygium			

subjects affected / exposed	0 / 121 (0.00%)	1 / 118 (0.85%)	
occurrences (all)	0	1	
Vision blurred			
subjects affected / exposed	0 / 121 (0.00%)	1 / 118 (0.85%)	
occurrences (all)	0	1	
Photophobia			
subjects affected / exposed	1 / 121 (0.83%)	0 / 118 (0.00%)	
occurrences (all)	1	0	
Retinopathy sickle cell			
subjects affected / exposed	1 / 121 (0.83%)	0 / 118 (0.00%)	
occurrences (all)	1	0	
Gastrointestinal disorders			
Abdominal distension			
subjects affected / exposed	1 / 121 (0.83%)	2 / 118 (1.69%)	
occurrences (all)	1	2	
Nausea			
subjects affected / exposed	1 / 121 (0.83%)	7 / 118 (5.93%)	
occurrences (all)	1	7	
Diarrhoea			
subjects affected / exposed	2 / 121 (1.65%)	5 / 118 (4.24%)	
occurrences (all)	2	5	
Abdominal pain			
subjects affected / exposed	3 / 121 (2.48%)	3 / 118 (2.54%)	
occurrences (all)	3	3	
Vomiting			
subjects affected / exposed	1 / 121 (0.83%)	3 / 118 (2.54%)	
occurrences (all)	1	3	
Abdominal pain upper			
subjects affected / exposed	2 / 121 (1.65%)	2 / 118 (1.69%)	
occurrences (all)	2	2	
Gastrooesophageal reflux disease			
subjects affected / exposed	1 / 121 (0.83%)	2 / 118 (1.69%)	
occurrences (all)	1	2	
Peptic ulcer			
subjects affected / exposed	1 / 121 (0.83%)	2 / 118 (1.69%)	
occurrences (all)	1	2	

Toothache			
subjects affected / exposed	0 / 121 (0.00%)	2 / 118 (1.69%)	
occurrences (all)	0	3	
Flatulence			
subjects affected / exposed	0 / 121 (0.00%)	1 / 118 (0.85%)	
occurrences (all)	0	1	
Reflux gastritis			
subjects affected / exposed	0 / 121 (0.00%)	1 / 118 (0.85%)	
occurrences (all)	0	1	
Tooth disorder			
subjects affected / exposed	0 / 121 (0.00%)	1 / 118 (0.85%)	
occurrences (all)	0	1	
Dental caries			
subjects affected / exposed	1 / 121 (0.83%)	0 / 118 (0.00%)	
occurrences (all)	1	0	
Dry mouth			
subjects affected / exposed	1 / 121 (0.83%)	0 / 118 (0.00%)	
occurrences (all)	1	0	
Dyspepsia			
subjects affected / exposed	2 / 121 (1.65%)	0 / 118 (0.00%)	
occurrences (all)	2	0	
Gastritis			
subjects affected / exposed	1 / 121 (0.83%)	0 / 118 (0.00%)	
occurrences (all)	1	0	
Haemorrhoids			
subjects affected / exposed	1 / 121 (0.83%)	0 / 118 (0.00%)	
occurrences (all)	1	0	
Hyperchlorhydria			
subjects affected / exposed	1 / 121 (0.83%)	0 / 118 (0.00%)	
occurrences (all)	1	0	
Stomatitis			
subjects affected / exposed	1 / 121 (0.83%)	0 / 118 (0.00%)	
occurrences (all)	1	0	
Constipation			
subjects affected / exposed	1 / 121 (0.83%)	2 / 118 (1.69%)	
occurrences (all)	1	3	

Hepatobiliary disorders			
Hepatic cytolysis			
subjects affected / exposed	0 / 121 (0.00%)	1 / 118 (0.85%)	
occurrences (all)	0	1	
Cholecystitis			
subjects affected / exposed	0 / 121 (0.00%)	1 / 118 (0.85%)	
occurrences (all)	0	1	
Cholelithiasis			
subjects affected / exposed	1 / 121 (0.83%)	1 / 118 (0.85%)	
occurrences (all)	1	1	
Cholestasis			
subjects affected / exposed	0 / 121 (0.00%)	1 / 118 (0.85%)	
occurrences (all)	0	1	
Hyperbilirubinaemia			
subjects affected / exposed	2 / 121 (1.65%)	1 / 118 (0.85%)	
occurrences (all)	2	1	
Ocular icterus			
subjects affected / exposed	0 / 121 (0.00%)	1 / 118 (0.85%)	
occurrences (all)	0	1	
Skin and subcutaneous tissue disorders			
Pityriasis alba			
subjects affected / exposed	1 / 121 (0.83%)	0 / 118 (0.00%)	
occurrences (all)	1	0	
Dry skin			
subjects affected / exposed	1 / 121 (0.83%)	0 / 118 (0.00%)	
occurrences (all)	1	0	
Blister			
subjects affected / exposed	1 / 121 (0.83%)	0 / 118 (0.00%)	
occurrences (all)	1	0	
Skin lesion			
subjects affected / exposed	1 / 121 (0.83%)	1 / 118 (0.85%)	
occurrences (all)	1	1	
Rash papular			
subjects affected / exposed	0 / 121 (0.00%)	1 / 118 (0.85%)	
occurrences (all)	0	1	
Skin ulcer			

subjects affected / exposed	1 / 121 (0.83%)	4 / 118 (3.39%)	
occurrences (all)	1	5	
Pruritus			
subjects affected / exposed	0 / 121 (0.00%)	3 / 118 (2.54%)	
occurrences (all)	0	4	
Dermatitis allergic			
subjects affected / exposed	1 / 121 (0.83%)	2 / 118 (1.69%)	
occurrences (all)	1	2	
Ecchymosis			
subjects affected / exposed	0 / 121 (0.00%)	2 / 118 (1.69%)	
occurrences (all)	0	2	
Rash			
subjects affected / exposed	0 / 121 (0.00%)	2 / 118 (1.69%)	
occurrences (all)	0	2	
Erythema			
subjects affected / exposed	0 / 121 (0.00%)	1 / 118 (0.85%)	
occurrences (all)	0	1	
Pruritus allergic			
subjects affected / exposed	0 / 121 (0.00%)	1 / 118 (0.85%)	
occurrences (all)	0	1	
Renal and urinary disorders			
Proteinuria			
subjects affected / exposed	1 / 121 (0.83%)	0 / 118 (0.00%)	
occurrences (all)	1	0	
Pollakiuria			
subjects affected / exposed	0 / 121 (0.00%)	1 / 118 (0.85%)	
occurrences (all)	0	1	
Nephropathy			
subjects affected / exposed	0 / 121 (0.00%)	1 / 118 (0.85%)	
occurrences (all)	0	1	
Hypertonic bladder			
subjects affected / exposed	0 / 121 (0.00%)	1 / 118 (0.85%)	
occurrences (all)	0	1	
Dysuria			
subjects affected / exposed	1 / 121 (0.83%)	1 / 118 (0.85%)	
occurrences (all)	1	1	

Acute kidney injury			
subjects affected / exposed	0 / 121 (0.00%)	3 / 118 (2.54%)	
occurrences (all)	0	4	
Endocrine disorders			
Thyroid mass			
subjects affected / exposed	1 / 121 (0.83%)	0 / 118 (0.00%)	
occurrences (all)	1	0	
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	12 / 121 (9.92%)	15 / 118 (12.71%)	
occurrences (all)	19	30	
Back pain			
subjects affected / exposed	14 / 121 (11.57%)	10 / 118 (8.47%)	
occurrences (all)	23	12	
Pain in extremity			
subjects affected / exposed	5 / 121 (4.13%)	7 / 118 (5.93%)	
occurrences (all)	6	10	
Muscle fatigue			
subjects affected / exposed	1 / 121 (0.83%)	0 / 118 (0.00%)	
occurrences (all)	1	0	
Joint swelling			
subjects affected / exposed	1 / 121 (0.83%)	0 / 118 (0.00%)	
occurrences (all)	1	0	
Costochondritis			
subjects affected / exposed	1 / 121 (0.83%)	0 / 118 (0.00%)	
occurrences (all)	1	0	
Spinal osteoarthritis			
subjects affected / exposed	0 / 121 (0.00%)	1 / 118 (0.85%)	
occurrences (all)	0	1	
Rheumatoid arthritis			
subjects affected / exposed	0 / 121 (0.00%)	1 / 118 (0.85%)	
occurrences (all)	0	1	
Osteoporosis			
subjects affected / exposed	0 / 121 (0.00%)	1 / 118 (0.85%)	
occurrences (all)	0	1	
Muscle twitching			

subjects affected / exposed	0 / 121 (0.00%)	1 / 118 (0.85%)	
occurrences (all)	0	1	
Osteonecrosis			
subjects affected / exposed	2 / 121 (1.65%)	2 / 118 (1.69%)	
occurrences (all)	2	2	
Musculoskeletal chest pain			
subjects affected / exposed	2 / 121 (1.65%)	3 / 118 (2.54%)	
occurrences (all)	2	4	
Bone pain			
subjects affected / exposed	3 / 121 (2.48%)	4 / 118 (3.39%)	
occurrences (all)	5	4	
Infections and infestations			
Cystitis			
subjects affected / exposed	0 / 121 (0.00%)	1 / 118 (0.85%)	
occurrences (all)	0	1	
Malaria			
subjects affected / exposed	24 / 121 (19.83%)	18 / 118 (15.25%)	
occurrences (all)	40	30	
Nasopharyngitis			
subjects affected / exposed	2 / 121 (1.65%)	9 / 118 (7.63%)	
occurrences (all)	3	10	
Upper respiratory tract infection			
subjects affected / exposed	12 / 121 (9.92%)	9 / 118 (7.63%)	
occurrences (all)	25	14	
COVID-19			
subjects affected / exposed	3 / 121 (2.48%)	4 / 118 (3.39%)	
occurrences (all)	4	4	
Urinary tract infection			
subjects affected / exposed	4 / 121 (3.31%)	4 / 118 (3.39%)	
occurrences (all)	4	4	
Gastroenteritis			
subjects affected / exposed	3 / 121 (2.48%)	2 / 118 (1.69%)	
occurrences (all)	3	2	
Influenza			
subjects affected / exposed	2 / 121 (1.65%)	2 / 118 (1.69%)	
occurrences (all)	2	2	

Pneumonia			
subjects affected / exposed	3 / 121 (2.48%)	2 / 118 (1.69%)	
occurrences (all)	4	2	
Respiratory tract infection			
subjects affected / exposed	2 / 121 (1.65%)	2 / 118 (1.69%)	
occurrences (all)	2	2	
Bacteraemia			
subjects affected / exposed	0 / 121 (0.00%)	1 / 118 (0.85%)	
occurrences (all)	0	1	
Cellulitis			
subjects affected / exposed	0 / 121 (0.00%)	1 / 118 (0.85%)	
occurrences (all)	0	1	
Fungal infection			
subjects affected / exposed	0 / 121 (0.00%)	1 / 118 (0.85%)	
occurrences (all)	0	1	
Herpes zoster			
subjects affected / exposed	1 / 121 (0.83%)	0 / 118 (0.00%)	
occurrences (all)	1	0	
Herpes simplex reactivation			
subjects affected / exposed	0 / 121 (0.00%)	1 / 118 (0.85%)	
occurrences (all)	0	1	
Hordeolum			
subjects affected / exposed	1 / 121 (0.83%)	1 / 118 (0.85%)	
occurrences (all)	1	1	
Lower respiratory tract infection			
subjects affected / exposed	0 / 121 (0.00%)	1 / 118 (0.85%)	
occurrences (all)	0	1	
Otitis media acute			
subjects affected / exposed	0 / 121 (0.00%)	1 / 118 (0.85%)	
occurrences (all)	0	1	
Pharyngitis			
subjects affected / exposed	3 / 121 (2.48%)	1 / 118 (0.85%)	
occurrences (all)	4	1	
Sepsis			
subjects affected / exposed	0 / 121 (0.00%)	1 / 118 (0.85%)	
occurrences (all)	0	1	

Sinusitis			
subjects affected / exposed	1 / 121 (0.83%)	1 / 118 (0.85%)	
occurrences (all)	1	1	
Staphylococcal bacteraemia			
subjects affected / exposed	0 / 121 (0.00%)	1 / 118 (0.85%)	
occurrences (all)	0	1	
Tonsillitis			
subjects affected / exposed	7 / 121 (5.79%)	1 / 118 (0.85%)	
occurrences (all)	9	1	
Vulvovaginitis			
subjects affected / exposed	0 / 121 (0.00%)	1 / 118 (0.85%)	
occurrences (all)	0	1	
Bacterial infection			
subjects affected / exposed	8 / 121 (6.61%)	0 / 118 (0.00%)	
occurrences (all)	10	0	
Bronchitis			
subjects affected / exposed	1 / 121 (0.83%)	0 / 118 (0.00%)	
occurrences (all)	1	0	
Conjunctivitis			
subjects affected / exposed	1 / 121 (0.83%)	0 / 118 (0.00%)	
occurrences (all)	1	0	
Gastroenteritis viral			
subjects affected / exposed	0 / 121 (0.00%)	1 / 118 (0.85%)	
occurrences (all)	0	1	
Infected skin ulcer			
subjects affected / exposed	1 / 121 (0.83%)	0 / 118 (0.00%)	
occurrences (all)	1	0	
Parainfluenzae virus infection			
subjects affected / exposed	1 / 121 (0.83%)	0 / 118 (0.00%)	
occurrences (all)	1	0	
Pneumonia bacterial			
subjects affected / exposed	1 / 121 (0.83%)	0 / 118 (0.00%)	
occurrences (all)	1	0	
Skin infection			
subjects affected / exposed	1 / 121 (0.83%)	0 / 118 (0.00%)	
occurrences (all)	1	0	

Tooth abscess			
subjects affected / exposed	1 / 121 (0.83%)	0 / 118 (0.00%)	
occurrences (all)	1	0	
Vulvovaginal candidiasis			
subjects affected / exposed	1 / 121 (0.83%)	0 / 118 (0.00%)	
occurrences (all)	1	0	
Wound sepsis			
subjects affected / exposed	1 / 121 (0.83%)	0 / 118 (0.00%)	
occurrences (all)	1	0	
Oral herpes			
subjects affected / exposed	1 / 121 (0.83%)	0 / 118 (0.00%)	
occurrences (all)	1	0	
Metabolism and nutrition disorders			
Vitamin B12 deficiency			
subjects affected / exposed	1 / 121 (0.83%)	1 / 118 (0.85%)	
occurrences (all)	1	1	
Metabolic acidosis			
subjects affected / exposed	0 / 121 (0.00%)	1 / 118 (0.85%)	
occurrences (all)	0	1	
Iron deficiency			
subjects affected / exposed	0 / 121 (0.00%)	1 / 118 (0.85%)	
occurrences (all)	0	1	
Hypokalaemia			
subjects affected / exposed	0 / 121 (0.00%)	1 / 118 (0.85%)	
occurrences (all)	0	1	
Hypertriglyceridaemia			
subjects affected / exposed	0 / 121 (0.00%)	1 / 118 (0.85%)	
occurrences (all)	0	1	
Hyperkalaemia			
subjects affected / exposed	0 / 121 (0.00%)	1 / 118 (0.85%)	
occurrences (all)	0	1	
Hyperferritinaemia			
subjects affected / exposed	0 / 121 (0.00%)	1 / 118 (0.85%)	
occurrences (all)	0	1	
Diabetes mellitus			

subjects affected / exposed	0 / 121 (0.00%)	1 / 118 (0.85%)	
occurrences (all)	0	1	
Decreased appetite			
subjects affected / exposed	1 / 121 (0.83%)	1 / 118 (0.85%)	
occurrences (all)	1	1	
Dehydration			
subjects affected / exposed	1 / 121 (0.83%)	0 / 118 (0.00%)	
occurrences (all)	1	0	
Vitamin D deficiency			
subjects affected / exposed	1 / 121 (0.83%)	0 / 118 (0.00%)	
occurrences (all)	1	0	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
17 December 2020	Amendment 1: The purpose of this amendment was to include the addition of biomarkers removal of exclusion criteria for positive HepB, HepC, or HIV and removal of exclusion criteria for participants with significant infections.
21 January 2021	Amendment 2: The purpose of this amendment was to change the duration of contraception for females and males after completion of treatment with study drug and to collect whole blood for voxelotor PK.
11 April 2022	Amendment 3: The purpose of this amendment was to add addictive condition" to "behavioral condition, clarified rules for management of infusion-related reactions; added treatment compliance assessment; and removed thrombin-antithrombin complex and tissue factory laboratory tests.
13 July 2023	Amendment 4: The purpose of this amendment was to add a futility analysis and align the protocol with language in Pfizer protocol template and standard operating procedures.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported