Clinical trial results:
An Open-label Extension Study to Evaluate the Long-term Safety of Inclacumab Administered to Participants With Sickle Cell Disease who Have Participated in an Inclacumab Clinical Trial

Summary

EudraCT number	2020-005289-32
Trial protocol	DE IT
Global end of trial date	06 November 2025

Results information

Result version number	v1 (current)
This version publication date	21 May 2026
First version publication date	21 May 2026

Trial information

Trial identification

Sponsor protocol code	C5361003

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT05348915
WHO universal trial number (UTN)	-
Other trial identifiers	GBT study ID: GBT2104-133

Notes:

Sponsors

Sponsor organisation name	Pfizer Inc.
Sponsor organisation address	66 East Hudson boulevard, New York, United States, NY 10001
Public contact	Pfizer ClinicalTrials.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)	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?	Yes

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	29 April 2026
Is this the analysis of the primary completion data?	Yes
Primary completion date	06 November 2025
Global end of trial reached?	Yes
Global end of trial date	06 November 2025
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

The primary objective of this study was to evaluate the long-term safety of every 12 weeks (Q12W) dosing of inclacumab in participants with sickle cell disease (SCD) who have completed a prior inclacumab clinical trial.

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	29 March 2022
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	Kenya: 61
Country: Number of subjects enrolled	Nigeria: 73
Country: Number of subjects enrolled	Tanzania, United Republic of: 9
Country: Number of subjects enrolled	Brazil: 22
Country: Number of subjects enrolled	Colombia: 16
Country: Number of subjects enrolled	Lebanon: 13
Country: Number of subjects enrolled	Oman: 5
Country: Number of subjects enrolled	Saudi Arabia: 2
Country: Number of subjects enrolled	Türkiye: 11
Country: Number of subjects enrolled	United States: 29
Worldwide total number of subjects	241
EEA total number of subjects	0

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)	21
Adults (18-64 years)	220
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

A total of 242 participants with SCD who had participated in studies GBT2104-131 and GBT2104-132 were screened in this open label extension study.

Pre-assignment

Screening details:

A total of 241 participants received the study treatment under the current study.

Period 1

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

Blinding implementation details:

No blinding, open label.

Arms

Arm title	Inclacumab

Arm description:

Participants with SCD who received inclacumab 30 milligrams/kilograms (mg/kg) intravenously (IV) Q12W.

Arm type	Experimental
Investigational medicinal product name	Inclacumab
Investigational medicinal product code	
Other name	GBT2104, PF-07940370
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Participants received inclacumab 30 mg/kg IV Q12W.

Number of subjects in period 1	Inclacumab
Started	241
Completed	0
Not completed	241
Physician decision	6
Consent withdrawn by subject	20
Adverse events	18
Pregnancy	7
Study terminated by sponsor	179
Unspecified	7
Lost to follow-up	3
Protocol deviation	1

Baseline characteristics

Reporting groups	
Reporting group title	Inclacumab
Reporting group description:	
Participants with SCD who received inclacumab 30 milligrams/kilograms (mg/kg) intravenously (IV) Q12W.	

Reporting group values	Inclacumab	Total	
Number of subjects	241	241	
Age Categorical Units: Subjects			
Age continuous Units: years			
arithmetic mean	25.0		
standard deviation	± 7.36	-	
Gender categorical Units: Subjects			
Male	119	119	
Female	122	122	
Ethnicity Units: Subjects			
Hispanic or Latino	37	37	
Not Hispanic or Latino	200	200	
Unknown or Not Reported	4	4	
Race Units: Subjects			
African	138	138	
American Indian or Alaska Native	4	4	
Arab	3	3	
Black or African American	43	43	
Middle Eastern	2	2	
White	16	16	
Multiracial	33	33	
Other	2	2	

End points

End points reporting groups

Reporting group title	Inclacumab

Reporting group description:

Participants with SCD who received inclacumab 30 milligrams/kilograms (mg/kg) intravenously (IV) Q12W.

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

End point title	Number of Participants With Treatment Emergent Adverse Events (TEAEs)[1]

End point description:

An adverse event (AE) was any unfavourable 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 in GBT2104-133. TEAEs included both serious and all other AEs. Safety analysis set was defined as all participants who received treatment with study drug (inclacumab) in the current study.

End point type	Primary

End point timeframe:

From first dose of study treatment (Day 1) up to end of study (an average of 90.2 weeks, maximum of 182.7 weeks)

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: No statistical analysis was planned for this endpoint

End point values	Inclacumab			
Subject group type	Reporting group			
Number of subjects analysed	241			
Units: Participants	211			

Statistical analyses

No statistical analyses for this end point

Secondary: Annualized Rate of VOCs That Required Admission to a Healthcare Facility and Treatment With Parenteral Pain Medication

End point title	Annualized Rate of VOCs That Required Admission to a Healthcare Facility and Treatment With Parenteral Pain Medication

End point description:

A VOC that required admission to a healthcare facility and treatment with parenteral pain medication was defined as an acute episode of pain that: 1) had no medically determined cause other than a vaso-occlusive event; 2) resulted in admission to a healthcare facility; 3) required parenteral narcotic agents or parenteral NSAIDs. Admission to a healthcare facility included: 1) a hospital admission or 2) an admission to an emergency room, observation unit, or infusion center for >= 12 hours or 3) 2 visits to an emergency room, observation unit, or infusion center over a 72-hour period. Annualized rate of VOC = (total number of VOC events)/(total person-years). Safety analysis set was defined as all participants who received treatment with study drug (inclacumab) in the current study.

End point type	Secondary

End point timeframe:

From first dose of study treatment (Day 1) up to end of study (an average of 90.2 weeks, maximum of 182.7 weeks)

End point values	Inclacumab			
Subject group type	Reporting group			
Number of subjects analysed	241			
Units: VOC events per person-year				
number (confidence interval 95%)	1.07 (0.97 to 1.17)			

Statistical analyses

No statistical analyses for this end point

Secondary: Annualized Rate of Vaso-occlusive Crises (VOCs)

End point title	Annualized Rate of Vaso-occlusive Crises (VOCs)

End point description:

A VOCs was defined as an acute episode of pain that: 1) had no medically determined cause other than a vaso-occlusive event; 2) 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; 3) required parenteral narcotic agents, parenteral nonsteroidal anti-inflammatory drugs (NSAIDs), or an increase in treatment with oral narcotics. Annualized rate of VOC = (total number of VOC events)/(total person-years). Safety analysis set was defined as all participants who received treatment with study drug (inclacumab) in the current study.

End point type	Secondary

End point timeframe:

From first dose of study treatment (Day 1) up to end of study (an average of 90.2 weeks, maximum of 182.7 weeks)

End point values	Inclacumab			
Subject group type	Reporting group			
Number of subjects analysed	241			
Units: VOC events per person-year				
number (confidence interval 95%)	1.89 (1.76 to 2.03)			

Statistical analyses

No statistical analyses for this end point

Secondary: Annualized Number of Inpatient Hospitalization Days for a VOC

End point title	Annualized Number of Inpatient Hospitalization Days for a VOC

End point description:

A VOCs was defined as an acute episode of pain that: 1) had no medically determined cause other than a vaso-occlusive event; 2) 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; 3) required parenteral narcotic agents, parenteral NSAIDs, or an increase in treatment with oral narcotics. Annualized rate of hospitalization days = (total number of hospitalization days)/(total person-years). Safety analysis set was defined as all participants who received treatment with study drug (inclacumab) in the current study.

End point type	Secondary

End point timeframe:

From first dose of study treatment (Day 1) up to end of study (an average of 90.2 weeks, maximum of 182.7 weeks)

End point values	Inclacumab			
Subject group type	Reporting group			
Number of subjects analysed	241			
Units: Hospitalization days per person-year				
number (confidence interval 95%)	7.07 (6.82 to 7.33)			

Statistical analyses

No statistical analyses for this end point

Secondary: Annualized Rate of SCD-related Urgent Care Visits

End point title	Annualized Rate of SCD-related Urgent Care Visits

End point description:

Urgent care visits included visits to the clinic, emergency room, and hospital. Analysis of this endpoint included both VOC and non-VOC SCD-related events. Annualized rate of visits = (total number of visits) /(total person-years). Safety analysis set was defined as all participants who received treatment with study drug (inclacumab) in the current study.

End point type	Secondary

End point timeframe:

From first dose of study treatment (Day 1) up to end of study (an average of 90.2 weeks, maximum of 182.7 weeks)

End point values	Inclacumab			
Subject group type	Reporting group			
Number of subjects analysed	241			
Units: Visits per person-year				
number (confidence interval 95%)	2.53 (2.38 to 2.69)			

Statistical analyses

No statistical analyses for this end point

Secondary: Annualized Rate of Red Blood Cell (RBC) Transfusions

End point title	Annualized Rate of Red Blood Cell (RBC) Transfusions

End point description:

Annualized RBC transfusion rate = (total number of RBC transfusions)/(total person-years). Safety analysis set was defined as all participants who received treatment with study drug (inclacumab) in the current study.

End point type	Secondary

End point timeframe:

From first dose of study treatment (Day 1) up to end of study (an average of 90.2 weeks, maximum of 182.7 weeks)

End point values	Inclacumab			
Subject group type	Reporting group			
Number of subjects analysed	241			
Units: RBC transfusions per person-year				
number (confidence interval 95%)	0.76 (0.68 to 0.85)			

Statistical analyses

No statistical analyses for this end point

Secondary: Annualized Rate of Complicated VOCs

End point title	Annualized Rate of Complicated VOCs

End point description:

A VOCs was defined as an acute episode of pain that: 1) had no medically determined cause other than a vaso-occlusive event; 2) 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; 3) required parenteral narcotic agents, parenteral NSAIDs, or an increase in treatment with oral narcotics. Complicated VOCs included VOCs that caused acute chest syndrome (ACS), hepatic sequestration, splenic sequestration, and priapism. Annualized VOC rate = (total number of VOC events)/(total person-years). Safety analysis set was defined as all participants who received treatment with study drug (inclacumab) in the current study.

End point type	Secondary

End point timeframe:

From first dose of study treatment (Day 1) up to end of study (an average of 90.2 weeks, maximum of 182.7 weeks)

End point values	Inclacumab			
Subject group type	Reporting group			
Number of subjects analysed	241			
Units: VOC events per person-year				
number (confidence interval 95%)	0.09 (0.06 to 0.12)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Total Days Missed From School or Work due to SCD Pain Symptoms for the First 48 Weeks

End point title	Percentage of Total Days Missed From School or Work due to SCD Pain Symptoms for the First 48 Weeks

End point description:

The percentage of total days missed from school or work due to SCD pain symptoms for the first 48 weeks out of the total expected days of treatment is presented in this endpoint. Only participants for whom the number of days of work and/or school that should have been attended is >0 were included in the analysis. Safety analysis set was defined as all participants who received treatment with study drug (inclacumab) in the current study. Here, 'Subjects Analyzed' signifies participants evaluable for this endpoint.

End point type	Secondary

End point timeframe:

From first dose of study treatment (Day 1) up to Week 48

End point values	Inclacumab			
Subject group type	Reporting group			
Number of subjects analysed	186			
Units: Percentage of Days				
arithmetic mean (standard deviation)	6.2 (± 8.25)			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

From first dose of study treatment (Day 1) up to end of study (an average of 90.2 weeks, maximum of 182.7 weeks)

Adverse event reporting additional description:

Same event term may appear as both non-SAE and SAE, but what is presented are distinct events. An event may be categorized as serious in one participant and non-serious in another participant or one participant may have experienced both serious and non-serious event. Safety analysis set was evaluated.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	28.1

Reporting groups

Reporting group title	Inclacumab

Reporting group description:

Participants with SCD who received inclacumab 30 mg/kg IV Q12W.

Serious adverse events	Inclacumab		
Total subjects affected by serious adverse events			
subjects affected / exposed	97 / 241 (40.25%)		
number of deaths (all causes)	17		
number of deaths resulting from adverse events	16		
Vascular disorders			
Haematoma			
subjects affected / exposed	1 / 241 (0.41%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pregnancy, puerperium and perinatal conditions			
Ectopic pregnancy			
subjects affected / exposed	1 / 241 (0.41%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Abortion spontaneous			
subjects affected / exposed	1 / 241 (0.41%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
General disorders and administration			

site conditions			
Fat necrosis			
subjects affected / exposed	1 / 241 (0.41%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Multiple organ dysfunction syndrome			
subjects affected / exposed	1 / 241 (0.41%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Non-cardiac chest pain			
subjects affected / exposed	1 / 241 (0.41%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Reproductive system and breast disorders			
Adnexa uteri cyst			
subjects affected / exposed	1 / 241 (0.41%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Respiratory, thoracic and mediastinal disorders			
Pulmonary embolism			
subjects affected / exposed	2 / 241 (0.83%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Acute respiratory distress syndrome			
subjects affected / exposed	1 / 241 (0.41%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Investigations			
Hepatic enzyme increased			
subjects affected / exposed	2 / 241 (0.83%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Prothrombin time prolonged			

subjects affected / exposed	1 / 241 (0.41%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
International normalised ratio increased				
subjects affected / exposed	1 / 241 (0.41%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
Injury, poisoning and procedural complications				
Road traffic accident				
subjects affected / exposed	2 / 241 (0.83%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Animal bite				
subjects affected / exposed	1 / 241 (0.41%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Pneumocephalus				
subjects affected / exposed	1 / 241 (0.41%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Skull fracture				
subjects affected / exposed	1 / 241 (0.41%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Tibia fracture				
subjects affected / exposed	1 / 241 (0.41%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Ulna fracture				
subjects affected / exposed	1 / 241 (0.41%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Craniofacial fracture				

subjects affected / exposed	1 / 241 (0.41%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Infusion related reaction			
subjects affected / exposed	1 / 241 (0.41%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Congenital, familial and genetic disorders			
Sickle cell anaemia			
subjects affected / exposed	1 / 241 (0.41%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Sickle cell disease			
subjects affected / exposed	1 / 241 (0.41%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Cardiac disorders			
Palpitations			
subjects affected / exposed	1 / 241 (0.41%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Cardiac Failure			
subjects affected / exposed	1 / 241 (0.41%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Nervous system disorders			
Haemorrhagic stroke			
subjects affected / exposed	1 / 241 (0.41%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Blood and lymphatic system disorders			
Haemolysis			

subjects affected / exposed	1 / 241 (0.41%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Haemolytic anaemia			
subjects affected / exposed	2 / 241 (0.83%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Anaemia			
subjects affected / exposed	35 / 241 (14.52%)		
occurrences causally related to treatment / all	0 / 57		
deaths causally related to treatment / all	0 / 1		
Ear and labyrinth disorders			
Vertigo positional			
subjects affected / exposed	1 / 241 (0.41%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal disorders			
Nausea			
subjects affected / exposed	1 / 241 (0.41%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Haemorrhoids			
subjects affected / exposed	1 / 241 (0.41%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Abdominal pain			
subjects affected / exposed	1 / 241 (0.41%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Hepatobiliary disorders			
Cholecystitis acute			
subjects affected / exposed	1 / 241 (0.41%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		

Biloma				
subjects affected / exposed	1 / 241 (0.41%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Jaundice cholecystitis				
subjects affected / exposed	1 / 241 (0.41%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Cholelithiasis				
subjects affected / exposed	1 / 241 (0.41%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Skin and subcutaneous tissue disorders				
Skin ulcer				
subjects affected / exposed	1 / 241 (0.41%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Renal and urinary disorders				
Renal papillary necrosis				
subjects affected / exposed	1 / 241 (0.41%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 1			
Musculoskeletal and connective tissue disorders				
Osteonecrosis				
subjects affected / exposed	3 / 241 (1.24%)			
occurrences causally related to treatment / all	0 / 4			
deaths causally related to treatment / all	0 / 0			
Back pain				
subjects affected / exposed	1 / 241 (0.41%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Osteoarthritis				

subjects affected / exposed	1 / 241 (0.41%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Pain in extremity				
subjects affected / exposed	1 / 241 (0.41%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Infections and infestations				
Malaria				
subjects affected / exposed	23 / 241 (9.54%)			
occurrences causally related to treatment / all	0 / 29			
deaths causally related to treatment / all	0 / 4			
Urinary tract infection				
subjects affected / exposed	8 / 241 (3.32%)			
occurrences causally related to treatment / all	0 / 10			
deaths causally related to treatment / all	0 / 0			
Pneumonia				
subjects affected / exposed	6 / 241 (2.49%)			
occurrences causally related to treatment / all	0 / 7			
deaths causally related to treatment / all	0 / 0			
Septic shock				
subjects affected / exposed	2 / 241 (0.83%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 2			
Infection				
subjects affected / exposed	4 / 241 (1.66%)			
occurrences causally related to treatment / all	0 / 4			
deaths causally related to treatment / all	0 / 0			
Osteomyelitis				
subjects affected / exposed	2 / 241 (0.83%)			
occurrences causally related to treatment / all	2 / 3			
deaths causally related to treatment / all	0 / 0			
Gastroenteritis				

subjects affected / exposed	2 / 241 (0.83%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Sepsis				
subjects affected / exposed	4 / 241 (1.66%)			
occurrences causally related to treatment / all	0 / 4			
deaths causally related to treatment / all	0 / 1			
Bacterial infection				
subjects affected / exposed	5 / 241 (2.07%)			
occurrences causally related to treatment / all	0 / 5			
deaths causally related to treatment / all	0 / 1			
Systemic bacterial infection				
subjects affected / exposed	2 / 241 (0.83%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Tonsillitis				
subjects affected / exposed	2 / 241 (0.83%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Arthritis bacterial				
subjects affected / exposed	1 / 241 (0.41%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Aspergilloma				
subjects affected / exposed	1 / 241 (0.41%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
COVID-19				
subjects affected / exposed	1 / 241 (0.41%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Cellulitis				

subjects affected / exposed	1 / 241 (0.41%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Infected skin ulcer				
subjects affected / exposed	1 / 241 (0.41%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Infectious mononucleosis				
subjects affected / exposed	1 / 241 (0.41%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Influenza				
subjects affected / exposed	1 / 241 (0.41%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Nasopharyngitis				
subjects affected / exposed	1 / 241 (0.41%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Osteomyelitis acute				
subjects affected / exposed	1 / 241 (0.41%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Pneumonia bacterial				
subjects affected / exposed	1 / 241 (0.41%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Pneumonia viral				
subjects affected / exposed	1 / 241 (0.41%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Pyelonephritis				

subjects affected / exposed	1 / 241 (0.41%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Upper respiratory tract infection			
subjects affected / exposed	1 / 241 (0.41%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Sinusitis			
subjects affected / exposed	1 / 241 (0.41%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Wound infection			
subjects affected / exposed	1 / 241 (0.41%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		

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

Non-serious adverse events	Inclacumab		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	203 / 241 (84.23%)		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Pituitary tumour benign			
subjects affected / exposed	1 / 241 (0.41%)		
occurrences (all)	1		
Vascular disorders			
Hypotension			
subjects affected / exposed	3 / 241 (1.24%)		
occurrences (all)	3		
Thrombophlebitis			
subjects affected / exposed	1 / 241 (0.41%)		
occurrences (all)	1		
Inferior vena cava syndrome			

subjects affected / exposed	1 / 241 (0.41%)		
occurrences (all)	1		
Hypertension			
subjects affected / exposed	1 / 241 (0.41%)		
occurrences (all)	1		
Hot flush			
subjects affected / exposed	2 / 241 (0.83%)		
occurrences (all)	2		
General disorders and administration site conditions			
Pain			
subjects affected / exposed	14 / 241 (5.81%)		
occurrences (all)	15		
Non-cardiac chest pain			
subjects affected / exposed	8 / 241 (3.32%)		
occurrences (all)	11		
Pyrexia			
subjects affected / exposed	6 / 241 (2.49%)		
occurrences (all)	7		
Chest discomfort			
subjects affected / exposed	3 / 241 (1.24%)		
occurrences (all)	3		
Influenza like illness			
subjects affected / exposed	3 / 241 (1.24%)		
occurrences (all)	3		
Asthenia			
subjects affected / exposed	2 / 241 (0.83%)		
occurrences (all)	2		
Facial pain			
subjects affected / exposed	2 / 241 (0.83%)		
occurrences (all)	2		
Malaise			
subjects affected / exposed	2 / 241 (0.83%)		
occurrences (all)	3		
Peripheral swelling			

subjects affected / exposed	2 / 241 (0.83%)		
occurrences (all)	2		
Chest pain			
subjects affected / exposed	1 / 241 (0.41%)		
occurrences (all)	1		
Chills			
subjects affected / exposed	1 / 241 (0.41%)		
occurrences (all)	1		
Feeling hot			
subjects affected / exposed	1 / 241 (0.41%)		
occurrences (all)	1		
Mucosal inflammation			
subjects affected / exposed	1 / 241 (0.41%)		
occurrences (all)	1		
Oedema peripheral			
subjects affected / exposed	1 / 241 (0.41%)		
occurrences (all)	1		
Thirst			
subjects affected / exposed	1 / 241 (0.41%)		
occurrences (all)	1		
Fatigue			
subjects affected / exposed	8 / 241 (3.32%)		
occurrences (all)	8		
Immune system disorders			
Drug hypersensitivity			
subjects affected / exposed	1 / 241 (0.41%)		
occurrences (all)	1		
Hypogammaglobulinaemia			
subjects affected / exposed	1 / 241 (0.41%)		
occurrences (all)	1		
Hypersensitivity			
subjects affected / exposed	1 / 241 (0.41%)		
occurrences (all)	1		
Reproductive system and breast disorders			

Penis disorder			
subjects affected / exposed	1 / 241 (0.41%)		
occurrences (all)	1		
Priapism			
subjects affected / exposed	4 / 241 (1.66%)		
occurrences (all)	5		
Dysmenorrhoea			
subjects affected / exposed	3 / 241 (1.24%)		
occurrences (all)	3		
Heavy menstrual bleeding			
subjects affected / exposed	2 / 241 (0.83%)		
occurrences (all)	2		
Vaginal discharge			
subjects affected / exposed	2 / 241 (0.83%)		
occurrences (all)	4		
Breast mass			
subjects affected / exposed	1 / 241 (0.41%)		
occurrences (all)	1		
Gynaecomastia			
subjects affected / exposed	1 / 241 (0.41%)		
occurrences (all)	1		
Infertility			
subjects affected / exposed	1 / 241 (0.41%)		
occurrences (all)	1		
Ovarian cyst			
subjects affected / exposed	1 / 241 (0.41%)		
occurrences (all)	1		
Respiratory, thoracic and mediastinal disorders			
Asthma			
subjects affected / exposed	1 / 241 (0.41%)		
occurrences (all)	2		
Allergic sinusitis			
subjects affected / exposed	1 / 241 (0.41%)		
occurrences (all)	1		
Tonsillar hypertrophy			

subjects affected / exposed	2 / 241 (0.83%)			
occurrences (all)	2			
Rhinorrhoea				
subjects affected / exposed	2 / 241 (0.83%)			
occurrences (all)	2			
Rhinitis allergic				
subjects affected / exposed	2 / 241 (0.83%)			
occurrences (all)	2			
Epsitaxis				
subjects affected / exposed	2 / 241 (0.83%)			
occurrences (all)	2			
Cough				
subjects affected / exposed	5 / 241 (2.07%)			
occurrences (all)	5			
Oropharyngeal pain				
subjects affected / exposed	6 / 241 (2.49%)			
occurrences (all)	6			
Bronchial hyperreactivity				
subjects affected / exposed	1 / 241 (0.41%)			
occurrences (all)	1			
Wheezing				
subjects affected / exposed	1 / 241 (0.41%)			
occurrences (all)	1			
Throat irritation				
subjects affected / exposed	1 / 241 (0.41%)			
occurrences (all)	1			
Sleep apnoea syndrome				
subjects affected / exposed	1 / 241 (0.41%)			
occurrences (all)	1			
Sinus congestion				
subjects affected / exposed	1 / 241 (0.41%)			
occurrences (all)	1			
Respiratory disorder				
subjects affected / exposed	1 / 241 (0.41%)			
occurrences (all)	1			
Pulmonary hypertension				

subjects affected / exposed	1 / 241 (0.41%)		
occurrences (all)	1		
Pleurla effusion			
subjects affected / exposed	1 / 241 (0.41%)		
occurrences (all)	1		
Dyspnoea			
subjects affected / exposed	1 / 241 (0.41%)		
occurrences (all)	1		
Nasal congestion			
subjects affected / exposed	1 / 241 (0.41%)		
occurrences (all)	1		
Nasal polyps			
subjects affected / exposed	1 / 241 (0.41%)		
occurrences (all)	1		
Psychiatric disorders			
Depression			
subjects affected / exposed	5 / 241 (2.07%)		
occurrences (all)	5		
Anxiety			
subjects affected / exposed	4 / 241 (1.66%)		
occurrences (all)	4		
Borderline personality disorder			
subjects affected / exposed	1 / 241 (0.41%)		
occurrences (all)	1		
Generalised anxiety disorder			
subjects affected / exposed	1 / 241 (0.41%)		
occurrences (all)	1		
Grief reaction			
subjects affected / exposed	1 / 241 (0.41%)		
occurrences (all)	1		
Insomnia			
subjects affected / exposed	1 / 241 (0.41%)		
occurrences (all)	1		
Post-traumatic stress disorder			
subjects affected / exposed	1 / 241 (0.41%)		
occurrences (all)	1		

Investigations			
Glomerular filtration rate decreased			
subjects affected / exposed	11 / 241 (4.56%)		
occurrences (all)	12		
Blood bilirubin increased			
subjects affected / exposed	8 / 241 (3.32%)		
occurrences (all)	13		
Alanine aminotransferase increased			
subjects affected / exposed	3 / 241 (1.24%)		
occurrences (all)	4		
Aspartate aminotransferase increased			
subjects affected / exposed	2 / 241 (0.83%)		
occurrences (all)	2		
Blood creatinine phosphokinase increased			
subjects affected / exposed	2 / 241 (0.83%)		
occurrences (all)	3		
Blood immunoglobulin G increased			
subjects affected / exposed	2 / 241 (0.83%)		
occurrences (all)	2		
Blood lactate dehydrogenase increased			
subjects affected / exposed	2 / 241 (0.83%)		
occurrences (all)	3		
C-reactive protein increased			
subjects affected / exposed	2 / 241 (0.83%)		
occurrences (all)	2		
Haemoglobin decreased			
subjects affected / exposed	2 / 241 (0.83%)		
occurrences (all)	3		
Hepatic enzyme increased			
subjects affected / exposed	2 / 241 (0.83%)		
occurrences (all)	2		
Reticulocyte count increased			
subjects affected / exposed	2 / 241 (0.83%)		
occurrences (all)	3		
Weight decreased			

subjects affected / exposed	1 / 241 (0.41%)			
occurrences (all)	1			
Serum ferratin increased				
subjects affected / exposed	2 / 241 (0.83%)			
occurrences (all)	2			
SARS-CoV-2 antibody test positive				
subjects affected / exposed	1 / 241 (0.41%)			
occurrences (all)	1			
Pulmonary arterial pressure increased				
subjects affected / exposed	1 / 241 (0.41%)			
occurrences (all)	1			
Prothrombin time abnormal				
subjects affected / exposed	1 / 241 (0.41%)			
occurrences (all)	1			
Platelet count decreased				
subjects affected / exposed	1 / 241 (0.41%)			
occurrences (all)	1			
Neutrophil count decreased				
subjects affected / exposed	1 / 241 (0.41%)			
occurrences (all)	1			
Neutrophil count abnormal				
subjects affected / exposed	1 / 241 (0.41%)			
occurrences (all)	1			
Lymphocyte count decreased				
subjects affected / exposed	1 / 241 (0.41%)			
occurrences (all)	1			
Influenza B virus test positive				
subjects affected / exposed	1 / 241 (0.41%)			
occurrences (all)	1			
Human rhinovirus test positive				
subjects affected / exposed	1 / 241 (0.41%)			
occurrences (all)	1			
Haematocrit decreased				
subjects affected / exposed	1 / 241 (0.41%)			
occurrences (all)	1			

HIV antigen positive			
subjects affected / exposed	1 / 241 (0.41%)		
occurrences (all)	1		
Gamma-glutamyltransferase increased			
subjects affected / exposed	1 / 241 (0.41%)		
occurrences (all)	1		
Blood iron decreased			
subjects affected / exposed	1 / 241 (0.41%)		
occurrences (all)	1		
Blood creatinine increased			
subjects affected / exposed	1 / 241 (0.41%)		
occurrences (all)	1		
Bilirubin conjugated increased			
subjects affected / exposed	1 / 241 (0.41%)		
occurrences (all)	1		
Bacterial test positive			
subjects affected / exposed	1 / 241 (0.41%)		
occurrences (all)	3		
Bacterial test			
subjects affected / exposed	1 / 241 (0.41%)		
occurrences (all)	1		
Adenovirus test positive			
subjects affected / exposed	1 / 241 (0.41%)		
occurrences (all)	1		
SARS-CoV-2 test positive			
subjects affected / exposed	1 / 241 (0.41%)		
occurrences (all)	1		
Injury, poisoning and procedural complications			
Burns second degree			
subjects affected / exposed	2 / 241 (0.83%)		
occurrences (all)	2		
Ligament sprain			
subjects affected / exposed	3 / 241 (1.24%)		
occurrences (all)	3		
Joint dislocation			

subjects affected / exposed	2 / 241 (0.83%)		
occurrences (all)	3		
Road tracffic accident			
subjects affected / exposed	2 / 241 (0.83%)		
occurrences (all)	2		
Tooth fracture			
subjects affected / exposed	2 / 241 (0.83%)		
occurrences (all)	2		
Delayed haemolytic transfusion reaction			
subjects affected / exposed	1 / 241 (0.41%)		
occurrences (all)	1		
Fall			
subjects affected / exposed	1 / 241 (0.41%)		
occurrences (all)	1		
Joint injury			
subjects affected / exposed	1 / 241 (0.41%)		
occurrences (all)	1		
Limb injury			
subjects affected / exposed	1 / 241 (0.41%)		
occurrences (all)	1		
Muscle strain			
subjects affected / exposed	1 / 241 (0.41%)		
occurrences (all)	1		
Soft tissue injury			
subjects affected / exposed	1 / 241 (0.41%)		
occurrences (all)	1		
Tibia fracture			
subjects affected / exposed	1 / 241 (0.41%)		
occurrences (all)	1		
Wound			
subjects affected / exposed	1 / 241 (0.41%)		
occurrences (all)	1		
Congenital, familial and genetic disorders			

Sickle cell disease			
subjects affected / exposed	1 / 241 (0.41%)		
occurrences (all)	1		
Cardiac disorders			
Palpitations			
subjects affected / exposed	2 / 241 (0.83%)		
occurrences (all)	3		
Left ventricular hypertrophy			
subjects affected / exposed	1 / 241 (0.41%)		
occurrences (all)	1		
Left ventricular dilatation			
subjects affected / exposed	1 / 241 (0.41%)		
occurrences (all)	1		
Cardiomegaly			
subjects affected / exposed	1 / 241 (0.41%)		
occurrences (all)	1		
Sinus bradycardia			
subjects affected / exposed	1 / 241 (0.41%)		
occurrences (all)	1		
Tachycardia			
subjects affected / exposed	1 / 241 (0.41%)		
occurrences (all)	1		
Nervous system disorders			
Central nervous system lesion			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 241 (0.41%)		
occurrences (all)	1		
Headache			
subjects affected / exposed	42 / 241 (17.43%)		
occurrences (all)	53		
Dizziness			
subjects affected / exposed	6 / 241 (2.49%)		
occurrences (all)	8		
Migraine			
subjects affected / exposed	6 / 241 (2.49%)		
occurrences (all)	8		

Intracranial aneurysm subjects affected / exposed occurrences (all)	2 / 241 (0.83%) 2		
Tremor subjects affected / exposed occurrences (all)	2 / 241 (0.83%) 2		
Amnesia subjects affected / exposed occurrences (all)	1 / 241 (0.41%) 1		
Carpal tunnel syndrome subjects affected / exposed occurrences (all)	1 / 241 (0.41%) 1		
Cerebrovascular disorder subjects affected / exposed occurrences (all)	1 / 241 (0.41%) 1		
Cervical radiculopathy subjects affected / exposed occurrences (all)	1 / 241 (0.41%) 1		
Neuropathy peripheral subjects affected / exposed occurrences (all)	1 / 241 (0.41%) 1		
Paraesthesia subjects affected / exposed occurrences (all)	1 / 241 (0.41%) 1		
Tension headache subjects affected / exposed occurrences (all)	1 / 241 (0.41%) 1		
Trigeminal neuralgia subjects affected / exposed occurrences (all)	1 / 241 (0.41%) 1		
Blood and lymphatic system disorders Sickle cell anaemia with crisis subjects affected / exposed occurrences (all)	68 / 241 (28.22%) 222		
Anaemia			

subjects affected / exposed occurrences (all)	19 / 241 (7.88%) 21		
Leukocytosis subjects affected / exposed occurrences (all)	9 / 241 (3.73%) 10		
Thrombocytopenia subjects affected / exposed occurrences (all)	7 / 241 (2.90%) 7		
Neutropenia subjects affected / exposed occurrences (all)	4 / 241 (1.66%) 8		
Neutrophilia subjects affected / exposed occurrences (all)	1 / 241 (0.41%) 1		
Leukopenia subjects affected / exposed occurrences (all)	2 / 241 (0.83%) 2		
Lymphadenopathy subjects affected / exposed occurrences (all)	2 / 241 (0.83%) 2		
Blood loss anaemia subjects affected / exposed occurrences (all)	1 / 241 (0.41%) 1		
Thrombocytosis subjects affected / exposed occurrences (all)	4 / 241 (1.66%) 5		
Ear and labyrinth disorders Vertigo subjects affected / exposed occurrences (all)	1 / 241 (0.41%) 1		
Eye disorders Vision blurred subjects affected / exposed occurrences (all)	2 / 241 (0.83%) 2		
Blepharitis			

subjects affected / exposed	1 / 241 (0.41%)		
occurrences (all)	1		
Dry eye			
subjects affected / exposed	1 / 241 (0.41%)		
occurrences (all)	1		
Retinopathy sickle cell			
subjects affected / exposed	1 / 241 (0.41%)		
occurrences (all)	1		
Vitreous floaters			
subjects affected / exposed	1 / 241 (0.41%)		
occurrences (all)	1		
Gastrointestinal disorders			
Abdominal pain upper			
subjects affected / exposed	4 / 241 (1.66%)		
occurrences (all)	5		
Gastritis			
subjects affected / exposed	10 / 241 (4.15%)		
occurrences (all)	13		
Vomiting			
subjects affected / exposed	9 / 241 (3.73%)		
occurrences (all)	9		
Nausea			
subjects affected / exposed	8 / 241 (3.32%)		
occurrences (all)	9		
Peptic ulcer			
subjects affected / exposed	6 / 241 (2.49%)		
occurrences (all)	7		
Dyspepsia			
subjects affected / exposed	5 / 241 (2.07%)		
occurrences (all)	5		
Abdominal pain			
subjects affected / exposed	4 / 241 (1.66%)		
occurrences (all)	4		
Diarrhoea			
subjects affected / exposed	10 / 241 (4.15%)		
occurrences (all)	10		

Constipation				
subjects affected / exposed	3 / 241 (1.24%)			
occurrences (all)	4			
Toothache				
subjects affected / exposed	1 / 241 (0.41%)			
occurrences (all)	1			
Gastrooesophageal reflux disease				
subjects affected / exposed	2 / 241 (0.83%)			
occurrences (all)	2			
Abdominal discomfort				
subjects affected / exposed	1 / 241 (0.41%)			
occurrences (all)	1			
Anal fissure				
subjects affected / exposed	1 / 241 (0.41%)			
occurrences (all)	1			
Apthous ulcer				
subjects affected / exposed	1 / 241 (0.41%)			
occurrences (all)	1			
Colitis				
subjects affected / exposed	1 / 241 (0.41%)			
occurrences (all)	1			
Dysphagia				
subjects affected / exposed	1 / 241 (0.41%)			
occurrences (all)	1			
Flatulence				
subjects affected / exposed	1 / 241 (0.41%)			
occurrences (all)	1			
Food poisoning				
subjects affected / exposed	1 / 241 (0.41%)			
occurrences (all)	1			
Gingival swelling				
subjects affected / exposed	1 / 241 (0.41%)			
occurrences (all)	1			
Haematochezia				
subjects affected / exposed	1 / 241 (0.41%)			
occurrences (all)	1			

Hyperchlorhydria subjects affected / exposed occurrences (all)	1 / 241 (0.41%) 1		
Oral pain subjects affected / exposed occurrences (all)	1 / 241 (0.41%) 1		
Rectal haemorrhage subjects affected / exposed occurrences (all)	1 / 241 (0.41%) 1		
Dental caries subjects affected / exposed occurrences (all)	2 / 241 (0.83%) 2		
Hepatobiliary disorders			
Liver disorder subjects affected / exposed occurrences (all)	1 / 241 (0.41%) 1		
Hyperbilirubinaemia subjects affected / exposed occurrences (all)	9 / 241 (3.73%) 9		
Cholelithiasis subjects affected / exposed occurrences (all)	1 / 241 (0.41%) 1		
Hepatomegaly subjects affected / exposed occurrences (all)	1 / 241 (0.41%) 1		
Skin and subcutaneous tissue disorders			
Dermatitis atopic subjects affected / exposed occurrences (all)	2 / 241 (0.83%) 2		
Chloasma subjects affected / exposed occurrences (all)	2 / 241 (0.83%) 2		
Urticaria subjects affected / exposed occurrences (all)	3 / 241 (1.24%) 3		
Skin ulcer			

subjects affected / exposed occurrences (all)	11 / 241 (4.56%) 14		
Seborrhoeic dermatitis subjects affected / exposed occurrences (all)	1 / 241 (0.41%) 1		
Hyperhidrosis subjects affected / exposed occurrences (all)	1 / 241 (0.41%) 1		
Eczema subjects affected / exposed occurrences (all)	1 / 241 (0.41%) 1		
Dermatitis acneiform subjects affected / exposed occurrences (all)	1 / 241 (0.41%) 1		
Rash subjects affected / exposed occurrences (all)	2 / 241 (0.83%) 2		
Pruritis subjects affected / exposed occurrences (all)	2 / 241 (0.83%) 7		
Dermatitis subjects affected / exposed occurrences (all)	1 / 241 (0.41%) 1		
Renal and urinary disorders			
Proteinuria subjects affected / exposed occurrences (all)	2 / 241 (0.83%) 2		
Acute kidney injury subjects affected / exposed occurrences (all)	4 / 241 (1.66%) 4		
Urinary retention subjects affected / exposed occurrences (all)	1 / 241 (0.41%) 1		
Renal colic subjects affected / exposed occurrences (all)	1 / 241 (0.41%) 1		

Pelvic-ureteric obstruction			
subjects affected / exposed	1 / 241 (0.41%)		
occurrences (all)	1		
Hydronephrosis			
subjects affected / exposed	1 / 241 (0.41%)		
occurrences (all)	1		
Heamaturia			
subjects affected / exposed	1 / 241 (0.41%)		
occurrences (all)	1		
Dysuria			
subjects affected / exposed	1 / 241 (0.41%)		
occurrences (all)	1		
Bladder obstruction			
subjects affected / exposed	1 / 241 (0.41%)		
occurrences (all)	1		
Urinary flow decreased			
subjects affected / exposed	1 / 241 (0.41%)		
occurrences (all)	1		
Renal injury			
subjects affected / exposed	1 / 241 (0.41%)		
occurrences (all)	1		
Musculoskeletal and connective tissue disorders			
Trigger finger			
subjects affected / exposed	1 / 241 (0.41%)		
occurrences (all)	1		
Tenosynovitis			
subjects affected / exposed	1 / 241 (0.41%)		
occurrences (all)	1		
Rotator cuff syndrome			
subjects affected / exposed	1 / 241 (0.41%)		
occurrences (all)	1		
Neck pain			
subjects affected / exposed	1 / 241 (0.41%)		
occurrences (all)	2		
Musculoskeletal pain			

subjects affected / exposed	1 / 241 (0.41%)		
occurrences (all)	1		
Groin pain			
subjects affected / exposed	1 / 241 (0.41%)		
occurrences (all)	1		
Dactylitis			
subjects affected / exposed	1 / 241 (0.41%)		
occurrences (all)	1		
Osteoarthritis			
subjects affected / exposed	2 / 241 (0.83%)		
occurrences (all)	2		
Myalgia			
subjects affected / exposed	2 / 241 (0.83%)		
occurrences (all)	2		
Musculoskeletal chest pain			
subjects affected / exposed	2 / 241 (0.83%)		
occurrences (all)	2		
Bone pain			
subjects affected / exposed	2 / 241 (0.83%)		
occurrences (all)	2		
Osteonecrosis			
subjects affected / exposed	12 / 241 (4.98%)		
occurrences (all)	16		
Back pain			
subjects affected / exposed	17 / 241 (7.05%)		
occurrences (all)	19		
Pain in extremity			
subjects affected / exposed	18 / 241 (7.47%)		
occurrences (all)	30		
Arthralgia			
subjects affected / exposed	26 / 241 (10.79%)		
occurrences (all)	33		
Infections and infestations			
Tinea versicolour			
subjects affected / exposed	3 / 241 (1.24%)		
occurrences (all)	3		

Malaria				
subjects affected / exposed	58 / 241 (24.07%)			
occurrences (all)	134			
Upper respiratory tract infection				
subjects affected / exposed	42 / 241 (17.43%)			
occurrences (all)	59			
Urinary tract infection				
subjects affected / exposed	24 / 241 (9.96%)			
occurrences (all)	31			
Tonsillitis				
subjects affected / exposed	17 / 241 (7.05%)			
occurrences (all)	19			
Gastroenteritis				
subjects affected / exposed	13 / 241 (5.39%)			
occurrences (all)	17			
Pneumonia				
subjects affected / exposed	12 / 241 (4.98%)			
occurrences (all)	14			
Pharyngitis				
subjects affected / exposed	8 / 241 (3.32%)			
occurrences (all)	8			
Nasopharyngitis				
subjects affected / exposed	6 / 241 (2.49%)			
occurrences (all)	8			
Bacterial infection				
subjects affected / exposed	5 / 241 (2.07%)			
occurrences (all)	6			
Conjunctivitis				
subjects affected / exposed	4 / 241 (1.66%)			
occurrences (all)	4			
Influenza				
subjects affected / exposed	4 / 241 (1.66%)			
occurrences (all)	4			
Osteomyelitis				
subjects affected / exposed	4 / 241 (1.66%)			
occurrences (all)	4			

Respiratory tract infection subjects affected / exposed occurrences (all)	4 / 241 (1.66%) 5			
Bacteraemia subjects affected / exposed occurrences (all)	3 / 241 (1.24%) 3			
Cellulitis subjects affected / exposed occurrences (all)	3 / 241 (1.24%) 3			
Cystitis subjects affected / exposed occurrences (all)	3 / 241 (1.24%) 3			
Infected skin ulcer subjects affected / exposed occurrences (all)	3 / 241 (1.24%) 3			
Pharyngitis streptococcal subjects affected / exposed occurrences (all)	3 / 241 (1.24%) 3			
Sepsis subjects affected / exposed occurrences (all)	3 / 241 (1.24%) 4			
Viral upper respiratory tract infection subjects affected / exposed occurrences (all)	3 / 241 (1.24%) 4			
Gingivitis subjects affected / exposed occurrences (all)	1 / 241 (0.41%) 1			
Arthritis bacterial subjects affected / exposed occurrences (all)	2 / 241 (0.83%) 2			
COVID-19 subjects affected / exposed occurrences (all)	2 / 241 (0.83%) 2			
Dengue fever subjects affected / exposed occurrences (all)	2 / 241 (0.83%) 2			

Fungal skin infection				
subjects affected / exposed	2 / 241 (0.83%)			
occurrences (all)	3			
Gastroenteritis viral				
subjects affected / exposed	2 / 241 (0.83%)			
occurrences (all)	2			
Lower respiratory tract infection				
subjects affected / exposed	2 / 241 (0.83%)			
occurrences (all)	2			
Osteomyelitis acute				
subjects affected / exposed	2 / 241 (0.83%)			
occurrences (all)	2			
Otitis media				
subjects affected / exposed	2 / 241 (0.83%)			
occurrences (all)	2			
Pharyngotonsillitis				
subjects affected / exposed	2 / 241 (0.83%)			
occurrences (all)	2			
Sinusitis				
subjects affected / exposed	2 / 241 (0.83%)			
occurrences (all)	2			
Viral infection				
subjects affected / exposed	2 / 241 (0.83%)			
occurrences (all)	2			
Abscess				
subjects affected / exposed	1 / 241 (0.41%)			
occurrences (all)	1			
Acute sinusitis				
subjects affected / exposed	1 / 241 (0.41%)			
occurrences (all)	1			
Bronchitis				
subjects affected / exposed	1 / 241 (0.41%)			
occurrences (all)	1			
Cornonavirus infection				
subjects affected / exposed	1 / 241 (0.41%)			
occurrences (all)	1			

Escherichia bacteraemia				
subjects affected / exposed	1 / 241 (0.41%)			
occurrences (all)	1			
Fungal infection				
subjects affected / exposed	1 / 241 (0.41%)			
occurrences (all)	1			
Furuncle				
subjects affected / exposed	1 / 241 (0.41%)			
occurrences (all)	1			
Gastroenteritis norovirus				
subjects affected / exposed	1 / 241 (0.41%)			
occurrences (all)	1			
Wound sepsis				
subjects affected / exposed	3 / 241 (1.24%)			
occurrences (all)	3			
Hepatitis C				
subjects affected / exposed	1 / 241 (0.41%)			
occurrences (all)	1			
Infection				
subjects affected / exposed	1 / 241 (0.41%)			
occurrences (all)	1			
Mumps				
subjects affected / exposed	1 / 241 (0.41%)			
occurrences (all)	1			
Oral bacterial infection				
subjects affected / exposed	1 / 241 (0.41%)			
occurrences (all)	1			
Osteomyelitis chronic				
subjects affected / exposed	1 / 241 (0.41%)			
occurrences (all)	1			
Otitis media acute				
subjects affected / exposed	1 / 241 (0.41%)			
occurrences (all)	1			
Parotitis				
subjects affected / exposed	1 / 241 (0.41%)			
occurrences (all)	1			

Pneumonia bacterial				
subjects affected / exposed	1 / 241 (0.41%)			
occurrences (all)	1			
Pneumonia viral				
subjects affected / exposed	1 / 241 (0.41%)			
occurrences (all)	1			
Pseudomonas infection				
subjects affected / exposed	1 / 241 (0.41%)			
occurrences (all)	1			
Pulpitis dental				
subjects affected / exposed	1 / 241 (0.41%)			
occurrences (all)	1			
Pyelonephritis				
subjects affected / exposed	1 / 241 (0.41%)			
occurrences (all)	1			
Pyoderma				
subjects affected / exposed	1 / 241 (0.41%)			
occurrences (all)	1			
Tinea cruris				
subjects affected / exposed	1 / 241 (0.41%)			
occurrences (all)	1			
Viral pharyngitis				
subjects affected / exposed	1 / 241 (0.41%)			
occurrences (all)	1			
Vulval abscess				
subjects affected / exposed	1 / 241 (0.41%)			
occurrences (all)	1			
Vulvitis				
subjects affected / exposed	1 / 241 (0.41%)			
occurrences (all)	1			
Wound infection				
subjects affected / exposed	1 / 241 (0.41%)			
occurrences (all)	1			
Herpes simplex				
subjects affected / exposed	1 / 241 (0.41%)			
occurrences (all)	1			

Metabolism and nutrition disorders			
Iron deficiency			
subjects affected / exposed	1 / 241 (0.41%)		
occurrences (all)	1		
Decreased appetite			
subjects affected / exposed	1 / 241 (0.41%)		
occurrences (all)	1		
Iron overload			
subjects affected / exposed	2 / 241 (0.83%)		
occurrences (all)	2		
Hypomagnesaemia			
subjects affected / exposed	2 / 241 (0.83%)		
occurrences (all)	2		
Hyperkalaemia			
subjects affected / exposed	3 / 241 (1.24%)		
occurrences (all)	3		
Hypokalaemia			
subjects affected / exposed	4 / 241 (1.66%)		
occurrences (all)	4		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
11 April 2022	Amendment 1: 1) Updated exploratory endpoints of Patient Global Impression of Change (PGI-C) and Clinician Global Impression of Change (CGI-C) ratings from "moderately improved" to "much improved". 2) Added description of Phase 1 study results. 3) Removed references to early termination globally. 4) Clarified rules for management of infusion-related reactions. 5) Editing changes made for clarity. 6) Added timepoints for pharmacodynamic (PD) collection in body. 7) Removed section on 'Continuation of Treatment'.
30 January 2023	Amendment 2: Added a safety assessment (ECG) and an exploratory efficacy assessment (EQ-5D-5L) as well as a few corrections and clarifications.
13 July 2023	Amendment 3: Aligned with Pfizer Protocol Template following the acquisition of GBT by Pfizer.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported