Clinical trial results:
A Phase 2, Randomized, Double-Blind, Placebo-Controlled Study to Evaluate Safety, Tolerability, and Efficacy of TAK-079 in Patients With Persistent/Chronic Primary Immune Thrombocytopenia

Summary

EudraCT number	2019-004103-12
Trial protocol	DE SI BG HR IT ES GR
Global end of trial date	29 April 2024

Results information

Result version number	v1 (current)
This version publication date	09 May 2025
First version publication date	09 May 2025

Trial information

Trial identification

Sponsor protocol code	TAK-079-1004

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT04278924
WHO universal trial number (UTN)	U1111-1245-3760

Notes:

Sponsors

Sponsor organisation name	Takeda
Sponsor organisation address	95 Hayden Avenue, Lexington, MA, United States, 02421
Public contact	Study Director, Takeda, TrialDisclosures@takeda.com
Scientific contact	Study Director, Takeda, TrialDisclosures@takeda.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	29 April 2024
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	29 April 2024
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The main objective of this trial was to evaluate the safety and tolerability of TAK-079 in participants with persistent/chronic primary immune thrombocytopenia (ITP).

Protection of trial subjects:

All study participants were required to read and sign an informed consent form (ICF).

Background therapy:

NA

Evidence for comparator:

NA

Actual start date of recruitment	09 November 2020
Long term follow-up planned	Yes
Long term follow-up rationale	Safety, Efficacy
Long term follow-up duration	4 Months
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Bulgaria: 12
Country: Number of subjects enrolled	China: 2
Country: Number of subjects enrolled	Croatia: 3
Country: Number of subjects enrolled	Greece: 4
Country: Number of subjects enrolled	Italy: 8
Country: Number of subjects enrolled	Japan: 1
Country: Number of subjects enrolled	Slovenia: 3
Country: Number of subjects enrolled	Spain: 4
Country: Number of subjects enrolled	Ukraine: 4
Worldwide total number of subjects	41
EEA total number of subjects	34

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37	0

wk	
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)	36
From 65 to 84 years	4
85 years and over	1

Subject disposition

Recruitment

Recruitment details:

Participants took part in the study at 24 investigative sites globally from 09 November 2020 to 29 April 2024.

Pre-assignment

Screening details:

Participants who had persistent/chronic primary immune thrombocytopenia (ITP) were randomized to receive either mezagitamab (TAK-079) or matching placebo in Part A or Part B of this study.

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	Part A & B: Double Blind Period: Placebo

Arm description:

Participants received TAK-079 placebo-matching injection SC, QW for 8 weeks. Following treatment participants were followed up for 8 weeks in a double blinded SFP up to Week 16. Placebo-assigned participants who did not opt to receive treatment with TAK-079 were followed up for another 16 weeks in an unblinded LFP up to Week 32.

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

Dosage and administration details:

Participants received TAK-079 placebo-matching injection SC, QW for 8 weeks. Following treatment participants were followed up for 8 weeks in a double blinded SFP up to Week 16. Placebo-assigned participants who did not opt to receive treatment with TAK-079 were followed up for another 16 weeks in an unblinded LFP up to Week 32.

Arm title	Part A: Double Blind Period: TAK-079 100 mg

Arm description:

Participants received TAK-079 100 mg, SC injection, QW for 8 weeks. Following treatment participants were followed up for 8 weeks in a double blinded SFP up to Week 16. Participants were then followed up for another 16 weeks in an unblinded LFP up to Week 32.

Arm type	Experimental
Investigational medicinal product name	TAK-079
Investigational medicinal product code	TAK-079
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Participants received TAK-079 100 mg, SC injection, QW for 8 weeks. Following treatment participants were followed up for 8 weeks in a double blinded SFP up to Week 16. Participants were then followed up for another 16 weeks in an unblinded LFP up to Week 32.

Arm title	Part A: Double Blind Period: TAK-079 300 mg

Arm description:

Participants received TAK-079 300 mg, SC injection, QW for 8 weeks. Following treatment participants were followed up for 8 weeks in a double blinded SFP up to Week 16. Participants were then followed up for another 16 weeks in an unblinded LFP up to Week 32.

Arm type	Experimental
Investigational medicinal product name	TAK-079
Investigational medicinal product code	TAK-079
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Participants received TAK-079 300 mg, SC injection, QW for 8 weeks. Following treatment participants were followed up for 8 weeks in a double blinded SFP up to Week 16. Participants were then followed up for another 16 weeks in an unblinded LFP up to Week 32.

Arm title	Part B: Double Blind Period: TAK-079 600 mg

Arm description:

Participants received TAK-079 600 mg, SC injection, QW for 8 weeks. Following treatment participants were followed up for 8 weeks in a double blinded SFP up to Week 16. Participants were then followed up for another 16 weeks in an unblinded LFP up to Week 32.

Arm type	Experimental
Investigational medicinal product name	TAK-079
Investigational medicinal product code	TAK-079
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Participants received TAK-079 600 mg, SC injection, QW for 8 weeks. Following treatment participants were followed up for 8 weeks in a double blinded SFP up to Week 16. Participants were then followed up for another 16 weeks in an unblinded LFP up to Week 32.

Number of subjects in period 1	Part A & B: Double Blind Period: Placebo	Part A: Double Blind Period: TAK-079 100 mg	Part A: Double Blind Period: TAK-079 300 mg
Started	13	9	8
Completed	12	7	8
Not completed	1	2	0
Consent withdrawn by subject	1	1	-
Reason Not Specified	-	1	-

Number of subjects in period 1	Part B: Double Blind Period: TAK-079 600 mg
Started	11
Completed	9
Not completed	2
Consent withdrawn by subject	2
Reason Not Specified	-

Period 2

Period 2 title	Open-label Extension Period
Is this the baseline period?	No
Allocation method	Non-randomised - controlled
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	Part A: Open-label Extension (OLE) Period: TAK-079 100 mg

Arm description:

Participants who received placebo in double-blind Part A and opted to receive treatment with TAK-079 were randomized to receive TAK-079 100 mg, SC injection, QW for 8 weeks in OLE Period of Part A. Following treatment participants were followed up for 8 weeks in a SFP and then for another 16 weeks in a LFP.

Arm type	Experimental
Investigational medicinal product name	TAK-079
Investigational medicinal product code	TAK-079
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Participants who received placebo in double-blind Part A and opted to receive treatment with TAK-079 were randomized to receive TAK-079 100 mg, SC injection, QW for 8 weeks in OLE Period of Part A. Following treatment participants were followed up for 8 weeks in a SFP and then for another 16 weeks in a LFP.

Arm title	Part A: OLE Period: TAK-079 300 mg

Arm description:

Participants who received placebo in double-blind Part A and opted to receive treatment with TAK-079 were randomized to receive TAK-079 300 mg, SC injection, QW for 8 weeks in OLE Period of Part A. Following treatment participants were followed up for 8 weeks in a SFP and then for another 16 weeks in a LFP.

Arm type	Experimental
Investigational medicinal product name	TAK-079
Investigational medicinal product code	TAK-079
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Participants who received placebo in double-blind Part A and opted to receive treatment with TAK-079 were randomized to receive TAK-079 300 mg, SC injection, QW for 8 weeks in OLE Period of Part A. Following treatment participants were followed up for 8 weeks in a SFP and then for another 16 weeks in a LFP.

Arm title	Part B: OLE Period: TAK-079 600 mg

Arm description:

Participants who received placebo in double-blind Part B and opted to receive treatment with TAK-079 received TAK-079 600 mg, SC injection, QW for 8 weeks in OLE Period of Part B. Following treatment participants were followed up for 8 weeks in a SFP and then for another 16 weeks in a LFP.

Arm type	Experimental

Investigational medicinal product name	TAK-079
Investigational medicinal product code	TAK-079
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Participants who received placebo in double-blind Part B and opted to receive treatment with TAK-079 received TAK-079 600 mg, SC injection, QW for 8 weeks in OLE Period of Part B. Following treatment participants were followed up for 8 weeks in a SFP and then for another 16 weeks in a LFP.

Number of subjects in period 2[1]	Part A: Open-label Extension (OLE) Period: TAK-079 100 mg	Part A: OLE Period: TAK-079 300 mg	Part B: OLE Period: TAK-079 600 mg
Started	4	4	4
Completed	4	4	4

Notes:

[1] - The number of subjects starting the period is not consistent with the number completing the preceding period. It is expected the number of subjects starting the subsequent period will be the same as the number completing the preceding period.

Justification: Only participants who received placebo in double-blind Part A and opted to receive treatment with TAK-079 were randomized to receive TAK-079 in Open-label Extension (OLE) Period.

Baseline characteristics

Reporting groups	
Reporting group title	Part A & B: Double Blind Period: Placebo
Reporting group description:	
Participants received TAK-079 placebo-matching injection SC, QW for 8 weeks. Following treatment participants were followed up for 8 weeks in a double blinded SFP up to Week 16. Placebo-assigned participants who did not opt to receive treatment with TAK-079 were followed up for another 16 weeks in an unblinded LFP up to Week 32.	
Reporting group title	Part A: Double Blind Period: TAK-079 100 mg
Reporting group description:	
Participants received TAK-079 100 mg, SC injection, QW for 8 weeks. Following treatment participants were followed up for 8 weeks in a double blinded SFP up to Week 16. Participants were then followed up for another 16 weeks in an unblinded LFP up to Week 32.	
Reporting group title	Part A: Double Blind Period: TAK-079 300 mg
Reporting group description:	
Participants received TAK-079 300 mg, SC injection, QW for 8 weeks. Following treatment participants were followed up for 8 weeks in a double blinded SFP up to Week 16. Participants were then followed up for another 16 weeks in an unblinded LFP up to Week 32.	
Reporting group title	Part B: Double Blind Period: TAK-079 600 mg
Reporting group description:	
Participants received TAK-079 600 mg, SC injection, QW for 8 weeks. Following treatment participants were followed up for 8 weeks in a double blinded SFP up to Week 16. Participants were then followed up for another 16 weeks in an unblinded LFP up to Week 32.	

Reporting group values	Part A & B: Double Blind Period: Placebo	Part A: Double Blind Period: TAK-079 100 mg	Part A: Double Blind Period: TAK-079 300 mg
Number of subjects	13	9	8
Age Categorical Units: Subjects			
Age continuous Units: years			
arithmetic mean	38.8	49.0	52.3
standard deviation	± 15.86	± 14.45	± 16.59
Gender categorical Units: Subjects			
Female	9	5	5
Male	4	4	3
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	1	0	0
Not Hispanic or Latino	12	9	8
Unknown or Not Reported	0	0	0
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	1	0	0
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	0	0	0
White	11	9	8

More than one race	0	0	0
Unknown or Not Reported	1	0	0

Reporting group values	Part B: Double Blind Period: TAK-079 600 mg	Total	
Number of subjects	11	41	
Age Categorical Units: Subjects			
Age continuous Units: years			
arithmetic mean	48.4		
standard deviation	± 19.68	-	
Gender categorical Units: Subjects			
Female	9	28	
Male	2	13	
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	0	1	
Not Hispanic or Latino	9	38	
Unknown or Not Reported	2	2	
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	0	0	
Asian	2	3	
Native Hawaiian or Other Pacific Islander	0	0	
Black or African American	0	0	
White	9	37	
More than one race	0	0	
Unknown or Not Reported	0	1	

End points

End points reporting groups

Reporting group title	Part A & B: Double Blind Period: Placebo
Reporting group description:	
Participants received TAK-079 placebo-matching injection SC, QW for 8 weeks. Following treatment participants were followed up for 8 weeks in a double blinded SFP up to Week 16. Placebo-assigned participants who did not opt to receive treatment with TAK-079 were followed up for another 16 weeks in an unblinded LFP up to Week 32.	
Reporting group title	Part A: Double Blind Period: TAK-079 100 mg
Reporting group description:	
Participants received TAK-079 100 mg, SC injection, QW for 8 weeks. Following treatment participants were followed up for 8 weeks in a double blinded SFP up to Week 16. Participants were then followed up for another 16 weeks in an unblinded LFP up to Week 32.	
Reporting group title	Part A: Double Blind Period: TAK-079 300 mg
Reporting group description:	
Participants received TAK-079 300 mg, SC injection, QW for 8 weeks. Following treatment participants were followed up for 8 weeks in a double blinded SFP up to Week 16. Participants were then followed up for another 16 weeks in an unblinded LFP up to Week 32.	
Reporting group title	Part B: Double Blind Period: TAK-079 600 mg
Reporting group description:	
Participants received TAK-079 600 mg, SC injection, QW for 8 weeks. Following treatment participants were followed up for 8 weeks in a double blinded SFP up to Week 16. Participants were then followed up for another 16 weeks in an unblinded LFP up to Week 32.	
Reporting group title	Part A: Open-label Extension (OLE) Period: TAK-079 100 mg
Reporting group description:	
Participants who received placebo in double-blind Part A and opted to receive treatment with TAK-079 were randomized to receive TAK-079 100 mg, SC injection, QW for 8 weeks in OLE Period of Part A. Following treatment participants were followed up for 8 weeks in a SFP and then for another 16 weeks in a LFP.	
Reporting group title	Part A: OLE Period: TAK-079 300 mg
Reporting group description:	
Participants who received placebo in double-blind Part A and opted to receive treatment with TAK-079 were randomized to receive TAK-079 300 mg, SC injection, QW for 8 weeks in OLE Period of Part A. Following treatment participants were followed up for 8 weeks in a SFP and then for another 16 weeks in a LFP.	
Reporting group title	Part B: OLE Period: TAK-079 600 mg
Reporting group description:	
Participants who received placebo in double-blind Part B and opted to receive treatment with TAK-079 received TAK-079 600 mg, SC injection, QW for 8 weeks in OLE Period of Part B. Following treatment participants were followed up for 8 weeks in a SFP and then for another 16 weeks in a LFP.	

Primary: Percentage of Participants with at Least One Grade 3 or Higher Treatment Emergent Adverse Event (TEAE), Treatment Emergent Serious Adverse Event (SAE), and TEAEs Leading to TAK-079 Discontinuation

End point title	Percentage of Participants with at Least One Grade 3 or Higher Treatment Emergent Adverse Event (TEAE), Treatment Emergent Serious Adverse Event (SAE), and TEAEs Leading to TAK-079 Discontinuation[1]
End point description:	
An adverse event (AE) was defined as any untoward medical occurrence in a participant administered a pharmaceutical product; the untoward medical occurrence does not necessarily have a causal relationship with the treatment. SAE means any untoward medical occurrence that at any dose: a) results in death; b) is life-threatening; c) requires inpatient hospitalization or prolongation of an existing hospitalization; d) results in persistent or significant disability or incapacity; e) is a congenital anomaly/birth defect; f) is a medically important event. TEAEs were defined as an AE having a start	

date and time equal to or later than the start date and time of the first dose of investigational medicinal product (IMP). Percentages were rounded off to the nearest single decimal place.

End point type	Primary

End point timeframe:

Up to Week 32 in each Period of the study

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: Only descriptive analyses were planned for this endpoint.

End point values	Part A & B: Double Blind Period: Placebo	Part A: Open-label Extension (OLE) Period: TAK-079 100 mg	Part A: Double Blind Period: TAK-079 100 mg	Part A: OLE Period: TAK-079 300 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	13	4	9	4
Units: percentage of participants				
number (not applicable)				
Grade 3 or Higher TEAE	23.1	0	22.2	0
Treatment Emergent SAE	7.7	25.0	22.2	0
TEAEs Leading to TAK-079 Discontinuation	0	25.0	22.2	0

End point values	Part A: Double Blind Period: TAK-079 300 mg	Part B: OLE Period: TAK-079 600 mg	Part B: Double Blind Period: TAK-079 600 mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	8	4	11	
Units: percentage of participants				
number (not applicable)				
Grade 3 or Higher TEAE	0	25.0	27.3	
Treatment Emergent SAE	0	0	18.2	
TEAEs Leading to TAK-079 Discontinuation	0	0	18.2	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants with Platelet Response at Weeks 16 and 32

End point title	Percentage of Participants with Platelet Response at Weeks 16 and 32

End point description:

Platelet response is defined as a platelet count ≥50,000/microliter (µL) and ≥20,000/µL above baseline on at least 2 visits without a dosing period-permitted rescue treatment in the previous 4 weeks and without any other previous rescue therapy. Percentages were rounded off to the nearest single decimal place.

End point type	Secondary

End point timeframe:
At Weeks 16 and 32

End point values	Part A & B: Double Blind Period: Placebo	Part A: Open-label Extension (OLE) Period: TAK-079 100 mg	Part A: Double Blind Period: TAK-079 100 mg	Part A: OLE Period: TAK-079 300 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	13	4	9	4
Units: percentage of participants				
number (confidence interval 95%)				
Week 16 (n=13, 4, 9, 4, 8, 4, 11)	23.08 (5.04 to 53.81)	50.00 (6.76 to 93.24)	66.67 (29.93 to 92.51)	50.00 (6.76 to 93.24)
Week 32 (n=0, 4, 9, 4, 8, 4, 11)	999 (999 to 999)	50.00 (6.76 to 93.24)	66.67 (29.93 to 92.51)	50.00 (6.76 to 93.24)

End point values	Part A: Double Blind Period: TAK-079 300 mg	Part B: OLE Period: TAK-079 600 mg	Part B: Double Blind Period: TAK-079 600 mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	8	4	11	
Units: percentage of participants				
number (confidence interval 95%)				
Week 16 (n=13, 4, 9, 4, 8, 4, 11)	62.50 (24.49 to 91.48)	25.00 (0.63 to 80.59)	90.91 (58.72 to 99.77)	
Week 32 (n=0, 4, 9, 4, 8, 4, 11)	62.50 (24.49 to 91.48)	25.00 (0.63 to 80.59)	90.91 (58.72 to 99.77)	

Statistical analyses

Statistical analysis title	Platelet Response at Weeks 16 and 32
Comparison groups	Part A & B: Double Blind Period: Placebo v Part A: Double Blind Period: TAK-079 100 mg
Number of subjects included in analysis	22
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.056
Method	Barnard's test
Parameter estimate	Risk difference
Point estimate	43.59
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.81
upper limit	73.35

Statistical analysis title	Platelet Response at Weeks 16 and 32
Comparison groups	Part A & B: Double Blind Period: Placebo v Part B: Double Blind Period: TAK-079 600 mg
Number of subjects included in analysis	24
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.001
Method	Barnard's test
Parameter estimate	Risk difference (RD)
Point estimate	67.83
Confidence interval	
level	95 %
sides	2-sided
lower limit	29.21
upper limit	87.29

Statistical analysis title	Platelet Response at Weeks 16 and 32
Comparison groups	Part A & B: Double Blind Period: Placebo v Part A: Double Blind Period: TAK-079 300 mg
Number of subjects included in analysis	21
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.088
Method	Barnard's test
Parameter estimate	Risk difference (RD)
Point estimate	39.42
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.24
upper limit	71.38

Secondary: Percentage of Participants with Complete Platelet Response at Weeks 16 and 32

End point title	Percentage of Participants with Complete Platelet Response at Weeks 16 and 32

End point description:

Complete platelet response is defined as a platelet count ≥100,000/μL on at least 2 visits without a dosing period-permitted rescue treatment in the previous 4 weeks and without any other previous rescue therapy. Percentages were rounded off to the nearest single decimal place.

End point type	Secondary

End point timeframe:

At Weeks 16 and 32

End point values	Part A & B: Double Blind Period: Placebo	Part A: Open-label Extension (OLE) Period: TAK-079 100 mg	Part A: Double Blind Period: TAK-079 100 mg	Part A: OLE Period: TAK-079 300 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	13	4	9	4
Units: percentage of participants				
number (confidence interval 95%)				
Week 16 (n=13, 4, 9, 4, 8, 4, 11)	0 (0.00 to 24.71)	0 (0.00 to 60.24)	55.56 (21.20 to 86.30)	25.00 (0.63 to 80.59)
Week 32 (n=0, 4, 9, 4, 8, 4, 11)	999 (999 to 999)	25.00 (0.63 to 80.59)	55.56 (21.20 to 86.30)	25.00 (0.63 to 80.59)

End point values	Part A: Double Blind Period: TAK-079 300 mg	Part B: OLE Period: TAK-079 600 mg	Part B: Double Blind Period: TAK-079 600 mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	8	4	11	
Units: percentage of participants				
number (confidence interval 95%)				
Week 16 (n=13, 4, 9, 4, 8, 4, 11)	50.00 (15.70 to 84.30)	25.00 (0.63 to 80.59)	81.82 (48.22 to 97.72)	
Week 32 (n=0, 4, 9, 4, 8, 4, 11)	50.00 (15.70 to 84.30)	25.00 (0.63 to 80.59)	81.82 (48.22 to 97.72)	

Statistical analyses

Statistical analysis title	Complete Platelet Response at Weeks 16 and 32
Comparison groups	Part A & B: Double Blind Period: Placebo v Part A: Double Blind Period: TAK-079 100 mg
Number of subjects included in analysis	22
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.001
Method	Barnard's test
Parameter estimate	Risk difference (RD)
Point estimate	55.56
Confidence interval	
level	95 %
sides	2-sided
lower limit	25.11
upper limit	81.51

Statistical analysis title	Complete Platelet Response at Weeks 16 and 32
Comparison groups	Part A & B: Double Blind Period: Placebo v Part B: Double Blind Period: TAK-079 600 mg
Number of subjects included in analysis	24
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Barnard's test
Parameter estimate	Risk difference (RD)
Point estimate	81.82
Confidence interval	
level	95 %
sides	2-sided
lower limit	51.24
upper limit	94.99

Statistical analysis title	Complete Platelet Response at Weeks 16 and 32
Comparison groups	Part A & B: Double Blind Period: Placebo v Part A: Double Blind Period: TAK-079 300 mg
Number of subjects included in analysis	21
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.004
Method	Barnard's test
Parameter estimate	Risk difference (RD)
Point estimate	50
Confidence interval	
level	95 %
sides	2-sided
lower limit	19.63
upper limit	78.95

Secondary: Percentage of Participants with Clinically Meaningful Platelet Response at Weeks 16 and 32

End point title	Percentage of Participants with Clinically Meaningful Platelet Response at Weeks 16 and 32

End point description:

A clinically meaningful platelet response is defined as a platelet count ≥20,000/μL above baseline on at least 2 visits without a dosing period-permitted rescue treatment in the previous 4 weeks and without any other previous rescue therapy. Percentages were rounded off to the nearest single decimal place.

End point type	Secondary

End point timeframe:

At Weeks 16 and 32

End point values	Part A & B: Double Blind Period: Placebo	Part A: Open-label Extension (OLE) Period: TAK-079 100 mg	Part A: Double Blind Period: TAK-079 100 mg	Part A: OLE Period: TAK-079 300 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	13	4	9	4
Units: percentage of participants				
number (confidence interval 95%)				
Week 16 (n=13, 4, 9, 4, 8, 4, 11)	30.77 (9.09 to 61.43)	75.00 (19.41 to 99.37)	66.67 (29.93 to 92.51)	50.00 (6.76 to 93.24)
Week 32 (n=0, 4, 9, 4, 8, 4, 11)	999 (999 to 999)	75.00 (19.41 to 99.37)	66.67 (29.93 to 92.51)	50.00 (6.76 to 93.24)

End point values	Part A: Double Blind Period: TAK-079 300 mg	Part B: OLE Period: TAK-079 600 mg	Part B: Double Blind Period: TAK-079 600 mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	8	4	11	
Units: percentage of participants				
number (confidence interval 95%)				
Week 16 (n=13, 4, 9, 4, 8, 4, 11)	75.00 (34.91 to 96.81)	25.00 (0.63 to 80.59)	90.91 (58.72 to 99.77)	
Week 32 (n=0, 4, 9, 4, 8, 4, 11)	75.00 (34.91 to 96.81)	25.00 (0.63 to 80.59)	90.91 (58.72 to 99.77)	

Statistical analyses

Statistical analysis title	Clinically Meaningful Platelet Response
Comparison groups	Part A & B: Double Blind Period: Placebo v Part A: Double Blind Period: TAK-079 100 mg
Number of subjects included in analysis	22
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.12
Method	Barnard's test
Parameter estimate	Risk difference (RD)
Point estimate	35.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	-7.22
upper limit	67.75

Statistical analysis title	Clinically Meaningful Platelet Response
Comparison groups	Part A & B: Double Blind Period: Placebo v Part B: Double Blind Period: TAK-079 600 mg
Number of subjects included in analysis	24
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.003
Method	Barnard's test
Parameter estimate	Risk difference (RD)
Point estimate	60.14
Confidence interval	
level	95 %
sides	2-sided
lower limit	21.33
upper limit	82.42

Statistical analysis title	Clinically Meaningful Platelet Response
Comparison groups	Part A & B: Double Blind Period: Placebo v Part A: Double Blind Period: TAK-079 300 mg
Number of subjects included in analysis	21
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.06
Method	Barnard's test
Parameter estimate	Risk difference (RD)
Point estimate	44.23
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.83
upper limit	73.77

Secondary: Percentage of Participants with Hemostatic Platelet Response at Weeks 16 and 32

End point title	Percentage of Participants with Hemostatic Platelet Response at Weeks 16 and 32

End point description:

A hemostatic platelet response is defined for participants with a baseline platelet count of <15,000/μL who achieved a platelet count of ≥30,000/μL and ≥20,000/μL above baseline on at least 2 visits without a dosing period-permitted rescue treatment in the previous 4 weeks and without any other previous rescue therapy. Percentages were rounded off to the nearest single decimal place.

End point type	Secondary

End point timeframe:

At Weeks 16 and 32

End point values	Part A & B: Double Blind Period: Placebo	Part A: Open-label Extension (OLE) Period: TAK-079 100 mg	Part A: Double Blind Period: TAK-079 100 mg	Part A: OLE Period: TAK-079 300 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	5	2	5	1
Units: percentage of participants				
number (confidence interval 95%)				
Week 16 (n=5, 2, 5, 1, 4, 3, 4)	0 (0.00 to 52.18)	100.00 (15.81 to 100.00)	40.00 (5.27 to 85.34)	100.00 (2.50 to 100.00)
Week 32 (n=0, 2, 5, 1, 4, 3, 4)	999 (999 to 999)	100.00 (15.81 to 100.00)	40.00 (5.27 to 85.34)	100.00 (2.50 to 100.00)

End point values	Part A: Double Blind Period: TAK-079 300 mg	Part B: OLE Period: TAK-079 600 mg	Part B: Double Blind Period: TAK-079 600 mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	4	3	4	
Units: percentage of participants				
number (confidence interval 95%)				
Week 16 (n=5, 2, 5, 1, 4, 3, 4)	25.00 (0.63 to 80.59)	0 (0.00 to 70.76)	100.00 (39.76 to 100.00)	
Week 32 (n=0, 2, 5, 1, 4, 3, 4)	25.00 (0.63 to 80.59)	0 (0.00 to 70.76)	100.00 (39.76 to 100.00)	

Statistical analyses

Statistical analysis title	Hemostatic Platelet Response at Weeks 16 and 32
Comparison groups	Part A & B: Double Blind Period: Placebo v Part A: Double Blind Period: TAK-079 100 mg
Number of subjects included in analysis	10
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.187
Method	Barnard's test
Parameter estimate	Risk difference (RD)
Point estimate	40
Confidence interval	
level	95 %
sides	2-sided
lower limit	-16.28
upper limit	78.17

Statistical analysis title	Hemostatic Platelet Response at Weeks 16 and 32
Comparison groups	Part A & B: Double Blind Period: Placebo v Part B: Double Blind Period: TAK-079 600 mg
Number of subjects included in analysis	9
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.004
Method	Barnard's test
Parameter estimate	Risk difference (RD)
Point estimate	100
Confidence interval	
level	95 %
sides	2-sided
lower limit	35.12
upper limit	100

Statistical analysis title	Hemostatic Platelet Response at Weeks 16 and 32
Comparison groups	Part A & B: Double Blind Period: Placebo v Part A: Double Blind Period: TAK-079 300 mg
Number of subjects included in analysis	9
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.315
Method	Barnard's test
Parameter estimate	Risk difference (RD)
Point estimate	25
Confidence interval	
level	95 %
sides	2-sided
lower limit	-28.85
upper limit	71.78

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Up to Week 32 in each Period of the study

Adverse event reporting additional description:

The Safety Analysis Set included all participants who received at least 1 dose of study drug.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	27.0

Reporting groups

Reporting group title	Part A: Double Blind Period: TAK-079 300 mg

Reporting group description:

Participants received TAK-079 300 mg, SC injection, QW for 8 weeks. Following treatment participants were followed up for 8 weeks in a double blinded SFP up to Week 16. Participants were then followed up for another 16 weeks in an unblinded LFP up to Week 32.

Reporting group title	Part A: Double Blind Period: TAK-079 100 mg

Reporting group description:

Participants received TAK-079 100 mg, SC injection, QW for 8 weeks. Following treatment participants were followed up for 8 weeks in a double blinded SFP up to Week 16. Participants were then followed up for another 16 weeks in an unblinded LFP up to Week 32.

Reporting group title	Part A & B: Double Blind Period: Placebo

Reporting group description:

Participants received TAK-079 placebo-matching injection SC, QW for 8 weeks. Following treatment participants were followed up for 8 weeks in a double blinded SFP up to Week 16. Placebo-assigned participants who did not opt to receive treatment with TAK-079 were followed up for another 16 weeks in an unblinded LFP up to Week 32.

Reporting group title	Part A: OLE Period: TAK-079 300 mg

Reporting group description:

Participants who received placebo in double-blind Part A and opted to receive treatment with TAK-079 were randomized to receive TAK-079 300 mg, SC injection, QW for 8 weeks in OLE Period of Part A. Following treatment participants were followed up for 8 weeks in a SFP and then for another 16 weeks in a LFP.

Reporting group title	Part A: Open-label Extension (OLE) Period: TAK-079 100 mg

Reporting group description:

Participants who received placebo in double-blind Part A and SFP and opted to receive treatment with TAK-079 were randomized to receive TAK-079 100 mg, SC injection, QW for 8 weeks in OLE Period of Part A. Following treatment participants were followed up for 8 weeks in a SFP and then for another 16 weeks in a LFP.

Reporting group title	Part B: OLE Period: TAK-079 600 mg

Reporting group description:

Participants who received placebo in double-blind Part B and opted to receive treatment with TAK-079 received TAK-079 600 mg, SC injection, QW for 8 weeks in OLE Period of Part B. Following treatment participants were followed up for 8 weeks in a SFP and then for another 16 weeks in a LFP.

Reporting group title	Part B: Double Blind Period: TAK-079 600 mg

Reporting group description:

Participants received TAK-079 600 mg, SC injection, QW for 8 weeks. Following treatment participants were followed up for 8 weeks in a double blinded SFP up to Week 16. Participants were then followed up for another 16 weeks in an unblinded LFP up to Week 32.

Serious adverse events	Part A: Double Blind Period: TAK-079 300 mg	Part A: Double Blind Period: TAK-079 100 mg	Part A & B: Double Blind Period: Placebo
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 8 (0.00%)	2 / 9 (22.22%)	1 / 13 (7.69%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Blood and lymphatic system disorders			
Immune thrombocytopenia			
subjects affected / exposed	0 / 8 (0.00%)	1 / 9 (11.11%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombocytopenia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 9 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
Conjunctivitis allergic			
subjects affected / exposed	0 / 8 (0.00%)	1 / 9 (11.11%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
Haemorrhagic ovarian cyst			
subjects affected / exposed	0 / 8 (0.00%)	0 / 9 (0.00%)	1 / 13 (7.69%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 8 (0.00%)	0 / 9 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
COVID-19			
subjects affected / exposed	0 / 8 (0.00%)	0 / 9 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyelonephritis chronic			

subjects affected / exposed	0 / 8 (0.00%)	0 / 9 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Staphylococcal bacteraemia			
subjects affected / exposed	0 / 8 (0.00%)	1 / 9 (11.11%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Part A: OLE Period: TAK-079 300 mg	Part A: Open-label Extension (OLE) Period: TAK-079 100 mg	Part B: OLE Period: TAK-079 600 mg
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 4 (0.00%)	1 / 4 (25.00%)	0 / 4 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Blood and lymphatic system disorders			
Immune thrombocytopenia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombocytopenia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
Conjunctivitis allergic			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
Haemorrhagic ovarian cyst			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			

Acute kidney injury			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
COVID-19			
subjects affected / exposed	0 / 4 (0.00%)	1 / 4 (25.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyelonephritis chronic			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Staphylococcal bacteraemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Part B: Double Blind Period: TAK-079 600 mg		
Total subjects affected by serious adverse events			
subjects affected / exposed	2 / 11 (18.18%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		
Blood and lymphatic system disorders			
Immune thrombocytopenia			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Thrombocytopenia			
subjects affected / exposed	1 / 11 (9.09%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Eye disorders			
Conjunctivitis allergic			

subjects affected / exposed	0 / 11 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Reproductive system and breast disorders			
Haemorrhagic ovarian cyst			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	1 / 11 (9.09%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Infections and infestations			
COVID-19			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pyelonephritis chronic			
subjects affected / exposed	1 / 11 (9.09%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Staphylococcal bacteraemia			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

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

Non-serious adverse events	Part A: Double Blind Period: TAK-079 300 mg	Part A: Double Blind Period: TAK-079 100 mg	Part A & B: Double Blind Period: Placebo
Total subjects affected by non-serious adverse events			
subjects affected / exposed	5 / 8 (62.50%)	7 / 9 (77.78%)	9 / 13 (69.23%)
Vascular disorders			

Aortic aneurysm			
subjects affected / exposed	0 / 8 (0.00%)	1 / 9 (11.11%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
Essential hypertension			
subjects affected / exposed	0 / 8 (0.00%)	0 / 9 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	3
Thrombophlebitis			
subjects affected / exposed	0 / 8 (0.00%)	1 / 9 (11.11%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
Hypertension			
subjects affected / exposed	0 / 8 (0.00%)	0 / 9 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Hypotension			
subjects affected / exposed	1 / 8 (12.50%)	0 / 9 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
Haematoma			
subjects affected / exposed	0 / 8 (0.00%)	0 / 9 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
General disorders and administration site conditions			
Administration site haematoma			
subjects affected / exposed	1 / 8 (12.50%)	0 / 9 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
Asthenia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 9 (0.00%)	2 / 13 (15.38%)
occurrences (all)	0	0	2
Chills			
subjects affected / exposed	0 / 8 (0.00%)	0 / 9 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Fatigue			
subjects affected / exposed	1 / 8 (12.50%)	0 / 9 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
Feeling cold			
subjects affected / exposed	0 / 8 (0.00%)	0 / 9 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Influenza like illness			

subjects affected / exposed	0 / 8 (0.00%)	0 / 9 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Pyrexia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 9 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Injection site reaction			
subjects affected / exposed	0 / 8 (0.00%)	0 / 9 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Injection site bruising			
subjects affected / exposed	0 / 8 (0.00%)	0 / 9 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	5
Injection site haematoma			
subjects affected / exposed	2 / 8 (25.00%)	0 / 9 (0.00%)	3 / 13 (23.08%)
occurrences (all)	2	0	3
Reproductive system and breast disorders			
Heavy menstrual bleeding			
subjects affected / exposed	0 / 8 (0.00%)	0 / 9 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Respiratory, thoracic and mediastinal disorders			
Productive cough			
subjects affected / exposed	0 / 8 (0.00%)	0 / 9 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Pharyngeal inflammation			
subjects affected / exposed	0 / 8 (0.00%)	0 / 9 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Oropharyngeal pain			
subjects affected / exposed	0 / 8 (0.00%)	1 / 9 (11.11%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
Epistaxis			
subjects affected / exposed	1 / 8 (12.50%)	0 / 9 (0.00%)	1 / 13 (7.69%)
occurrences (all)	1	0	1
Dyspnoea			
subjects affected / exposed	0 / 8 (0.00%)	0 / 9 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Chronic obstructive pulmonary disease			

subjects affected / exposed	0 / 8 (0.00%)	0 / 9 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Anxiety			
subjects affected / exposed	1 / 8 (12.50%)	0 / 9 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
Confusional state			
subjects affected / exposed	0 / 8 (0.00%)	1 / 9 (11.11%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
Investigations			
Electrocardiogram abnormal			
subjects affected / exposed	1 / 8 (12.50%)	0 / 9 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
Blood urine present			
subjects affected / exposed	0 / 8 (0.00%)	0 / 9 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Blood bilirubin increased			
subjects affected / exposed	0 / 8 (0.00%)	0 / 9 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Fall			
subjects affected / exposed	0 / 8 (0.00%)	1 / 9 (11.11%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
Contusion			
subjects affected / exposed	0 / 8 (0.00%)	0 / 9 (0.00%)	2 / 13 (15.38%)
occurrences (all)	0	0	2
Traumatic haematoma			
subjects affected / exposed	1 / 8 (12.50%)	0 / 9 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
Post procedural haemorrhage			
subjects affected / exposed	0 / 8 (0.00%)	0 / 9 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Joint injury			
subjects affected / exposed	0 / 8 (0.00%)	0 / 9 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Injection related reaction			

subjects affected / exposed	1 / 8 (12.50%)	0 / 9 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
Nervous system disorders			
Vocal cord paralysis			
subjects affected / exposed	0 / 8 (0.00%)	1 / 9 (11.11%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
Post-traumatic headache			
subjects affected / exposed	0 / 8 (0.00%)	1 / 9 (11.11%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
Nystagmus			
subjects affected / exposed	0 / 8 (0.00%)	0 / 9 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Headache			
subjects affected / exposed	0 / 8 (0.00%)	1 / 9 (11.11%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
Dizziness			
subjects affected / exposed	0 / 8 (0.00%)	0 / 9 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Iron deficiency anaemia			
subjects affected / exposed	0 / 8 (0.00%)	1 / 9 (11.11%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
Anaemia			
subjects affected / exposed	2 / 8 (25.00%)	0 / 9 (0.00%)	0 / 13 (0.00%)
occurrences (all)	2	0	0
Thrombocytopenia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 9 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	2
Leukocytosis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 9 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
Vertigo			
subjects affected / exposed	0 / 8 (0.00%)	0 / 9 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Eye disorders			

Conjunctival haemorrhage			
subjects affected / exposed	0 / 8 (0.00%)	1 / 9 (11.11%)	2 / 13 (15.38%)
occurrences (all)	0	1	2
Myopia			
subjects affected / exposed	0 / 8 (0.00%)	1 / 9 (11.11%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
Optic neuropathy			
subjects affected / exposed	0 / 8 (0.00%)	1 / 9 (11.11%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	1 / 8 (12.50%)	0 / 9 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
Gingival bleeding			
subjects affected / exposed	1 / 8 (12.50%)	0 / 9 (0.00%)	1 / 13 (7.69%)
occurrences (all)	1	0	1
Anal fissure			
subjects affected / exposed	0 / 8 (0.00%)	0 / 9 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Abdominal pain upper			
subjects affected / exposed	1 / 8 (12.50%)	0 / 9 (0.00%)	0 / 13 (0.00%)
occurrences (all)	3	0	0
Abdominal pain lower			
subjects affected / exposed	1 / 8 (12.50%)	0 / 9 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
Abdominal pain			
subjects affected / exposed	2 / 8 (25.00%)	0 / 9 (0.00%)	0 / 13 (0.00%)
occurrences (all)	2	0	0
Glossitis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 9 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	0 / 8 (0.00%)	0 / 9 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Vomiting			

subjects affected / exposed	1 / 8 (12.50%)	0 / 9 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
Haematochezia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 9 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Mouth haemorrhage			
subjects affected / exposed	0 / 8 (0.00%)	1 / 9 (11.11%)	0 / 13 (0.00%)
occurrences (all)	0	2	0
Skin and subcutaneous tissue disorders			
Ecchymosis			
subjects affected / exposed	0 / 8 (0.00%)	1 / 9 (11.11%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
Eczema			
subjects affected / exposed	0 / 8 (0.00%)	0 / 9 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Urticaria			
subjects affected / exposed	0 / 8 (0.00%)	0 / 9 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Pruritus			
subjects affected / exposed	0 / 8 (0.00%)	0 / 9 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Petechiae			
subjects affected / exposed	0 / 8 (0.00%)	0 / 9 (0.00%)	2 / 13 (15.38%)
occurrences (all)	0	0	5
Renal and urinary disorders			
Urinary retention			
subjects affected / exposed	0 / 8 (0.00%)	0 / 9 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Pain in extremity			
subjects affected / exposed	1 / 8 (12.50%)	0 / 9 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
Osteoarthritis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 9 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	2
Myalgia			

subjects affected / exposed	1 / 8 (12.50%)	1 / 9 (11.11%)	1 / 13 (7.69%)
occurrences (all)	2	1	1
Exostosis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 9 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Polyarthritis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 9 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Upper respiratory tract infection			
subjects affected / exposed	0 / 8 (0.00%)	0 / 9 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Injection site cellulitis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 9 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Influenza			
subjects affected / exposed	0 / 8 (0.00%)	0 / 9 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
COVID-19			
subjects affected / exposed	0 / 8 (0.00%)	2 / 9 (22.22%)	1 / 13 (7.69%)
occurrences (all)	0	2	1
Bacteriuria			
subjects affected / exposed	0 / 8 (0.00%)	0 / 9 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Hyperuricaemia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 9 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Diabetes mellitus			
subjects affected / exposed	0 / 8 (0.00%)	0 / 9 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	2
Iron deficiency			
subjects affected / exposed	0 / 8 (0.00%)	0 / 9 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1

Non-serious adverse events	Part A: OLE Period: TAK-079 300 mg	Part A: Open-label Extension (OLE) Period: TAK-079 100	Part B: OLE Period: TAK-079 600 mg

		mg	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	4 / 4 (100.00%)	2 / 4 (50.00%)	2 / 4 (50.00%)
Vascular disorders			
Aortic aneurysm			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Essential hypertension			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Thrombophlebitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hypertension			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hypotension			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Haematoma			
subjects affected / exposed	1 / 4 (25.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
General disorders and administration site conditions			
Administration site haematoma			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Asthenia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Chills			
subjects affected / exposed	1 / 4 (25.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Fatigue			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Feeling cold			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Influenza like illness			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
subjects affected / exposed	1 / 4 (25.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Injection site reaction			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Injection site bruising			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Injection site haematoma			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Heavy menstrual bleeding			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Productive cough			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Pharyngeal inflammation			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Epistaxis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Dyspnoea			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Chronic obstructive pulmonary disease			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Psychiatric disorders			
Anxiety			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Confusional state			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Investigations			
Electrocardiogram abnormal			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Blood urine present			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Blood bilirubin increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Fall			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Contusion			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Traumatic haematoma			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Post procedural haemorrhage			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Joint injury			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Injection related reaction			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Vocal cord paralysis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Post-traumatic headache			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Nystagmus			
subjects affected / exposed	1 / 4 (25.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Headache			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Dizziness			
subjects affected / exposed	1 / 4 (25.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	2	0	0
Blood and lymphatic system disorders			
Iron deficiency anaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Anaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Thrombocytopenia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Leukocytosis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	3
Ear and labyrinth disorders			

Vertigo			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Conjunctival haemorrhage			
subjects affected / exposed	0 / 4 (0.00%)	1 / 4 (25.00%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Myopia			
subjects affected / exposed	1 / 4 (25.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Optic neuropathy			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Gingival bleeding			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Anal fissure			
subjects affected / exposed	1 / 4 (25.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Abdominal pain upper			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Abdominal pain lower			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Abdominal pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Glossitis			
subjects affected / exposed	1 / 4 (25.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Nausea			

subjects affected / exposed	1 / 4 (25.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Vomiting			
subjects affected / exposed	1 / 4 (25.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Haematochezia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Mouth haemorrhage			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Ecchymosis			
subjects affected / exposed	1 / 4 (25.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Eczema			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Urticaria			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pruritus			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Petechiae			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Urinary retention			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Pain in extremity			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Osteoarthritis			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Myalgia			
subjects affected / exposed	1 / 4 (25.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Exostosis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Polyarthritis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Upper respiratory tract infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Injection site cellulitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Influenza			
subjects affected / exposed	1 / 4 (25.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
COVID-19			
subjects affected / exposed	0 / 4 (0.00%)	1 / 4 (25.00%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Bacteriuria			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Hyperuricaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Diabetes mellitus			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Iron deficiency			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Part B: Double Blind Period: TAK-079 600 mg		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	6 / 11 (54.55%)		
Vascular disorders			
Aortic aneurysm			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences (all)	0		
Essential hypertension			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences (all)	0		
Thrombophlebitis			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences (all)	0		
Hypertension			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences (all)	0		
Hypotension			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences (all)	0		
Haematoma			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences (all)	0		
General disorders and administration site conditions			
Administration site haematoma			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences (all)	0		
Asthenia			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences (all)	0		
Chills			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences (all)	0		
Fatigue			

subjects affected / exposed occurrences (all)	0 / 11 (0.00%) 0		
Feeling cold subjects affected / exposed occurrences (all)	0 / 11 (0.00%) 0		
Influenza like illness subjects affected / exposed occurrences (all)	0 / 11 (0.00%) 0		
Pyrexia subjects affected / exposed occurrences (all)	2 / 11 (18.18%) 2		
Injection site reaction subjects affected / exposed occurrences (all)	1 / 11 (9.09%) 1		
Injection site bruising subjects affected / exposed occurrences (all)	0 / 11 (0.00%) 0		
Injection site haematoma subjects affected / exposed occurrences (all)	0 / 11 (0.00%) 0		
Reproductive system and breast disorders Heavy menstrual bleeding subjects affected / exposed occurrences (all)	0 / 11 (0.00%) 0		
Respiratory, thoracic and mediastinal disorders Productive cough subjects affected / exposed occurrences (all)	0 / 11 (0.00%) 0		
Pharyngeal inflammation subjects affected / exposed occurrences (all)	0 / 11 (0.00%) 0		
Oropharyngeal pain subjects affected / exposed occurrences (all)	1 / 11 (9.09%) 1		
Epistaxis			

subjects affected / exposed	0 / 11 (0.00%)		
occurrences (all)	0		
Dyspnoea			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences (all)	0		
Chronic obstructive pulmonary disease			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences (all)	0		
Psychiatric disorders			
Anxiety			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences (all)	0		
Confusional state			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences (all)	0		
Investigations			
Electrocardiogram abnormal			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences (all)	0		
Blood urine present			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences (all)	0		
Blood bilirubin increased			
subjects affected / exposed	1 / 11 (9.09%)		
occurrences (all)	1		
Injury, poisoning and procedural complications			
Fall			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences (all)	0		
Contusion			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences (all)	0		
Traumatic haematoma			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences (all)	0		
Post procedural haemorrhage			

subjects affected / exposed	0 / 11 (0.00%)		
occurrences (all)	0		
Joint injury			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences (all)	0		
Injection related reaction			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences (all)	0		
Nervous system disorders			
Vocal cord paralysis			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences (all)	0		
Post-traumatic headache			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences (all)	0		
Nystagmus			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences (all)	0		
Headache			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences (all)	0		
Dizziness			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences (all)	0		
Blood and lymphatic system disorders			
Iron deficiency anaemia			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences (all)	0		
Anaemia			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences (all)	0		
Thrombocytopenia			
subjects affected / exposed	1 / 11 (9.09%)		
occurrences (all)	2		
Leukocytosis			

subjects affected / exposed occurrences (all)	0 / 11 (0.00%) 0		
Ear and labyrinth disorders Vertigo subjects affected / exposed occurrences (all)	 0 / 11 (0.00%) 0		
Eye disorders Conjunctival haemorrhage subjects affected / exposed occurrences (all) Myopia subjects affected / exposed occurrences (all) Optic neuropathy subjects affected / exposed occurrences (all)	 0 / 11 (0.00%) 0 0 / 11 (0.00%) 0 0 / 11 (0.00%) 0		
Gastrointestinal disorders Diarrhoea subjects affected / exposed occurrences (all) Gingival bleeding subjects affected / exposed occurrences (all) Anal fissure subjects affected / exposed occurrences (all) Abdominal pain upper subjects affected / exposed occurrences (all) Abdominal pain lower subjects affected / exposed occurrences (all) Abdominal pain subjects affected / exposed occurrences (all) Glossitis	 0 / 11 (0.00%) 0 0 / 11 (0.00%) 0 0 / 11 (0.00%) 0 0 / 11 (0.00%) 0 0 / 11 (0.00%) 0 0 / 11 (0.00%) 0		

subjects affected / exposed occurrences (all) Nausea subjects affected / exposed occurrences (all) Vomiting subjects affected / exposed occurrences (all) Haematochezia subjects affected / exposed occurrences (all) Mouth haemorrhage subjects affected / exposed occurrences (all)	0 / 11 (0.00%) 0 1 / 11 (9.09%) 1 0 / 11 (0.00%) 0 0 / 11 (0.00%) 0 0 / 11 (0.00%) 0		
Skin and subcutaneous tissue disorders Ecchymosis subjects affected / exposed occurrences (all) Eczema subjects affected / exposed occurrences (all) Urticaria subjects affected / exposed occurrences (all) Pruritus subjects affected / exposed occurrences (all) Petechiae subjects affected / exposed occurrences (all)	 0 / 11 (0.00%) 0 1 / 11 (9.09%) 1 1 / 11 (9.09%) 1 0 / 11 (0.00%) 0 0 / 11 (0.00%) 0		
Renal and urinary disorders Urinary retention subjects affected / exposed occurrences (all)	 1 / 11 (9.09%) 1		
Musculoskeletal and connective tissue disorders			

Pain in extremity subjects affected / exposed occurrences (all)	0 / 11 (0.00%) 0		
Osteoarthritis subjects affected / exposed occurrences (all)	0 / 11 (0.00%) 0		
Myalgia subjects affected / exposed occurrences (all)	0 / 11 (0.00%) 0		
Exostosis subjects affected / exposed occurrences (all)	1 / 11 (9.09%) 1		
Polyarthritis subjects affected / exposed occurrences (all)	1 / 11 (9.09%) 1		
Infections and infestations Upper respiratory tract infection subjects affected / exposed occurrences (all)	0 / 11 (0.00%) 0		
Injection site cellulitis subjects affected / exposed occurrences (all)	1 / 11 (9.09%) 1		
Influenza subjects affected / exposed occurrences (all)	0 / 11 (0.00%) 0		
COVID-19 subjects affected / exposed occurrences (all)	1 / 11 (9.09%) 1		
Bacteriuria subjects affected / exposed occurrences (all)	1 / 11 (9.09%) 1		
Metabolism and nutrition disorders Hyperuricaemia subjects affected / exposed occurrences (all)	0 / 11 (0.00%) 0		
Diabetes mellitus			

subjects affected / exposed	0 / 11 (0.00%)		
occurrences (all)	0		
Iron deficiency			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences (all)	0		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
07 October 2020	The following changes were made as per Amendment 02: 1. Allowed participants to receive predefined rescue therapies during the dosing period without automatic discontinuation from IMP dosing and advancement to the SFP. 2. Enhanced access to the OLE for placebo participants who receive rescue therapies during the study. 3. Add contingency plans for the coronavirus disease 2019 (COVID-19) pandemic by incorporating flexibility for study participants, investigators, and study-site monitors while continuing to maintain participant safety and study integrity as per local site regulations.
18 December 2020	The following changes were made as per Amendment 03: 1. Revised timing of sample collection for the ITP Bleeding Scores to decrease the routine frequency of administrations of the test for participant comfort. 2. Revised the procedure for occult blood samples to provide more detailed description of the ITP Bleeding Score, including the collection of samples as part of the assessment.
05 May 2021	The following change was made as per Amendment 04: 1. Changed the legal entity name for the sponsor to Takeda Development Center Americas, Inc.
28 April 2022	The following changes were made as per Amendment 05: 1. Updated the number of participants enrolled in each study part to expedite the safety review of Part A. 2. Updated exclusion criteria to also exclude participants with significant ocular medical conditions and participants in vaccine studies. 3. Added urticaria, fever, and blurred vision to the list of hypersensitivity symptoms to ensure that these symptoms were examined by the investigator in determining any potential hypersensitivity reaction. 4. Modified the prophylactic coadministration regimens for each dose of mezagitamab, to prevent possible infusion related reactions and provide an option for updating guidance to sites based on emerging data. 5. Added that an equivalent of tocilizumab may be used for symptomatic treatment of cytokine release syndrome (CRS) to allow investigators flexibility in treatment and support of study participants.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported