Clinical trial results:
An open label, multi-center imatinib roll-over protocol for patients who have completed a previous Novartis-sponsored imatinib study and are judged by the investigator to benefit from continued imatinib treatment

Summary

EudraCT number	2012-002540-25
Trial protocol	FI GB FR
Global end of trial date	20 April 2026

Results information

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

Trial information

Trial identification

Sponsor protocol code	CSTI571A2406

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01742299
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Novartis Pharma AG
Sponsor organisation address	Lichtstrasse 35, Basel, Switzerland, 4056
Public contact	Clinical Disclosure Office, Novartis Pharma AG, 41 613241111, novartis.email@novartis.com
Scientific contact	Clinical Disclosure Office, Novartis Pharma AG, 41 613241111, novartis.email@novartis.com

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	No
Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	No
Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	No

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	20 April 2026
Is this the analysis of the primary completion data?	Yes
Primary completion date	20 April 2026
Global end of trial reached?	Yes
Global end of trial date	20 April 2026
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The main objective of the trial was to assess the long-term safety of imatinib in patients who had completed a previous Novartis-sponsored imatinib study and were deemed by the investigator to continue benefiting from treatment.

Protection of trial subjects:

The study was in compliance with the ethical principles derived from the Declaration of Helsinki and the International Conference on Harmonization (ICH) Good Clinical Practice (GCP) guidelines. All the local regulatory requirements pertinent to safety of trial subjects were also followed during the conduct of the trial.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	26 March 2013
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	China: 30
Country: Number of subjects enrolled	Finland: 1
Country: Number of subjects enrolled	France: 6
Country: Number of subjects enrolled	Hong Kong: 2
Country: Number of subjects enrolled	Romania: 3
Country: Number of subjects enrolled	Singapore: 6
Country: Number of subjects enrolled	Switzerland: 1
Country: Number of subjects enrolled	Thailand: 2
Country: Number of subjects enrolled	Türkiye: 2
Country: Number of subjects enrolled	United Kingdom: 2
Country: Number of subjects enrolled	United States: 100
Worldwide total number of subjects	155
EEA total number of subjects	10

Notes:

Subjects enrolled per age group

In utero	0

Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	63
From 65 to 84 years	89
85 years and over	3

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

The study was conducted globally across 11 countries: China, Finland, France, Hong Kong, Romania, Singapore, Switzerland, Thailand, Turkey, United Kingdom, and USA.

Period 1

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

Arms

Arm title	imatinib mesylate

Arm description:

Participants who completed a previous Novartis-sponsored imatinib study and continue to derive clinical benefit receive imatinib therapy.

Arm type	Experimental
Investigational medicinal product name	Imatinib
Investigational medicinal product code	
Other name	STI571
Pharmaceutical forms	Film-coated tablet, Tablet, Oral solution
Routes of administration	Oral use

Dosage and administration details:

Imatinib was administered orally at a total daily dose ranging from 100 to 800 milligrams. The starting dose was the same as the dose received in the parent study and could subsequently be adjusted based on the investigator's clinical judgment. Imatinib was supplied as 100 milligram and 400 milligram tablets and was administered once daily or, for patients receiving 800 milligrams daily, as 400 milligrams twice daily.

Number of subjects in period 1	imatinib mesylate
Started	155
Completed	25
Not completed	130
Adverse event, serious fatal	23
Physician decision	27
Consent withdrawn by subject	20
Adverse event, non-fatal	16
Technical Problems	2
Subject/Guardian Decision	16
Lost to follow-up	5
Disease Progression	20
Protocol deviation	1

Baseline characteristics

Reporting groups	
Reporting group title	imatinib mesylate
Reporting group description:	
Participants who completed a previous Novartis-sponsored imatinib study and continue to derive clinical benefit receive imatinib therapy.	

Reporting group values	imatinib mesylate	Total	
Number of subjects	155	155	
Age categorical Units: Subjects			
In utero	0	0	
Preterm newborn infants (gestational age < 37 wks)	0	0	
Newborns (0-27 days)	0	0	
Infants and toddlers (28 days-23 months)	0	0	
Children (2-11 years)	0	0	
Adolescents (12-17 years)	0	0	
Adults (18-64 years)	63	63	
From 65-84 years	89	89	
85 years and over	3	3	
Age Continuous Units: Years			
arithmetic mean	64.3		
standard deviation	± 13.07	-	
Sex: Female, Male Units: Participants			
Female	63	63	
Male	92	92	

End points

End points reporting groups

Reporting group title	imatinib mesylate

Reporting group description:

Participants who completed a previous Novartis-sponsored imatinib study and continue to derive clinical benefit receive imatinib therapy.

Primary: Frequency and Severity of Adverse Events (AEs) and Serious Adverse Events (SAEs)

End point title	Frequency and Severity of Adverse Events (AEs) and Serious Adverse Events (SAEs)[1]

End point description:

Long-term safety was evaluated by assessing the frequency and severity of adverse events and serious adverse events occurring during the study.

End point type	Primary

End point timeframe:

From first dose of study treatment through 30 days after the last dose of imatinib (up to approximately 157 months)

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: Descriptive statistics performed

End point values	imatinib mesylate			
Subject group type	Reporting group			
Number of subjects analysed	155			
Units: Participants				
All deaths	27			
On treatment deaths	19			
Adverse Events (AEs) - all grades	88			
Treatment-related Adverse events - all grades	47			
Serious Adverse Events (SAEs) - all grades	48			
Dose discontinuation AEs - all grades	21			
Dose adjustment/interruption AEs - all grades	50			

Statistical analyses

No statistical analyses for this end point

Secondary: Proportion of Participants With Clinical Benefit as Assessed by the Investigator

End point title	Proportion of Participants With Clinical Benefit as Assessed by the Investigator

End point description:

Clinical benefit was assessed by the investigator at scheduled visits, and the proportion of patients who continued to derive clinical benefit from imatinib treatment was summarized throughout the study. At each assessment, the investigator confirmed whether the patient continued to have clinical benefit and could remain on treatment.

End point type	Secondary

End point timeframe:

Up to approximately 157 months

End point values	imatinib mesylate			
Subject group type	Reporting group			
Number of subjects analysed	155			
Units: Participants				
Week 24	7			
Week 48	49			
Week 72	8			
Week 96	41			
Year 3	77			
Year 4	74			
Year 5	66			
Year 6	63			
Year 7	56			
Year 8	50			
Year 9	47			
Year 10	42			
Year 11	35			
Year 12	22			
Year 13	18			
Year 14	6			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Adverse events were collected from the first dose of study treatment through 30 days after the last dose of imatinib (up to approximately 157 months).

Adverse event reporting additional description:

Consistent with EudraCT disclosure specifications, Novartis has reported under the Serious adverse events field "number of deaths resulting from adverse events" all those deaths, resulting from serious adverse events that are deemed to be causally related to treatment by the investigator.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	29.0

Reporting groups

Reporting group title	All Patients

Reporting group description:

All Patients

Serious adverse events	All Patients		
Total subjects affected by serious adverse events			
subjects affected / exposed	58 / 155 (37.42%)		
number of deaths (all causes)	27		
number of deaths resulting from adverse events	0		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Bladder cancer			
subjects affected / exposed	1 / 155 (0.65%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Myelodysplastic syndrome			
subjects affected / exposed	2 / 155 (1.29%)		
occurrences causally related to treatment / all	1 / 2		
deaths causally related to treatment / all	0 / 0		
Metastasis			
subjects affected / exposed	1 / 155 (0.65%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Metastases to bone			

subjects affected / exposed	1 / 155 (0.65%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Malignant neoplasm of renal pelvis				
subjects affected / exposed	1 / 155 (0.65%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Invasive ductal breast carcinoma				
subjects affected / exposed	1 / 155 (0.65%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Colon cancer				
subjects affected / exposed	2 / 155 (1.29%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Neoplasm prostate				
subjects affected / exposed	1 / 155 (0.65%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Squamous cell carcinoma of the tongue				
subjects affected / exposed	1 / 155 (0.65%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Second primary malignancy				
subjects affected / exposed	4 / 155 (2.58%)			
occurrences causally related to treatment / all	0 / 4			
deaths causally related to treatment / all	0 / 0			
Prostate cancer recurrent				
subjects affected / exposed	1 / 155 (0.65%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 1			
Vascular disorders				
Hypotension				

subjects affected / exposed	1 / 155 (0.65%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Hypertension				
subjects affected / exposed	2 / 155 (1.29%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Peripheral ischaemia				
subjects affected / exposed	1 / 155 (0.65%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Orthostatic hypotension				
subjects affected / exposed	1 / 155 (0.65%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Venous thrombosis				
subjects affected / exposed	1 / 155 (0.65%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
General disorders and administration site conditions				
Chest pain				
subjects affected / exposed	1 / 155 (0.65%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Influenza like illness				
subjects affected / exposed	1 / 155 (0.65%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Death				
subjects affected / exposed	3 / 155 (1.94%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 3			
Non-cardiac chest pain				

subjects affected / exposed	2 / 155 (1.29%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Sudden death			
subjects affected / exposed	1 / 155 (0.65%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Oedema peripheral			
subjects affected / exposed	1 / 155 (0.65%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Oedema			
subjects affected / exposed	1 / 155 (0.65%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Respiratory, thoracic and mediastinal disorders			
Dyspnoea			
subjects affected / exposed	2 / 155 (1.29%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Dyspnoea exertional			
subjects affected / exposed	1 / 155 (0.65%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Idiopathic pulmonary fibrosis			
subjects affected / exposed	1 / 155 (0.65%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Pulmonary embolism			
subjects affected / exposed	1 / 155 (0.65%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Psychiatric disorders			

Depression				
subjects affected / exposed	1 / 155 (0.65%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Mental status changes				
subjects affected / exposed	2 / 155 (1.29%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Investigations				
Blood creatinine increased				
subjects affected / exposed	1 / 155 (0.65%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Injury, poisoning and procedural complications				
Bone contusion				
subjects affected / exposed	1 / 155 (0.65%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Compression fracture				
subjects affected / exposed	1 / 155 (0.65%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Fall				
subjects affected / exposed	2 / 155 (1.29%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Hip fracture				
subjects affected / exposed	6 / 155 (3.87%)			
occurrences causally related to treatment / all	0 / 6			
deaths causally related to treatment / all	0 / 0			
Injury				
subjects affected / exposed	1 / 155 (0.65%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			

Lumbar vertebral fracture				
subjects affected / exposed	1 / 155 (0.65%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Poisoning				
subjects affected / exposed	1 / 155 (0.65%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Post procedural complication				
subjects affected / exposed	1 / 155 (0.65%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 1			
Procedural complication				
subjects affected / exposed	1 / 155 (0.65%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Procedural pain				
subjects affected / exposed	1 / 155 (0.65%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Rib fracture				
subjects affected / exposed	1 / 155 (0.65%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Spinal fracture				
subjects affected / exposed	2 / 155 (1.29%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Cardiac disorders				
Acute myocardial infarction				
subjects affected / exposed	2 / 155 (1.29%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 1			
Angina pectoris				

subjects affected / exposed	1 / 155 (0.65%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Cardiac failure				
subjects affected / exposed	2 / 155 (1.29%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 1			
Cardiac failure congestive				
subjects affected / exposed	4 / 155 (2.58%)			
occurrences causally related to treatment / all	0 / 4			
deaths causally related to treatment / all	0 / 0			
Cardiac arrest				
subjects affected / exposed	1 / 155 (0.65%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 1			
Cardiomyopathy				
subjects affected / exposed	1 / 155 (0.65%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Atrial fibrillation				
subjects affected / exposed	3 / 155 (1.94%)			
occurrences causally related to treatment / all	0 / 4			
deaths causally related to treatment / all	0 / 0			
Atrioventricular block complete				
subjects affected / exposed	1 / 155 (0.65%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
Myocardial infarction				
subjects affected / exposed	3 / 155 (1.94%)			
occurrences causally related to treatment / all	1 / 3			
deaths causally related to treatment / all	0 / 2			
Sinus bradycardia				

subjects affected / exposed	1 / 155 (0.65%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Nervous system disorders			
Cerebrovascular accident			
subjects affected / exposed	2 / 155 (1.29%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Cerebral infarction			
subjects affected / exposed	1 / 155 (0.65%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Amnesia			
subjects affected / exposed	1 / 155 (0.65%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Headache			
subjects affected / exposed	1 / 155 (0.65%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Lumbar radiculopathy			
subjects affected / exposed	1 / 155 (0.65%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Myelitis transverse			
subjects affected / exposed	1 / 155 (0.65%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Parkinson's disease			
subjects affected / exposed	1 / 155 (0.65%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Primary progressive aphasia			

subjects affected / exposed	1 / 155 (0.65%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Vertebrobasilar insufficiency				
subjects affected / exposed	1 / 155 (0.65%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Syncope				
subjects affected / exposed	2 / 155 (1.29%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Blood and lymphatic system disorders				
Anaemia				
subjects affected / exposed	4 / 155 (2.58%)			
occurrences causally related to treatment / all	0 / 5			
deaths causally related to treatment / all	0 / 0			
Gastrointestinal disorders				
Diarrhoea				
subjects affected / exposed	1 / 155 (0.65%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Colitis				
subjects affected / exposed	1 / 155 (0.65%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Abdominal pain				
subjects affected / exposed	1 / 155 (0.65%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Abdominal distension				
subjects affected / exposed	1 / 155 (0.65%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Small intestinal obstruction				

subjects affected / exposed	2 / 155 (1.29%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Melaena			
subjects affected / exposed	1 / 155 (0.65%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal haemorrhage			
subjects affected / exposed	3 / 155 (1.94%)		
occurrences causally related to treatment / all	1 / 3		
deaths causally related to treatment / all	0 / 0		
Upper gastrointestinal haemorrhage			
subjects affected / exposed	1 / 155 (0.65%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Hepatobiliary disorders			
Acute hepatic failure			
subjects affected / exposed	1 / 155 (0.65%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Skin and subcutaneous tissue disorders			
Decubitus ulcer			
subjects affected / exposed	1 / 155 (0.65%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Rash			
subjects affected / exposed	1 / 155 (0.65%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Renal and urinary disorders			
Haematuria			
subjects affected / exposed	1 / 155 (0.65%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		

Acute kidney injury				
subjects affected / exposed	2 / 155 (1.29%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 1			
Renal failure				
subjects affected / exposed	1 / 155 (0.65%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Renal haemorrhage				
subjects affected / exposed	1 / 155 (0.65%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Musculoskeletal and connective tissue disorders				
Arthralgia				
subjects affected / exposed	1 / 155 (0.65%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Osteoarthritis				
subjects affected / exposed	1 / 155 (0.65%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Arthritis				
subjects affected / exposed	1 / 155 (0.65%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Infections and infestations				
Appendicitis				
subjects affected / exposed	1 / 155 (0.65%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Acinetobacter infection				
subjects affected / exposed	1 / 155 (0.65%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			

Pneumonia			
subjects affected / exposed	13 / 155 (8.39%)		
occurrences causally related to treatment / all	0 / 18		
deaths causally related to treatment / all	0 / 5		
Meningitis			
subjects affected / exposed	1 / 155 (0.65%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Infection			
subjects affected / exposed	3 / 155 (1.94%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 1		
Gastroenteritis			
subjects affected / exposed	1 / 155 (0.65%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Endocarditis			
subjects affected / exposed	1 / 155 (0.65%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
COVID-19			
subjects affected / exposed	2 / 155 (1.29%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Bronchitis viral			
subjects affected / exposed	1 / 155 (0.65%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Bronchitis			
subjects affected / exposed	1 / 155 (0.65%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Sepsis			

subjects affected / exposed	3 / 155 (1.94%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 0			
Septic shock				
subjects affected / exposed	2 / 155 (1.29%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 1			
Urinary tract infection				
subjects affected / exposed	4 / 155 (2.58%)			
occurrences causally related to treatment / all	0 / 4			
deaths causally related to treatment / all	0 / 0			
Respiratory syncytial virus infection				
subjects affected / exposed	1 / 155 (0.65%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Pneumonia fungal				
subjects affected / exposed	1 / 155 (0.65%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Metabolism and nutrition disorders				
Hypoproteinaemia				
subjects affected / exposed	1 / 155 (0.65%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Dehydration				
subjects affected / exposed	3 / 155 (1.94%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 0			
Hyperkalaemia				
subjects affected / exposed	1 / 155 (0.65%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Hypokalaemia				

subjects affected / exposed	1 / 155 (0.65%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		

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

Non-serious adverse events	All Patients		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	53 / 155 (34.19%)		
Investigations			
Blood creatinine increased			
subjects affected / exposed	17 / 155 (10.97%)		
occurrences (all)	22		
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	11 / 155 (7.10%)		
occurrences (all)	15		
General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	8 / 155 (5.16%)		
occurrences (all)	10		
Oedema peripheral			
subjects affected / exposed	8 / 155 (5.16%)		
occurrences (all)	9		
Eye disorders			
Periorbital oedema			
subjects affected / exposed	8 / 155 (5.16%)		
occurrences (all)	8		
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	11 / 155 (7.10%)		
occurrences (all)	13		
Nausea			
subjects affected / exposed	12 / 155 (7.74%)		
occurrences (all)	14		
Musculoskeletal and connective tissue disorders			

Arthralgia subjects affected / exposed occurrences (all) Back pain subjects affected / exposed occurrences (all) Muscle spasms subjects affected / exposed occurrences (all) Myalgia subjects affected / exposed occurrences (all)	9 / 155 (5.81%) 11 11 / 155 (7.10%) 15 9 / 155 (5.81%) 10 10 / 155 (6.45%) 11		
Infections and infestations COVID-19 subjects affected / exposed occurrences (all)	9 / 155 (5.81%) 9		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
07 April 2016	Amendment 01: • Changed primary objective to long-term safety evaluation of imatinib. • Added hepatitis B virus testing due to risk of reactivation with BCR::ABL TKIs. • Added collection of all AEs and requirement for investigator confirmation of ongoing clinical benefit. • Updated safety-related sections (AE/SAE collection, liver injury follow-up, hepatitis B procedures). • Updated contraception requirements and pregnancy testing, including monthly home tests for women of childbearing potential. • Added dose-modification guidance, concomitant medication section, and template-required updates. • Updated statistical analysis, objectives, medical history collection, and eCRF requirements. • Informed Consent impacted; IRB/IEC approval required.
04 August 2017	Amendment 02: • Corrected language related to male contraception and pregnancy outcome collection; male participants are not required to use contraception, and pregnancy outcomes from female partners will not be collected. • Updated the reference safety information for Glivec® (imatinib) by discontinuing use of the Investigator's Brochure and adopting the latest approved national/regional product label as the reference safety information (RSI). • Updated protocol visit requirements to allow on-site or remote visits at the investigator's discretion, addressing concerns regarding increased visit frequency and alignment with current NCCN recommendations. • Updated safety- and reference-related sections throughout the protocol to remove references to the Investigator's Brochure and align with the approved product label.
08 April 2019	Amendment 03: • Clarified end-of-study definition and study duration following completion of recruitment (155 enrolled; 71 ongoing at that time) • Updated Sections 4.1 and 4.3 to define end of study as completion of last protocol-required assessment including safety follow-up • Updated premature withdrawal criteria and terminology (Subject Patient). • Updated glossary, consent withdrawal language. • Included several template-driven updates across Sections 4–7. • Aligned early termination.

07 November 2019	Amendment 04: •Clarified long-term study duration to ensure patients may continue receiving treatment as long as they have clinical benefit, including a 20-year treatment window from FPFV with possible 5-year extensions or until such time that all enrolled patients no longer need treatment with imatinib, whichever comes earlier. • Removed all statements requiring discontinuation once treatment becomes commercially available and reimbursed. • Corrected study codes in the Risk and Benefits section. • Clarified the definition of end of study to allow continued treatment based on clinical benefit. • Removed references to a review board, as none exists for this study. • Updated the definition of highly effective contraception to include total hysterectomy and revised “tubal ligation” to “bilateral tubal ligation.”
03 February 2025	Amendment 05: • Provided clarity on study closeout in view of the broad commercial availability of the study medication, as well as the very well established safety profile.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported