Clinical trial results:
A Phase 3, Open-label, Non-controlled Study to Evaluate the Pharmacokinetics, Safety and Tolerability, and Efficacy of TAK-771 in Japanese Subjects with Primary Immunodeficiency Diseases (PID)

Summary

EudraCT number	2022-003622-45
Trial protocol	Outside EU/EEA
Global end of trial date	28 August 2023

Results information

Result version number	v1 (current)
This version publication date	06 March 2024
First version publication date	06 March 2024

Trial information

Trial identification

Sponsor protocol code	TAK-771-3004

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT05150340
WHO universal trial number (UTN)	-
Other trial identifiers	jRCT: jRCT2031210457

Notes:

Sponsors

Sponsor organisation name	Takeda
Sponsor organisation address	5 Hayden Avenue , Lexington , United States, MA 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	28 August 2023
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	28 August 2023
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The purpose of the trial included Clinical phase 3 study to evaluate the efficacy, tolerability and safety of subcutaneous human immunoglobulin (octanorm) in patients with primary immunodeficiency diseases.

Protection of trial subjects:

All study participants were required to read and sign an Informed Consent Form.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	24 January 2022
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	Japan: 16
Worldwide total number of subjects	16
EEA total number of subjects	0

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	4
Adolescents (12-17 years)	1
Adults (18-64 years)	11
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Participants with a confirmed diagnosis of primary immunodeficiency diseases (PID) took part in the study at 12 investigative sites in Japan from 24 January 2022 to 28 August 2023.

Pre-assignment

Screening details:

Participants with PID, who had been receiving a consistent dose of intravenous immunoglobulin (IVIG), conventional subcutaneous immunoglobulin (cSCIG) or TAK-664 (immune globulin subcutaneous [human], 20% solution [20%SCIG]) for at least 3 months prior to screening were enrolled in the study to receive TAK-771.

Period 1

Period 1 title	Epoch 1
Is this the baseline period?	Yes
Allocation method	Not applicable
Blinding used	Not blinded

Arms

Arm title	Epoch 1: TAK-771 Ramp up Period

Arm description:

TAK-771 included IGI 10% and Recombinant Human Hyaluronidase (rHuPH20). Participants received subcutaneous infusion of rHuPH20 solution at a dose of 80 U/g IgG first, followed by SC infusion of 10% IGI within 10 minutes of completion of the infusion of rHuPH20 solution. The dose of 10% IGI was increased from 1/3 of full dose to full dose in 3 weeks for participants who received TAK-771 once every 3 weeks, or from 1/4 of full dose to full dose in 6 weeks for participants who received TAK-771 once every 4 weeks.

Arm type	Experimental
Investigational medicinal product name	TAK-771 (10% IGI with rHuPH20)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Subcutaneous use

Dosage and administration details:

80 U/g IgG (rHuPH20 drug product: 160 U/mL)

Number of subjects in period 1	Epoch 1: TAK-771 Ramp up Period
Started	16
Pharmacokinetic Analysis Set 1	16
Completed	16

Period 2

Period 2 title	Epoch 2
Is this the baseline period?	No
Allocation method	Not applicable
Blinding used	Not blinded

Arms

Arm title	Epoch 2: TAK-771 Full Dose Treatment Period

Arm description:

TAK-771 included Immune Globulin Infusion (IGI) 10% and Recombinant Human Hyaluronidase (rHuPH20). Participants received subcutaneous infusion of rHuPH20 solution at a dose of 80 U/g IgG first, followed by SC infusion of 10% IGI within 10 minutes of completion of the infusion of rHuPH20 solution, every 3, or 4 weeks for up to Week 27 for participants with 4-Week dosing interval or Week 25 for participants with 3-Week dosing interval.

Arm type	Experimental
Investigational medicinal product name	TAK-771 (10% IGI with rHuPH20)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Subcutaneous use

Dosage and administration details:

80 U/g IgG (rHuPH20 drug product: 160 U/mL)

Number of subjects in period 2	Epoch 2: TAK-771 Full Dose Treatment Period
Started	16
Pharmacokinetic Analysis Set 1	16
Pharmacokinetic Analysis Set 2	4 [1]
Completed	16

Notes:

[1] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.
Justification: The participants who completed Epoch 1 were included in Epoch 2.

Baseline characteristics

Reporting groups	
Reporting group title	Epoch 1

Reporting group description: -

Reporting group values	Epoch 1	Total	
Number of subjects	16	16	
Age categorical Units: Subjects			
In utero		0	
Preterm newborn infants (gestational age < 37 wks)		0	
Newborns (0-27 days)		0	
Infants and toddlers (28 days-23 months)		0	
Children (2-11 years)		0	
Adolescents (12-17 years)		0	
Adults (18-64 years)		0	
From 65-84 years		0	
85 years and over		0	
Age continuous			
Safety Analysis Set (SAS) included all enrolled subjects who received investigational drug at least once. Analyses of safety, tolerability and product administration were based on the SAS.			
Units: years			
arithmetic mean	25.2		
standard deviation	± 16.86	-	
Gender categorical Units: Subjects			
Female	6	6	
Male	10	10	
Ethnicity Units: Subjects			
Hispanic or Latino	0	0	
Not Hispanic or Latino	16	16	
Unknown or Not Reported	0	0	
Race Units: Subjects			
American Indian or Alaska Native	0	0	
Asian	16	16	
Native Hawaiian or Other Pacific Islander	0	0	
Black or African American	0	0	
White	0	0	
More than one race	0	0	
Unknown or Not Reported	0	0	

End points

End points reporting groups

Reporting group title	Epoch 1: TAK-771 Ramp up Period

Reporting group description:

TAK-771 included IGI 10% and Recombinant Human Hyaluronidase (rHuPH20). Participants received subcutaneous infusion of rHuPH20 solution at a dose of 80 U/g IgG first, followed by SC infusion of 10% IGI within 10 minutes of completion of the infusion of rHuPH20 solution. The dose of 10% IGI was increased from 1/3 of full dose to full dose in 3 weeks for participants who received TAK-771 once every 3 weeks, or from 1/4 of full dose to full dose in 6 weeks for participants who received TAK-771 once every 4 weeks.

Reporting group title	Epoch 2: TAK-771 Full Dose Treatment Period

Reporting group description:

TAK-771 included Immune Globulin Infusion (IGI) 10% and Recombinant Human Hyaluronidase (rHuPH20). Participants received subcutaneous infusion of rHuPH20 solution at a dose of 80 U/g IgG first, followed by SC infusion of 10% IGI within 10 minutes of completion of the infusion of rHuPH20 solution, every 3, or 4 weeks for up to Week 27 for participants with 4-Week dosing interval or Week 25 for participants with 3-Week dosing interval.

Subject analysis set title	Epoch 1 and 2
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Pharmacokinetic Analysis Set included all enrolled participants who received investigational drug at least once, have had at least 1 evaluable serum IgG concentration, and no major protocol deviations or events that would affect the serum IgG concentration analysis results. Pharmacokinetic Analysis Set included the analysis of total serum IgG trough levels for total serum levels of IgG and IgG subclasses. Number analyzed are the number of participants with data available for analysis at given timepoint.

Primary: Epoch 2: Serum Trough Levels of Total IgG Antibodies after Administration of TAK-771

End point title	Epoch 2: Serum Trough Levels of Total IgG Antibodies after Administration of TAK-771[1]

End point description:

The data was reported at Week 7, 11, 15, 19, 23, 27, and 31 for 4-Week interval and at Week 4, 7, 10, 13, 16, 19, 22, 25 and 28 for 3-Week interval. Pharmacokinetic analysis set included all enrolled participants who received investigational drug at least once, have had at least 1 evaluable serum IgG concentration, and no major protocol deviations or events that would affect the serum IgG concentration analysis results. Pharmacokinetic analysis set 1 included the analysis of total serum IgG trough levels for total serum levels of IgG and IgG subclasses. ‘n’ signifies number of participants analyzed at specific time point and '9999' signifies no geometric mean or geometric coefficient of variation were calculated due to 0 participants in that particular arm at specific time point.

End point type	Primary

End point timeframe:

Up to Week 31 for Participants with 4-Week Dosing Interval or Up to Week 28 for Participants with 3-Week Dosing Interval

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 statistical analysis was collected for this endpoint.

End point values	Epoch 2: TAK-771 Full Dose Treatment Period			
Subject group type	Reporting group			
Number of subjects analysed	16			
Units: grams/Liter (g/L)				
geometric mean (geometric coefficient of variation)				

Week 7, 4-Week Interval (n=12)	9.372 (± 10.3)			
Week 11, 4-Week Interval (n=12)	8.741 (± 13.7)			
Week 15, 4-Week Interval (n=11)	8.929 (± 13.0)			
Week 19, 4-Week Interval (n=12)	9.150 (± 15.5)			
Week 23, 4-Week Interval (n=12)	8.944 (± 20.9)			
Week 27, 4-Week Interval (n=11)	9.006 (± 18.4)			
Week 31, 4-Week Interval (n=12)	9.159 (± 20.8)			
Week 4, 3-Week Interval (n=2)	13.51 (± 29.7)			
Week 7, 3-Week Interval (n=2)	13.15 (± 35.7)			
Week 10, 3-Week Interval (n=2)	12.54 (± 43.2)			
Week 13, 3-Week Interval (n=0)	9999 (± 9999)			
Week 16, 3-Week Interval (n=2)	13.50 (± 39.7)			
Week 19, 3-Week Interval (n=2)	12.76 (± 46.9)			
Week 22, 3-Week Interval (n=2)	12.79 (± 40.1)			
Week 25, 3-Week Interval (n=2)	12.95 (± 57.6)			
Week 28, 3-Week Interval (n=2)	12.70 (± 43.0)			

Statistical analyses

No statistical analyses for this end point

Secondary: Epoch 2: Maximum Concentration (Cmax) of Total Serum Levels of IgG and IgG Subclasses

End point title	Epoch 2: Maximum Concentration (Cmax) of Total Serum Levels of IgG and IgG Subclasses

End point description:

Pharmacokinetic analysis set included all enrolled participants who received investigational drug at least once, have had at least 1 evaluable serum IgG concentration, and no major protocol deviations or events that would affect the serum IgG concentration analysis results. Pharmacokinetic analysis set 2 included the analysis of PK parameters for total serum levels of IgG, for baseline-corrected total serum levels of IgG, and for IgG subclasses in Epoch 2.

End point type	Secondary

End point timeframe:

Pre-infusion at last dose (Week 27 for participants with 4-Week dosing interval (DI) or Week 25 for participants with 3-Week DI) and post infusion at multiple time points up to Week 31 for participants with 4-Week DI and up to Week 28 with 3-Week DI

End point values	Epoch 2: TAK-771 Full Dose Treatment Period			
Subject group type	Reporting group			
Number of subjects analysed	4			
Units: gram(s)/litre (g/L				
geometric mean (geometric coefficient of variation)				
Total IgG	12.72 (± 23.4)			
IgG Subclass (IgG 1)	7.694 (± 16.7)			
IgG Subclass (IgG 2)	4.140 (± 23.0)			

IgG Subclass (IgG 3)	0.2396 (± 46.7)			
IgG Subclass (IgG 4)	0.3200 (± 36.3)			

Statistical analyses

No statistical analyses for this end point

Secondary: Epoch 2: Time to Maximum Concentration (Tmax) of Total Serum Levels of IgG and IgG Subclasses (IgG1, IgG2, IgG3, and IgG4)

End point title	Epoch 2: Time to Maximum Concentration (Tmax) of Total Serum Levels of IgG and IgG Subclasses (IgG1, IgG2, IgG3, and IgG4)

End point description:

Pharmacokinetic analysis set included all enrolled participants who received investigational drug at least once, have had at least 1 evaluable serum IgG concentration, and no major protocol deviations or events that would affect the serum IgG concentration analysis results. Pharmacokinetic analysis set 2 included the analysis of PK parameters for total serum levels of IgG, for baseline-corrected total serum levels of IgG, and for IgG subclasses in Epoch 2.

End point type	Secondary

End point timeframe:

Pre-infusion at last dose (Week 27 for participants with 4-Week dosing interval (DI) or Week 25 for participants with 3-Week DI) and post infusion at multiple time points up to Week 31 for participants with 4-Week DI and up to Week 28 with 3-Week DI

End point values	Epoch 2: TAK-771 Full Dose Treatment Period			
Subject group type	Reporting group			
Number of subjects analysed	4			
Units: day				
median (full range (min-max))				
Total IgG	6.94 (2.94 to 8.85)			
IgG Subclass (IgG 1)	3.92 (2.94 to 8.83)			
IgG Subclass (IgG 2)	3.92 (2.94 to 8.83)			
IgG Subclass (IgG 3)	2.99 (2.80 to 8.83)			
IgG Subclass (IgG 4)	3.88 (2.80 to 5.04)			

Statistical analyses

No statistical analyses for this end point

Secondary: Epoch 2: Area Under the Curve (AUC) of Total Serum Levels of IgG and IgG Subclasses (IgG1, IgG2, IgG3, and IgG4)

End point title	Epoch 2: Area Under the Curve (AUC) of Total Serum Levels of IgG and IgG Subclasses (IgG1, IgG2, IgG3, and IgG4)

End point description:

Pharmacokinetic analysis set included all enrolled participants who received investigational drug at least once, have had at least 1 evaluable serum IgG concentration, and no major protocol deviations or events that would affect the serum IgG concentration analysis results. Pharmacokinetic analysis set 2 included the analysis of PK parameters for total serum levels of IgG, for baseline-corrected total serum levels of IgG, and for IgG subclasses in Epoch 2. The number of participants analyzed are the number of participants available for analysis. 'n' signifies number of subjects analyzed at specific time point

End point type	Secondary

End point timeframe:

Pre-infusion Day at the last dose of TAK-771(Week 27 for participants with 4-Week dosing interval or Week 25 for participants with 3-Week dosing interval) and post infusion at multiple time points up to Week 31 for participants with 4-Week dosing interval

End point values	Epoch 2: TAK-771 Full Dose Treatment Period			
Subject group type	Reporting group			
Number of subjects analysed	4			
Units: grams per day/grams per kg				
geometric mean (geometric coefficient of variation)				
Total IgG, AUCtau/Dose (n=3)	767.9 (± 40.0)			
Total IgG, AUClast/Dose (n=4)	625.6 (± 55.2)			
IgG Subclass (IgG 1), AUCtau/Dose (n=4)	432.4 (± 36.2)			
IgG Subclass (IgG 1), AUClast/Dose (n=4)	370.7 (± 53.0)			
IgG Subclass (IgG 2), AUCtau/Dose (n=4)	230.4 (± 25.2)			
IgG Subclass (IgG 2), AUClast/Dose (n=4)	197.4 (± 40.5)			
IgG Subclass (IgG 3), AUCtau/Dose (n=4)	7.916 (± 165.6)			
IgG Subclass (IgG 3), AUClast/Dose (n=4)	5.449 (± 227.2)			
IgG Subclass (IgG 4), AUCtau/Dose (n=4)	15.65 (± 37.1)			
IgG Subclass (IgG 4), AUClast/Dose (n=4)	12.08 (± 53.4)			

Statistical analyses

No statistical analyses for this end point

Secondary: Epoch 2: Half-life of Total Serum Levels of IgG and IgG Subclasses (IgG1, IgG2, IgG3, and IgG4)

End point title	Epoch 2: Half-life of Total Serum Levels of IgG and IgG Subclasses (IgG1, IgG2, IgG3, and IgG4)

End point description:

Pharmacokinetic analysis set included all enrolled participants who received investigational drug at least once, have had at least 1 evaluable serum IgG concentration, and no major protocol deviations or events that would affect the serum IgG concentration analysis results. Pharmacokinetic analysis set 2 included the analysis of PK parameters for total serum levels of IgG, for baseline-corrected total serum levels of IgG, and for IgG subclasses in Epoch 2. The number of participants analyzed is the number of participant available for analysis. ‘n’ signifies number of subjects analyzed at specific time point. ‘9999’ signifies median and full range was not determined for a single participant. '99999' signifies median and full range was not estimable for two participants.

End point type	Secondary

End point timeframe:

Pre-infusion at last dose (Week 27 for participants with 4-Week dosing interval (DI) or Week 25 for participants with 3-Week DI) and post infusion at multiple time points up to Week 31 for participants with 4-Week DI and up to Week 28 with 3-Week DI

End point values	Epoch 2: TAK-771 Full Dose Treatment Period			
Subject group type	Reporting group			
Number of subjects analysed	4			
Units: day				
median (full range (min-max))				
Total IgG (n=1)	9999 (9999 to 9999)			
IgG Subclass (IgG 1) (n=3)	59.7 (40.4 to 77.9)			
IgG Subclass (IgG 2) (n=3)	49.6 (40.8 to 71.4)			
IgG Subclass (IgG 3) (n=2)	99999 (99999 to 99999)			
IgG Subclass (IgG 4) (n=3)	35.9 (35.8 to 46.3)			

Statistical analyses

No statistical analyses for this end point

Secondary: Epoch 2: Apparent Total Clearance (CL/F) of Total Serum Levels of IgG and IgG Subclasses (IgG1, IgG2, IgG3, and IgG4)

End point title	Epoch 2: Apparent Total Clearance (CL/F) of Total Serum Levels of IgG and IgG Subclasses (IgG1, IgG2, IgG3, and IgG4)

End point description:

Pharmacokinetic analysis set included all enrolled participants who received investigational drug at least once, have had at least 1 evaluable serum IgG concentration, and no major protocol deviations or events that would affect the serum IgG concentration analysis results. Pharmacokinetic analysis set 2 included the analysis of PK parameters for total serum levels of IgG, for baseline-corrected total serum levels of IgG, and for IgG subclasses in Epoch 2. The number of participants analyzed is the number of participant available for analysis. 'n' signifies number of subjects analyzed at specific time point.

End point type	Secondary

End point timeframe:

Pre-infusion at last dose (Week 27 for participants with 4-Week dosing interval (DI) or Week 25 for participants with 3-Week DI) and post infusion at multiple time points up to Week 31 for participants

End point values	Epoch 2: TAK-771 Full Dose Treatment Period			
Subject group type	Reporting group			
Number of subjects analysed	4			
Units: milliliters per day (mL/day)				
geometric mean (geometric coefficient of variation)				
Total IgG (n=3)	76.84 (± 29.4)			
IgG Subclass (IgG 1) (n=4)	117.0 (± 37.9)			
IgG Subclass (IgG 2) (n=4)	219.6 (± 36.8)			
IgG Subclass (IgG 3) (n=4)	6392 (± 176.6)			
IgG Subclass (IgG 4) (n=4)	3234 (± 58.0)			

Statistical analyses

No statistical analyses for this end point

Secondary: Epoch 2: Apparent Volume of Distribution (Vz/F) of Total Serum Levels of IgG and IgG Subclasses (IgG1, IgG2, IgG3, and IgG4)

End point title	Epoch 2: Apparent Volume of Distribution (Vz/F) of Total Serum Levels of IgG and IgG Subclasses (IgG1, IgG2, IgG3, and IgG4)

End point description:

Pharmacokinetic analysis set included all enrolled participants who received investigational drug at least once, have had at least 1 evaluable serum IgG concentration, and no major protocol deviations or events that would affect the serum IgG concentration analysis results. Pharmacokinetic analysis set 2 included the analysis of PK parameters for total serum levels of IgG, for baseline-corrected total serum levels of IgG, and for IgG subclasses in Epoch 2. Number participants analyzed are the number of participants available for analysis. 'n' signifies number of subjects analyzed at specific time point. 999 indicates that the geometric mean and geometric coefficient of variation was not determined for single participant. 9999 indicates that the geometric mean and geometric coefficient of variation was not determined for two participants.

End point type	Secondary

End point timeframe:

Pre-infusion at last dose (Week 27 for participants with 4-Week dosing interval (DI) or Week 25 for participants with 3-Week DI) and post infusion at multiple time points up to Week 31 for participants with 4-Week DI and up to Week 28 with 3-Week DI

End point values	Epoch 2: TAK-771 Full Dose Treatment Period			
Subject group type	Reporting group			
Number of subjects analysed	4			
Units: millilitre(s)				

geometric mean (geometric coefficient of variation)				
Total IgG (n=1)	999 (± 999)			
IgG Subclass (IgG 1) (n=3)	8193 (± 54.9)			
IgG Subclass (IgG 2) (n=3)	14650 (± 57.0)			
IgG Subclass (IgG 3) (n=2)	9999 (± 9999)			
IgG Subclass (IgG 4) (n=3)	165900 (± 88.3)			

Statistical analyses

No statistical analyses for this end point

Secondary: Epoch 2: Minimum Concentration (Cmin) of Total Serum Levels of IgG and IgG Subclasses (IgG1, IgG2, IgG3, and IgG4)

End point title	Epoch 2: Minimum Concentration (Cmin) of Total Serum Levels of IgG and IgG Subclasses (IgG1, IgG2, IgG3, and IgG4)

End point description:

Pharmacokinetic analysis set included all enrolled participants who received investigational drug at least once, have had at least 1 evaluable serum IgG concentration, and no major protocol deviations or events that would affect the serum IgG concentration analysis results. Pharmacokinetic analysis set 2 included the analysis of PK parameters for total serum levels of IgG, for baseline-corrected total serum levels of IgG, and for IgG subclasses in Epoch 2. The number of participants analyzed are the number of participants available for analysis. 'n' signifies number of subjects analyzed at specific time point. 999 indicates that the geometric mean and geometric coefficient of variation was not estimable for single participant.

End point type	Secondary

End point timeframe:

Pre-infusion at last dose (Week 27 for participants with 4-Week dosing interval (DI) or Week 25 for participants with 3-Week DI) and post infusion at multiple time points up to Week 31 for participants with 4-Week DI and up to Week 28 with 3-Week DI

End point values	Epoch 2: TAK-771 Full Dose Treatment Period			
Subject group type	Reporting group			
Number of subjects analysed	4			
Units: gram(s)/litre				
geometric mean (geometric coefficient of variation)				
Total IgG (n=4)	9.347 (± 17.9)			
IgG Subclass (IgG 1) (n=4)	5.479 (± 10.7)			
IgG Subclass (IgG 2) (n=4)	2.941 (± 19.8)			
IgG Subclass (IgG 3) (n=1)	999 (± 999)			
IgG Subclass (IgG 4) (n=3)	0.2255 (± 8.4)			

Statistical analyses

No statistical analyses for this end point

Secondary: Epoch 2: Serum Trough Levels of IgG Subclasses (IgG1, IgG2, IgG3, and IgG4) After Administration of TAK-771

End point title	Epoch 2: Serum Trough Levels of IgG Subclasses (IgG1, IgG2, IgG3, and IgG4) After Administration of TAK-771

End point description:

Pharmacokinetic analysis set included all enrolled participants who received investigational drug at least once, have had at least 1 evaluable serum IgG concentration, and no major protocol deviations or events that would affect the serum IgG concentration analysis results. Pharmacokinetic analysis set 2 included the analysis of PK parameters for total serum levels of IgG, for baseline-corrected total serum levels of IgG, and for IgG subclasses in Epoch 2. Number analyzed are the number of participants with data available for analysis at the given time point. 'n' signifies number of subjects analyzed at specific time point. 999 indicates that no geometric mean and geometric coefficient of variation were calculated due to 0 subjects in that particular arm at specific time point. 9999 indicates that the geometric coefficient of variation could not determined for single participant.

End point type	Secondary

End point timeframe:

4-Week dosing interval (Week 7, Week 11, Week 15, Week 19, Week 23, Week 27, and Week 31); 3-Week dosing interval (Week 4, week 7, Week 10, Week 16, Week 19, Week 22, Week 25, and Week 28)

End point values	Epoch 2: TAK-771 Full Dose Treatment Period			
Subject group type	Reporting group			
Number of subjects analysed	16			
Units: gram(s)/litre				
geometric mean (geometric coefficient of variation)				
IgG 1, Week 7, 4-Week Interval (n=12)	5.478 (± 12.1)			
IgG 1, Week 11, 4-Week Interval (n=12)	5.106 (± 15.6)			
IgG 1, Week 15, 4-Week Interval (n=11)	4.987 (± 11.9)			
IgG 1, Week 19, 4-Week Interval (n=11)	5.063 (± 10.1)			
IgG 1, Week 23, 4-Week Interval (n=11)	4.873 (± 10.1)			
IgG 1, Week 27, 4-Week Interval (n=11)	5.066 (± 16.6)			
IgG 1, Week 31, 4-Week Interval (n=11)	5.104 (± 14.0)			
IgG 2, Week 7, 4-Week Interval (n=12)	3.147 (± 20.1)			
IgG 2, Week 11, 4-Week Interval (n=12)	2.931 (± 15.0)			
IgG 2, Week 15, 4-Week Interval (n=11)	2.912 (± 13.5)			
IgG 2, Week 19, 4-Week Interval (n=11)	3.043 (± 16.5)			
IgG 2, Week 23, 4-Week Interval (n=11)	2.976 (± 16.7)			
IgG 2, Week 27, 4-Week Interval (n=11)	3.078 (± 15.5)			
IgG 2, Week 31, 4-Week Interval (n=11)	3.091 (± 18.3)			

IgG 3, Week 7, 4-Week Interval (n=1)	0.1380 (± 9999)			
IgG 3, Week 11, 4-Week Interval (n=1)	0.1780 (± 9999)			
IgG 3, Week 15, 4-Week Interval (n=1)	0.1390 (± 9999)			
IgG 3, Week 19, 4-Week Interval (n=0)	999 (± 999)			
IgG 3, Week 23, 4-Week Interval (n=0)	999 (± 999)			
IgG 3, Week 27, 4-Week Interval (n=1)	0.2280 (± 9999)			
IgG 3, Week 31, 4-Week Interval (n=0)	999 (± 999)			
IgG 4, Week 7, 4-Week Interval (n=12)	0.1933 (± 15.9)			
IgG 4, Week 11, 4-Week Interval (n=12)	0.1965 (± 22.7)			
IgG 4, Week 15, 4-Week Interval (n=11)	0.2020 (± 16.8)			
IgG 4, Week 19, 4-Week Interval (n=11)	0.2057 (± 16.1)			
IgG 4, Week 23, 4-Week Interval (n=11)	0.2054 (± 14.6)			
IgG 4, Week 27, 4-Week Interval (n=11)	0.2228 (± 24.6)			
IgG 4, Week 31, 4-Week Interval (n=11)	0.2265 (± 25.6)			
IgG 1, Week 4, 3-Week Interval (n=2)	9.699 (± 55.6)			
IgG 1, Week 7, 3-Week Interval (n=2)	8.906 (± 67.0)			
IgG 1, Week 10, 3-Week Interval (n=2)	8.661 (± 66.7)			
IgG 1, Week 13, 3-Week Interval (n=0)	9999 (± 9999)			
IgG 1, Week 16, 3-Week Interval (n=2)	8.860 (± 68.0)			
IgG 1, Week 19, 3-Week Interval (n=2)	8.687 (± 68.9)			
IgG 1, Week 22, 3-Week Interval (n=2)	8.641 (± 64.3)			
IgG 1, Week 25, 3-Week Interval (n=2)	8.573 (± 82.9)			
IgG 1, Week 28, 3-Week Interval (n=2)	8.845 (± 68.3)			
IgG 2, Week 4, 3-Week Interval (n=2)	1.936 (± 105.6)			
IgG 2, Week 7, 3-Week Interval (n=2)	1.859 (± 89.7)			
IgG 2, Week 10, 3-Week Interval (n=2)	1.852 (± 83.0)			
IgG 2, Week 13, 3-Week Interval (n=0)	9999 (± 9999)			
IgG 2, Week 16, 3-Week Interval (n=2)	1.964 (± 82.5)			
IgG 2, Week 19, 3-Week Interval (n=2)	1.944 (± 82.1)			
IgG 2, Week 22, 3-Week Interval (n=2)	1.957 (± 89.1)			
IgG 2, Week 25, 3-Week Interval (n=2)	1.910 (± 73.5)			
IgG 2, Week 28, 3-Week Interval (n=2)	1.948 (± 88.1)			
IgG 3, Week 4, 3-Week Interval (n=0)	9999 (± 9999)			
IgG 3, Week 7, 3-Week Interval (n=0)	9999 (± 9999)			
IgG 3, Week 10, 3-Week Interval (n=0)	9999 (± 9999)			
IgG 3, Week 13, 3-Week Interval (n=0)	9999 (± 9999)			
IgG 3, Week 16, 3-Week Interval (n=0)	9999 (± 9999)			
IgG 3, Week 19, 3-Week Interval (n=0)	9999 (± 9999)			
IgG 3, Week 22, 3-Week Interval (n=0)	9999 (± 9999)			
IgG 3, Week 25, 3-Week Interval (n=0)	9999 (± 9999)			
IgG 3, Week 28, 3-Week Interval (n=0)	9999 (± 9999)			
IgG 4, Week 4, 3-Week Interval (n=1)	0.1680 (± 999)			
IgG 4, Week 7, 3-Week Interval (n=1)	0.1680 (± 999)			
IgG 4, Week 10, 3-Week Interval (n=1)	0.2010 (± 999)			

IgG 4, Week 13, 3-Week Interval (n=0)	9999 (± 9999)			
IgG 4, Week 16, 3-Week Interval (n=1)	0.2280 (± 999)			
IgG 4, Week 19, 3-Week Interval (n=1)	0.2120 (± 999)			
IgG 4, Week 22, 3-Week Interval (n=1)	0.2230 (± 999)			
IgG 4, Week 25, 3-Week Interval (n=1)	0.2060 (± 999)			
IgG 4, Week 28, 3-Week Interval (n=1)	0.2390 (± 999)			

Statistical analyses

No statistical analyses for this end point

Secondary: Epoch 1 and 2: Trough Levels of Anti-Clostridium Tetani Toxoid Antibody After Administration of TAK-771

End point title	Epoch 1 and 2: Trough Levels of Anti-Clostridium Tetani Toxoid Antibody After Administration of TAK-771

End point description:

Pharmacokinetic Analysis Set included all enrolled participants who received investigational drug at least once, have had at least 1 evaluable serum IgG concentration, and no major protocol deviations or events that would affect the serum IgG concentration analysis results. Pharmacokinetic Analysis Set included the analysis of total serum IgG trough levels for total serum levels of IgG and IgG subclasses. Number analyzed are the number of participants with data available for analysis at given timepoint. 'n' signifies number of subjects analyzed at specific time point.

End point type	Secondary

End point timeframe:

From Week 1, up to end of trial (EOS: Week 31 for participants with 4-Week dosing interval or Week 28 for participants with 3-Week dosing interval)

End point values	Epoch 1 and 2			
Subject group type	Subject analysis set			
Number of subjects analysed	16			
Units: international unit(s)/milligram (IU/mL)				
geometric mean (geometric coefficient of variation)				
Week 1 (n=16)	1.334 (± 84.4)			
End of Trial (EOS) (n=14)	1.578 (± 68.4)			

Statistical analyses

No statistical analyses for this end point

Secondary: Epoch 1 and 2: Trough Levels of Anti-HBV Antibody After Administration of TAK-771

End point title	Epoch 1 and 2: Trough Levels of Anti-HBV Antibody After Administration of TAK-771

End point description:

Pharmacokinetic Analysis Set included all enrolled participants who received investigational drug at least

once, have had at least 1 evaluable serum IgG concentration, and no major protocol deviations or events that would affect the serum IgG concentration analysis results. Pharmacokinetic Analysis Set included the analysis of total serum IgG trough levels for total serum levels of IgG and IgG subclasses. Number analyzed are the number of participants with data available for analysis at given timepoint. 'n' signifies number of subjects analyzed at specific time point.

End point type	Secondary

End point timeframe:

From Week 1, up to end of trial (EOS: Week 31 for participants with 4-Week dosing interval or Week 28 for participants with 3-Week dosing interval)

End point values	Epoch 1 and 2			
Subject group type	Subject analysis set			
Number of subjects analysed	16			
Units: milliinternational unit(s)/milliliter				
geometric mean (geometric coefficient of variation)				
Week 1 (n=16) End of Trial (EOS) (n=14)	278.38 (± 125.0) 383.37 (± 57.7)			

Statistical analyses

No statistical analyses for this end point

Secondary: Epoch 1 and 2: Trough Levels of Anti-HIB Antibody After Administration of TAK-771

End point title	Epoch 1 and 2: Trough Levels of Anti-HIB Antibody After Administration of TAK-771

End point description:

Pharmacokinetic Analysis Set included all enrolled participants who received investigational drug at least once, have had at least 1 evaluable serum IgG concentration, and no major protocol deviations or events that would affect the serum IgG concentration analysis results. Pharmacokinetic Analysis Set included the analysis of total serum IgG trough levels for total serum levels of IgG and IgG subclasses. Number analyzed are the number of participants with data available for analysis at given timepoint. 'n' signifies number of subjects analyzed at specific time point.

End point type	Secondary

End point timeframe:

From Week 1, up to end of trial (EOS: Week 31 for participants with 4-Week dosing interval or Week 28 for participants with 3-Week dosing interval).

End point values	Epoch 1 and 2			
Subject group type	Subject analysis set			
Number of subjects analysed	16			
Units: microgram(s)/millilitre ug/mL				
geometric mean (geometric coefficient of variation)				
Week 1 (n=16)	1.958 (± 45.7)			

End of Trial (EOS) (n=14)	1.519 (± 46.8)			

Statistical analyses

No statistical analyses for this end point

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

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

End point description:

TEAEs are defined as Adverse events (AEs) with onset after date-time of first dose of Investigational product (IP), or medical conditions present prior to the start of IP but increased in severity or relationship after date-time of first dose of IP. Safety analysis set included all enrolled participants who received investigational drug at least once. Epoch 2 Safety Analysis Set included all participants who received investigational drug at least once in Epoch 2.

End point type	Secondary

End point timeframe:

From Week 1 up to Week 31 for Participants with 4-Week Dosing Interval or up to Week 28 for Participants with 3-Week Dosing Interval

End point values	Epoch 1: TAK-771 Ramp up Period	Epoch 2: TAK-771 Full Dose Treatment Period		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	16	16		
Units: percentage of participants				
number (not applicable)	81.3	93.8		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants With TAK-771-Related and TAK-771-Non-Related TEAEs

End point title	Percentage of Participants With TAK-771-Related and TAK-771-Non-Related TEAEs

End point description:

TEAEs are defined as AEs with onset after date-time of first dose of IP, or medical conditions present prior to the start of IP but increased in severity or relationship after date-time of first dose of IP. Safety analysis set included all enrolled participants who received investigational drug at least once. Epoch 2 Safety Analysis Set included all participants who received investigational drug at least once in Epoch 2.

End point type	Secondary

End point timeframe:

From Week 1 up to Week 31 for Participants with 4-Week Dosing Interval or up to Week 28 for

End point values	Epoch 1: TAK-771 Ramp up Period	Epoch 2: TAK-771 Full Dose Treatment Period		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	16	16		
Units: Percentage of participants				
number (not applicable)				
TEAE Related	56.3	68.8		
TEAE Non-Related	62.5	81.3		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants With Serious and Non-serious TEAEs

End point title	Percentage of Participants With Serious and Non-serious TEAEs

End point description:

TEAEs are defined as AEs with onset after date-time of first dose of IP, or medical conditions present prior to the start of IP but increased in severity or relationship after date-time of first dose of IP. Serious TEAE=any untoward clinical manifestation of signs, symptoms, outcomes (related to IP or not) at any dose: results in death, was life-threatening, requires inpatient/prolongation of hospitalization, resulted in persistent/significant disability/incapacity, congenital abnormality/birth defect, important medical event. AESI=investigator-reported hypersensitivity reactions, events of disordered coagulation as bleeding/hypercoagulable AESI. Safety analysis set included all enrolled participants who received investigational drug at least once. Epoch 2 Safety Analysis Set included all participants who received investigational drug at least once in Epoch 2.

End point type	Secondary

End point timeframe:

From Week 1 up to Week 31 for Participants with 4-Week Dosing Interval or up to Week 28 for Participants with 3-Week Dosing Interval

End point values	Epoch 1: TAK-771 Ramp up Period	Epoch 2: TAK-771 Full Dose Treatment Period		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	16	16		
Units: Percentage of participants				
number (not applicable)				
Serious TEAEs	6.3	6.3		
Non-serious TEAEs	81.3	93.8		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants With Severe TEAEs

End point title	Percentage of Participants With Severe TEAEs

End point description:

Safety analysis set included all enrolled participants who received investigational drug at least once. Epoch 2 Safety Analysis Set included all participants who received investigational drug at least once in Epoch 2. 999 indicates that the percentage of participants with severe TEAEs was 0.

End point type	Secondary

End point timeframe:

From Week 1 up to Week 31 for Participants with 4-Week Dosing Interval or up to Week 28 for Participants with 3-Week Dosing Interval

End point values	Epoch 1: TAK-771 Ramp up Period	Epoch 2: TAK-771 Full Dose Treatment Period		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	16	16		
Units: Percentage of participants				
number (not applicable)	999	6.3		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants With Local and Systemic TEAEs

End point title	Percentage of Participants With Local and Systemic TEAEs

End point description:

Safety analysis set included all enrolled participants who received investigational drug at least once. Epoch 2 Safety Analysis Set included all participants who received investigational drug at least once in Epoch 2.

End point type	Secondary

End point timeframe:

From Week 1 up to Week 31 for Participants with 4-Week Dosing Interval or up to Week 28 for Participants with 3-Week Dosing Interval

End point values	Epoch 1: TAK-771 Ramp up Period	Epoch 2: TAK-771 Full Dose Treatment Period		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	16	16		
Units: Percentage of participants				
number (not applicable)				

Local TEAEs	43.8	43.8		
Systemic TEAEs	75.0	87.5		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants With TEAEs Leading to Premature Discontinuation From Study

End point title	Percentage of Participants With TEAEs Leading to Premature Discontinuation From Study

End point description:

Safety analysis set included all enrolled participants who received investigational drug at least once. Epoch 2 Safety Analysis Set included all participants who received investigational drug at least once in Epoch 2. 999 indicates that the percentage of participants with TEAEs leading to discontinuation from the study were 0.

End point type	Secondary

End point timeframe:

From Week 1 up to Week 31 for Participants with 4-Week Dosing Interval or up to Week 28 for Participants with 3-Week Dosing Interval

End point values	Epoch 1: TAK-771 Ramp up Period	Epoch 2: TAK-771 Full Dose Treatment Period		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	16	16		
Units: Percentage of participants				
number (not applicable)	999	999		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants With Infusion-associated TEAEs

End point title	Percentage of Participants With Infusion-associated TEAEs

End point description:

Safety analysis set included all enrolled participants who received investigational drug at least once. Epoch 2 Safety Analysis Set included all participants who received investigational drug at least once in Epoch 2.

End point type	Secondary

End point timeframe:

From Week 1 up to Week 31 for Participants with 4-Week Dosing Interval or up to Week 28 for Participants with 3-Week Dosing Interval

End point values	Epoch 1: TAK-771 Ramp up Period	Epoch 2: TAK-771 Full Dose Treatment Period		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	16	16		
Units: Percentage of participants				
number (not applicable)	37.5	50.0		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants With Clinically Significant Changes in Clinical Laboratory Parameters Recorded as TEAEs

End point title	Percentage of Participants With Clinically Significant Changes in Clinical Laboratory Parameters Recorded as TEAEs

End point description:

Safety analysis set included all enrolled participants who received investigational drug at least once. Epoch 2 Safety Analysis Set included all participants who received investigational drug at least once in Epoch 2. 999 indicates that the percentage of participants with clinically significant changes in clinical laboratory parameters recorded as TEAEs were 0

End point type	Secondary

End point timeframe:

From Week 1 up to Week 31 for Participants with 4-Week Dosing Interval or up to Week 28 for Participants with 3-Week Dosing Interval

End point values	Epoch 1: TAK-771 Ramp up Period	Epoch 2: TAK-771 Full Dose Treatment Period		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	16	16		
Units: Percentage of participants				
number (not applicable)	999	999		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants With Clinically Significant Changes in Vital Signs and Body Weight Recorded as TEAEs

End point title	Percentage of Participants With Clinically Significant Changes in Vital Signs and Body Weight Recorded as TEAEs

End point description:

Safety analysis set included all enrolled participants who received investigational drug at least once. Epoch 2 Safety Analysis Set included all participants who received investigational drug at least once in Epoch 2. 999 indicates that the percentage of participants with clinically significant changes in vital signs and body weight recorded as TEAEs was 0.

End point type	Secondary

End point timeframe:

From Week 1 up to Week 31 for Participants with 4-Week Dosing Interval or up to Week 28 for Participants with 3-Week Dosing Interval

End point values	Epoch 1: TAK-771 Ramp up Period	Epoch 2: TAK-771 Full Dose Treatment Period		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	16	16		
Units: Percentage of participants				
number (not applicable)	999	999		

Statistical analyses

No statistical analyses for this end point

Secondary: Epoch 2: Percentage of Participants Who Develop Anti-rHuPH20 Binding Antibody Titers of Greater Than or Equal to 1:160

End point title	Epoch 2: Percentage of Participants Who Develop Anti-rHuPH20 Binding Antibody Titers of Greater Than or Equal to 1:160

End point description:

Epoch 2 Safety Analysis Set included all participants who received investigational drug at least once in Epoch 2. 999 indicates that the percentage of participants who develop Anti-rHuPH20 Binding Antibody titers of greater than or equal to 1:160 was 0.

End point type	Secondary

End point timeframe:

4-Week Dosing Interval (Week 7, Week 19, and Week 31); 3-Week Dosing Interval (Week 4, Week 16, and Week 28)

End point values	Epoch 2: TAK-771 Full Dose Treatment Period			
Subject group type	Reporting group			
Number of subjects analysed	16			
Units: Percentage of participants				
number (not applicable)	999			

Statistical analyses

No statistical analyses for this end point

Secondary: Epoch 2: Percentage of Participants Who Develop Neutralizing Antibodies to rHuPH20

End point title	Epoch 2: Percentage of Participants Who Develop Neutralizing Antibodies to rHuPH20

End point description:

Epoch 2 Safety Analysis Set included all participants who received investigational drug at least once in Epoch 2. 999 indicates that the percentage of participants who develop neutralizing antibodies to rHuPH20 was 0.

End point type	Secondary

End point timeframe:

4-Week Dosing Interval (Week 7, Week 19, and Week 31); 3-Week Dosing Interval (Week 4, Week 16, and Week 28)

End point values	Epoch 2: TAK-771 Full Dose Treatment Period			
Subject group type	Reporting group			
Number of subjects analysed	16			
Units: Percentage of participants				
number (not applicable)	999			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants Who Experienced Tolerability Events Related to the Infusion of TAK-771

End point title	Percentage of Participants Who Experienced Tolerability Events Related to the Infusion of TAK-771

End point description:

Tolerability events is defined as a case that the infusion rate is reduced, or that the infusion is interrupted or stopped, due to a TEAE related to TAK-771 infusion. Safety Analysis Set included all enrolled participants who received investigational drug at least once. Epoch 2 Safety Analysis Set included all participants who received investigational drug at least once in Epoch 2. 999 indicates that the percentage of who experienced tolerability events related to the infusion of TAK-771 was 0.

End point type	Secondary

End point timeframe:

From Week 1 up to Week 31 for Participants with 4-Week Dosing Interval or up to Week 28 for Participants with 3-Week Dosing Interval

End point values	Epoch 1: TAK-771 Ramp up Period	Epoch 2: TAK-771 Full Dose Treatment Period		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	16	16		
Units: Percentage of participants				
number (not applicable)	999	999		

Statistical analyses

No statistical analyses for this end point

Secondary: Epoch 1: Number of Weeks to Reach Final Dose Interval (3 Weeks or 4 Weeks)

End point title	Epoch 1: Number of Weeks to Reach Final Dose Interval (3 Weeks or 4 Weeks)

End point description:

The number of weeks to reach final dose interval is defined as treatment duration of Epoch 1. Safety Analysis Set included all enrolled participants who received investigational drug at least once.

End point type	Secondary

End point timeframe:

Up to Week 4 for Participants with 4-Week Dosing Interval or Up to Week 3 for Participants with 3-Week Dosing Interval

End point values	Epoch 1: TAK-771 Ramp up Period			
Subject group type	Reporting group			
Number of subjects analysed	16			
Units: week				
median (full range (min-max))	6.00 (3.0 to 6.9)			

Statistical analyses

No statistical analyses for this end point

Secondary: Epoch 2: Percentage of Participants Who Achieve a Treatment Interval of 3 or 4 Weeks

End point title	Epoch 2: Percentage of Participants Who Achieve a Treatment Interval of 3 or 4 Weeks

End point description:

Epoch 2 Safety Analysis Set included all participants who received investigational drug at least once in Epoch 2.

End point type	Secondary

End point timeframe:

Up to Week 31 for Participants with 4-Week Dosing Interval or Up to Week 28 for Participants with 3-Week Dosing Interval

End point values	Epoch 2: TAK-771 Full Dose Treatment Period			
Subject group type	Reporting group			
Number of subjects analysed	16			
Units: Percentage of participants				
number (not applicable)	100			

Statistical analyses

No statistical analyses for this end point

Secondary: Epoch 2: Percentage of Participants Who Maintain a Treatment Interval of 3 or 4 Weeks

End point title	Epoch 2: Percentage of Participants Who Maintain a Treatment Interval of 3 or 4 Weeks

End point description:

Epoch 2 Safety Analysis Set included all participants who received investigational drug at least once in Epoch 2.

End point type	Secondary

End point timeframe:

Up to Week 31 for Participants with 4-Week Dosing Interval or Up to Week 28 for Participants with 3-Week Dosing Interval

End point values	Epoch 2: TAK-771 Full Dose Treatment Period			
Subject group type	Reporting group			
Number of subjects analysed	16			
Units: Percentage of participants				
number (not applicable)	100			

Statistical analyses

No statistical analyses for this end point

Secondary: Annual Rate of Validated Acute Serious Bacterial Infections (ASBIs)

End point title	Annual Rate of Validated Acute Serious Bacterial Infections

	(ASBIs)

End point description:

The annual rate of validated ASBIs is calculated as the mean number of ASBIs per participant per year. The data was collected using Poisson estimate. Point-estimate and 99% confidence bound (i.e., the upper bound of two-sided 98% confidence interval) were calculated using a Poisson model with subject-year in study as the offset variable. Full Analysis Set included all enrolled participants who received investigational drug at least once. 999 indicates that the annual rate of validated ASBIs was 0.

End point type	Secondary

End point timeframe:

From Week 1 up to Week 31 for Participants with 4-Week Dosing Interval or up to Week 28 for Participants with 3-Week Dosing Interval

End point values	Epoch 1 and 2			
Subject group type	Subject analysis set			
Number of subjects analysed	16			
Units: ASBIs/person-year				
number (not applicable)	999			

Statistical analyses

No statistical analyses for this end point

Secondary: Annual Rate of All Infections Per Participant

End point title	Annual Rate of All Infections Per Participant

End point description:

The annual rate of all infections is calculated as the mean number of infections per participant per year. Full Analysis Set included all enrolled participants who received investigational drug at least once.

End point type	Secondary

End point timeframe:

From Week 1 up to Week 31 for Participants with 4-Week Dosing Interval or up to Week 28 for Participants with 3-Week Dosing Interval

End point values	Epoch 1 and 2			
Subject group type	Subject analysis set			
Number of subjects analysed	16			
Units: Infections/person-year				
number (confidence interval 95%)	2.74 (1.40 to 4.74)			

Statistical analyses

No statistical analyses for this end point

Secondary: Healthcare Resource Utilization: Days Not Able To Attend School/Work or To Perform Normal Daily Activities Due to Illness/Infection

End point title	Healthcare Resource Utilization: Days Not Able To Attend School/Work or To Perform Normal Daily Activities Due to Illness/Infection

End point description:

Full Analysis Set included all enrolled participants who received investigational drug at least once. 99999 indicates that the median and minimum (full range) were 0.

End point type	Secondary

End point timeframe:

From Week 1 up to Week 31 for Participants with 4-Week Dosing Interval or up to Week 28 for Participants with 3-Week Dosing Interval

End point values	Epoch 1 and 2			
Subject group type	Subject analysis set			
Number of subjects analysed	16			
Units: Number of days				
median (full range (min-max))	0 (0 to 26.8)			

Statistical analyses

No statistical analyses for this end point

Secondary: Healthcare Resource Utilization: Days on Antibiotics

End point title	Healthcare Resource Utilization: Days on Antibiotics

End point description:

Full Analysis Set included all enrolled participants who received investigational drug at least once. 99999 indicates that the median and minimum (full range) were 0.

End point type	Secondary

End point timeframe:

From Week 1 up to Week 31 for Participants with 4-Week Dosing Interval or up to Week 28 for Participants with 3-Week Dosing Interval

End point values	Epoch 1 and 2			
Subject group type	Subject analysis set			
Number of subjects analysed	16			
Units: number of days				
median (full range (min-max))	0 (0 to 40.2)			

Statistical analyses

No statistical analyses for this end point

Secondary: Healthcare Resource Utilization: Number of Hospitalizations Due to Illness/Infection

End point title	Healthcare Resource Utilization: Number of Hospitalizations Due to Illness/Infection

End point description:

Full Analysis Set included all enrolled participants who received investigational drug at least once.

End point type	Secondary

End point timeframe:

From Week 1 up to Week 31 for Participants with 4-Week Dosing Interval or up to Week 28 for Participants with 3-Week Dosing Interval

End point values	Epoch 1 and 2			
Subject group type	Subject analysis set			
Number of subjects analysed	16			
Units: hospitalizations per year				
arithmetic mean (standard deviation)	0.22 (± 0.591)			

Statistical analyses

No statistical analyses for this end point

Secondary: Healthcare Resource Utilization: Length of Stay in Days of Hospitalizations Due to Illness/Infection

End point title	Healthcare Resource Utilization: Length of Stay in Days of Hospitalizations Due to Illness/Infection

End point description:

Full Analysis Set included all enrolled participants who received investigational drug at least once. 99999 indicates that the median and the minimum (full range) were 0.

End point type	Secondary

End point timeframe:

From Week 1 up to Week 31 for Participants with 4-Week Dosing Interval or up to Week 28 for Participants with 3-Week Dosing Interval

End point values	Epoch 1 and 2			
Subject group type	Subject analysis set			
Number of subjects analysed	16			
Units: hospitalization days per year				
median (full range (min-max))	0 (0 to 10.5)			

Statistical analyses

No statistical analyses for this end point

Secondary: Healthcare Resource Utilization: Number of Acute (Urgent or Unscheduled) Physician Visits Due to Illness/Infection

End point title	Healthcare Resource Utilization: Number of Acute (Urgent or Unscheduled) Physician Visits Due to Illness/Infection

End point description:

Full Analysis Set included all enrolled participants who received investigational drug at least once. 99999 indicates that the minimum (full range) was 0.

End point type	Secondary

End point timeframe:

From Week 1 up to Week 31 for Participants with 4-Week Dosing Interval or up to Week 28 for Participants with 3-Week Dosing Interval

End point values	Epoch 1 and 2			
Subject group type	Subject analysis set			
Number of subjects analysed	16			
Units: number of visits				
median (full range (min-max))	1.74 (0 to 11.7)			

Statistical analyses

No statistical analyses for this end point

Secondary: Infusion Parameters in Epoch 2: Number of Infusion Sites Per Infusion

End point title	Infusion Parameters in Epoch 2: Number of Infusion Sites Per Infusion

End point description:

Total number of infusion sites injected in Epoch 2 / Total number of infusions administered in Epoch 2. Epoch 2 Full Analysis Set included all participants who received investigational drug at least once in Epoch 2.

End point type	Secondary

End point timeframe:

From Week 7 up to Week 31 for Participants with 4-Week Dosing Interval or From Week 4 up to Week 28 for Participants with 3-Week Dosing Interval

End point values	Epoch 2: TAK-771 Full Dose Treatment Period			
Subject group type	Reporting group			
Number of subjects analysed	16			
Units: infusion sites per infusion				
arithmetic mean (standard deviation)	1.77 (± 0.394)			

Statistical analyses

No statistical analyses for this end point

Secondary: Infusion Parameters in Epoch 2: Number of Infusion Sites Per Month

End point title	Infusion Parameters in Epoch 2: Number of Infusion Sites Per Month

End point description:

Total number of infusion sites injected in Epoch 2 / (duration of Epoch 2 / 30.4375), where duration of Epoch 2 is calculated as the end date of the Epoch 2 – the start date of the Epoch 2 + 1. Epoch 2 Full Analysis Set included all participants who received investigational drug at least once in Epoch 2.

End point type	Secondary

End point timeframe:

From Week 7 up to Week 31 for Participants with 4-Week Dosing Interval or From Week 4 up to Week 28 for Participants with 3-Week Dosing Interval

End point values	Epoch 2: TAK-771 Full Dose Treatment Period			
Subject group type	Reporting group			
Number of subjects analysed	16			
Units: infusion sites per month				
arithmetic mean (standard deviation)	2.02 (± 0.514)			

Statistical analyses

No statistical analyses for this end point

Secondary: Infusion Parameters in Epoch 2: Duration of Individual Infusions

End point title	Infusion Parameters in Epoch 2: Duration of Individual Infusions

End point description:

End date and time of infusion in Epoch 2 – Start date and time of infusion in Epoch 2, for each infusion per participant. Epoch 2 Full Analysis Set included all participants who received investigational drug at least once in Epoch 2.

End point type	Secondary

End point timeframe:

From Week 7 up to Week 31 for Participants with 4-Week Dosing Interval or From Week 4 up to Week 28 for Participants with 3-Week Dosing Interval

End point values	Epoch 2: TAK-771 Full Dose Treatment Period			
Subject group type	Reporting group			
Number of subjects analysed	16			
Units: minute				
median (full range (min-max))	74.0 (18 to 207)			

Statistical analyses

No statistical analyses for this end point

Secondary: Infusion Parameters in Epoch 2: Maximum Infusion Rate Per Site

End point title	Infusion Parameters in Epoch 2: Maximum Infusion Rate Per Site

End point description:

Maximum Infusion Rate results from CRF / number of infusion sites/body.. Epoch 2 Full Analysis Set included all participants who received investigational drug at least once in Epoch 2.

End point type	Secondary

End point timeframe:

From Week 7 up to Week 31 for Participants with 4-Week Dosing Interval or From Week 4 up to Week 28 for Participants with 3-Week Dosing Interval

End point values	Epoch 2: TAK-771 Full Dose Treatment Period			
Subject group type	Reporting group			
Number of subjects analysed	16			
Units: mL/h				
arithmetic mean (standard deviation)	222.3 (± 83.77)			

Statistical analyses

No statistical analyses for this end point

Secondary: Infusion Parameters in Epoch 2: Infusion Volume Per Site

End point title	Infusion Parameters in Epoch 2: Infusion Volume Per Site

End point description:

Infusion Volume per Site is scheduled Dose results from CRF / number of infusion sites/body. Epoch 2 Full Analysis Set included all participants who received investigational drug at least once in Epoch 2.

Number analyzed are the number of participants with data available for analysis at given timepoint.

End point type	Secondary

End point timeframe:

From Week 7 up to Week 31 for Participants with 4-Week Dosing Interval or From Week 4 up to Week 28 for Participants with 3-Week Dosing Interval

End point values	Epoch 2: TAK-771 Full Dose Treatment Period			
Subject group type	Reporting group			
Number of subjects analysed	16			
Units: millilitre(s)				
arithmetic mean (standard deviation)	117.3 (± 77.73)			

Statistical analyses

No statistical analyses for this end point

Secondary: Quality of Life (QOL): Pediatric Quality of Life Inventory (PEDS-QL)

End point title	Quality of Life (QOL): Pediatric Quality of Life Inventory (PEDS-QL)

End point description:

PEDS-QL is generic Health-Related Quality of Life (HR QoL) instrument designed specifically for a pediatric population. It captures following domains: general health/activities, feelings/emotional, social functioning, school functioning. In this study, 2-7 years (parent as observer), 8-13 years (participant as observer) for PEDS-QL health questionnaire was analyzed. Higher scores indicate better quality of life (QOL) for all domains of the PEDS-QL. This modular instrument uses 5-point scale: 0 (never) to 4 (almost always). Items are reversed scored and linearly transformed to 0-100 scale as follows: 0=100, 1=75, 2=50, 3=25, 4=0. Four dimensions (physical, emotional, social, & school functioning) are scored. Full Analysis Set: all enrolled participants who received investigational drug at least once. 'n' signifies number of participants analyzed at specific time point and '9999' signifies SD was not estimable for single participant. CFB signifies change from baseline.

End point type	Secondary

End point timeframe:

4-Week Dosing Interval (Week 1, Week 19, and Week 31); 3-Week Dosing Interval (Week 1, Week 16, and Week 28)

End point values	Epoch 1 and 2			
Subject group type	Subject analysis set			
Number of subjects analysed	16			
Units: score on a scale				
arithmetic mean (standard deviation)				
Week 1, 2-7 years, 4-week interval (n=1)	93.48 (± 9999)			
Week 1, 2-7 years, 3-week interval (n=1)	76.09 (± 9999)			

Week 1, 8-13 years, 4-week interval (n=3)	77.17 (± 18.091)			
CFB (EOS/ET), 2-7 years, 4-week interval (n=1)	2.17 (± 9999)			
CFB (EOS/ET), 2-7 years, 3-week interval (n=1)	11.96 (± 9999)			
CFB (EOS/ET), 8-13 years, 4-week interval (n=2)	11.41 (± 3.843)			

Statistical analyses

No statistical analyses for this end point

Secondary: QOL: Short Form-36 Health Survey Version 2 (SF-36 v2)

End point title	QOL: Short Form-36 Health Survey Version 2 (SF-36 v2)

End point description:

SF-36 is a generic quality-of-life instrument used to assess Health-Related Quality of Life (HR QoL) of participants (pts). In study, ≥14 years (yrs) (pt as observer) for SF-36 health questionnaire was analyzed. Generic instruments are used in general populations to assess a wide range of domains applicable to variety of health states, conditions, and diseases. SF-36 consists of 36 items that are aggregated into 8 multi-item scales (physical functioning, role - physical, bodily pain, general health, vitality, social functioning, role - emotional, and mental health), with scores ranging from 0-100. Higher scores=better HR QoL. Epoch 2 Full Analysis Set: all pts who received investigational drug at least once in Epoch 2. Number analyzed: number of pts with data available for analysis at given timepoint. PCS: Physical component summary, MCS: Mental component summary, RCS: Role/social component summary. Change from baseline (CFB). Week (wk). Interval (int). (-) = decline

End point type	Secondary

End point timeframe:

4-Week Dosing Interval (Week 1, Week 19, and Week 31); 3-Week Dosing Interval (Week 1, Week 16, and Week 28)

End point values	Epoch 1 and 2			
Subject group type	Subject analysis set			
Number of subjects analysed	16			
Units: score on a scale				
arithmetic mean (standard deviation)				
Week 1, ≥14 yrs, PCS score, 4-week interval (n=6)	51.85 (± 3.458)			
Week 1, ≥14 yrs, PCS score, 3-week interval (n=2)	53.30 (± 2.546)			
Week 1, ≥14 yrs, MCS score, 4-week interval (n=6)	51.38 (± 14.060)			
Week 1, ≥14 yrs, MCS score, 3-week interval (n=2)	59.90 (± 10.465)			
Week 1, ≥14 yrs, RCS score, 4-week interval (n=6)	49.67 (± 8.495)			
Week 1, ≥14 yrs, RCS score, 3-week interval (n=2)	53.50 (± 8.768)			
CFB (EOS/ET), ≥14 yrs, PCS score, 4-wk int (n=6)	0.20 (± 8.709)			
CFB (EOS/ET), ≥14 yrs, PCS score, 3-wk int (n=2)	-1.85 (± 1.202)			

CFB (EOS/ET), ≥14 yrs, MCS score, 4-wk int (n=6)	-3.12 (± 5.605)			
CFB (EOS/ET), ≥14 yrs, MCS score, 3-wk int (n=2)	-3.55 (± 0.636)			
CFB (EOS/ET), ≥14 yrs, RCS score, 4-wk int (n=6)	-0.80 (± 6.592)			
CFB (EOS/ET), ≥14 yrs, RCS score, 3-wk int (n=2)	4.90 (± 3.394)			

Statistical analyses

No statistical analyses for this end point

Secondary: QOL: EuroQoL (Quality of Life)-5 Dimensions 3 Levels (EQ-5D-3L) Health Questionnaire

End point title	QOL: EuroQoL (Quality of Life)-5 Dimensions 3 Levels (EQ-5D-3L) Health Questionnaire

End point description:

EQ-5D-3L health questionnaire is a participant answered questionnaire scoring 5 dimensions - mobility, self-care, usual activities, pain/discomfort and anxiety/depression. In this study, 2-11 years (parent as observer),12 years and older (participant as observer) for EQ-5D-3L health questionnaire will be analyzed. The EQ-5D-3L total score ranges from 0 (worst health state) to 1 (perfect health state) and 1 reflects the best outcome. Full Analysis Set included all enrolled participants who received investigational drug at least once. 9999 signifies SD was not estimable for single participant. Week (wk), Interval (int), Change from Baseline (CFB), Years (yrs), Index (In), Score (sc). 999 signifies the mean and/or SD was 0. Negative indicates worsening health outcome.

End point type	Secondary

End point timeframe:

4-Week dosing interval (Week 1, Week 19, and Week 31); 3-Week dosing interval (Week 1, Week 16, and Week 28)

End point values	Epoch 1 and 2			
Subject group type	Subject analysis set			
Number of subjects analysed	16			
Units: score on a scale				
arithmetic mean (standard deviation)				
Wk 1, 2-11 yrs, EQ-5D index score, 4-wk int (n=2)	1.0000 (± 999)			
Wk 1, 2-11 yrs, EQ-5D index score, 3-wk int (n=1)	0.6750 (± 9999)			
Wk 1, 2-11 yrs, EQ-5D VAS In score, 4-wk int (n=2)	95.0 (± 7.07)			
Wk 1, 2-11 yrs, EQ-5D VAS In score, 3-wk int (n=1)	100.0 (± 9999)			
Wk 1, ≥12 yrs, EQ-5D Index score, 4-wk int (n=7)	0.9271 (± 0.12655)			
Wk 1, ≥12 yrs, EQ-5D Index score, 3-wk int (n=2)	1 (± 999)			
Wk 1, ≥12 yrs, EQ-5D VAS In score, 4-wk int (n=7)	76.3 (± 13.24)			
Wk 1, ≥12 yrs, EQ-5D VAS In score, 3-wk int (n=2)	85.0 (± 7.07)			

CFB (EOS/ET), 2-11 yrs, EQ-5D in sc 4-wk int (n=1)	999 (± 9999)			
CFB (EOS/ET), 2-11 yrs, EQ-5D in sc 3-wk int (n=1)	0.3250 (± 9999)			
CFB (EOS/ET), 2-11 yrs, EQ-5D VAS sc 4-wk int(n=1)	-5.0 (± 9999)			
CFB (EOS/ET), 2-11 yrs, EQ-5D VAS sc 3-wk int(n=1)	-10 (± 9999)			
CFB (EOS/ET), ≥12 yrs, EQ-5D in sc 4-wk int(n=7)	0.0729 (± 0.12655)			
CFB (EOS/ET), ≥12 yrs, EQ-5D in sc 3-wk int(n=2)	999 (± 999)			
CFB (EOS/ET), ≥12 yrs, EQ-5D VAS sc 4-wk int(n=7)	6.3 (± 9.78)			
CFB (EOS/ET), ≥12 yrs, EQ-5D VAS sc 3-wk int(n=2)	-2.5 (± 3.54)			

Statistical analyses

No statistical analyses for this end point

Secondary: Treatment Preference

End point title	Treatment Preference

End point description:

Treatment preference questionnaire (q) is a self-administered q developed to assess participants' (pt) preference (p) towards the administration (adm) of new subcutaneous immunoglobulin (SCIG) therapy. There are 4-items on the q, which investigate a pt's p on the clinic(cl)/hospital(hosp)/home(h) setting of receiving (rec) the IG therapy, the pt's rating on the frequency (freq) and method of adm, and the pt's p to continue rec the IGSC treatment (trt). Full Analysis Set included all enrolled pts who received investigational drug at least once. 'n'= number of pts analyzed at specific time point, Before (bf), Where (wr), Prefer (pf), Like very much (LVM), Needlesticks (ns), Total (tl), Month (m), Potential (ptl), Dislike very much (DVM), Schedule (skd), Convenience (conv), Amount (amt), Complexity (Cplx), Without (w/o), Medical supervision (ms), Dislike (DL) Immune Globulin Infusion 10%(10% IGI), Recombinant Human Hyaluronidase (rHuPH20), Experience (exp), Different (d), Would (w), With

End point type	Secondary

End point timeframe:

Up to Week 31 for Participants with 4-Week Dosing Interval or Up to Week 28 for Participants with 3-Week Dosing Interval

End point values	Epoch 1 and 2			
Subject group type	Subject analysis set			
Number of subjects analysed	16			
Units: participants				
2-13 yrs, Bf wr did you rec your IG?= Hosp (n= 5)	4			
2-13 yrs, Bf wr did you rec your IG?= At h (n= 5)	2			
2-13 yrs, Wr do you pf to rec your IG?=Hosp (n= 5)	2			
2-13 yrs, Wr do you pf to rec your IG?=At h (n= 5)	1			
2-13 yrs, Wr do you pf to rec your IG?=No p (n= 5)	2			

2-13 yrs, Freq of adm = LVM (n=5)	3			
2-13 yrs, Freq of adm = Like (n=5)	1			
2-13 yrs, Freq of adm = No p (n=5)	1			
2-13 yrs, No of ns per month = LVM (n=5)	2			
2-13 yrs, No of ns per month = Like (n=5)	2			
2-13 yrs, No of ns per month = No p (n=5)	1			
2-13 yrs, Tl time spent for trt per m = Like (n=5)	3			
2-13 yrs, Tl time spent for trt per m = No p (n=5)	2			
2-13 yrs, Ease of adm =Like (n=5)	1			
2-13 yrs, Ease of adm =No p (n=5)	3			
2-13 yrs, Ease of adm =Dislike (n=5)	1			
2-13 yrs, Ptl to self-adm =LVM (n=5)	1			
2-13 yrs, Ptl to self-adm = No p (n=5)	2			
2-13 yrs, Ptl to self-adm = Dislike (n=5)	1			
2-13 yrs, Ptl to self-adm = DVM (n=5)	1			
2-13 yrs, Ability to fit trt into skd = Like (n=5)	3			
2-13 yrs, Ability to fit trt into skd = No p (n=5)	2			
2-13 yrs, Overall conv= Like (n=5)	4			
2-13 yrs, Overall conv= No p (n=5)	1			
2-13 yrs, Amt of time adm takes= Like (n=5)	2			
2-13 yrs, Amt of time adm takes= No p (n=5)	2			
2-13 yrs, Amt of time adm takes= Dislike (n=5)	1			
2-13 yrs, Cplx of adm process= Like (n=5)	2			
2-13 yrs, Cplx of adm process= No p (n=5)	2			
2-13 yrs, Cplx of adm process= Dislike (n=5)	1			
2-13 yrs, My ability to self-adm w/o ms=LVM (n=5)	1			
2-13 yrs, My ability to self-adm w/o ms=No p (n=5)	1			
2-13 yrs, My ability to self-adm w/o ms=DL (n=5)	1			
2-13 yrs, My ability to self-adm w/o ms=DVM (n=5)	2			
2-13 yrs, would you receive 10% IGI SC?=Yes (n=5)	5			
≥14 yrs, Bf wr did you rec your IG?= Hosp (n= 11)	8			
≥14 yrs, Bf wr did you rec your IG?= At h (n= 11)	7			
≥14 yrs, Bf wr did you rec your IG? = Other (n=11)	1			
≥14 yrs, Wr do you pf to rec your IG?=Hosp (n= 11)	2			
≥14 yrs, Wr do you pf to rec your IG?=At h (n= 11)	7			
≥14 yrs, Wr do you pf to rec your IG?=No p (n= 11)	2			

≥14 yrs, Freq of adm = LVM (n=11)	3			
≥14 yrs, Freq of adm = Like (n=11)	7			
≥14 yrs, Freq of adm = No p (n=11)	1			
≥14 yrs, No of ns per month = Like (n=11)	8			
≥14 yrs, No of ns per month = No p (n=11)	3			
≥14 yrs, Tl time spent for trt per m = LVM (n=11)	1			
≥14 yrs, Tl time spent for trt per m = Like (n=11)	6			
≥14 yrs, Tl time spent for trt per m = No p (n=11)	2			
≥14 yrs, Tl time spent for trt per m = DL (n=11)	2			
≥14 yrs, Ease of adm =Like (n=11)	2			
≥14 yrs, Ease of adm =No p (n=11)	2			
≥14 yrs, Ease of adm =Dislike (n=11)	6			
≥14 yrs, Ease of adm =DVM (n=11)	1			
≥14 yrs, Ptl to self-adm =Like (n=11)	8			
≥14 yrs, Ptl to self-adm = No p (n=11)	1			
≥14 yrs, Ptl to self-adm = Dislike (n=11)	1			
≥14 yrs, Ptl to self-adm = DVM (n=11)	1			
≥14 yrs, Ability to fit trt into skd = LVM (n=11)	1			
≥14 yrs, Ability to fit trt into skd = Like (n=11)	7			
≥14 yrs, Ability to fit trt into skd = No p (n=11)	2			
≥14 yrs, Ability to fit trt into skd = DL (n=11)	1			
≥14 yrs, Overall conv= Like (n=11)	8			
≥14 yrs, Overall conv= No p (n=11)	2			
≥14 yrs, Overall conv= Dislike (n=11)	1			
≥14 yrs, Amt of time adm takes= Like (n=11)	7			
≥14 yrs, Amt of time adm takes= No p (n=11)	3			
≥14 yrs, Amt of time adm takes= Dislike (n=11)	1			
≥14 yrs, Cplx of adm process= LVM (n=11)	1			
≥14 yrs, Cplx of adm process= Like (n=11)	1			
≥14 yrs, Cplx of adm process= No p (n=11)	2			
≥14 yrs, Cplx of adm process= Dislike (n=11)	6			
≥14 yrs, Cplx of adm process= DVM (n=11)	1			
≥14 yrs, My ability to self-adm w/o ms=LVM (n=11)	1			
≥14 yrs, My ability to self-adm w/o ms=Like (n=11)	6			
≥14 yrs, My ability to self-adm w/o ms=No p (n=11)	1			
≥14 yrs, My ability to self-adm w/o ms=DL (n=11)	2			

≥14 yrs, My ability to self-adm w/o ms=DVM (n=11)	1			
≥14 yrs, would you receive 10% IGI SC?=Yes (n=11)	9			
≥14 yrs, would you receive 10% IGI SC?=No (n=11)	2			

Statistical analyses

No statistical analyses for this end point

Secondary: Treatment Satisfaction: Questionnaire for Medication-9 (TSQM-9)

End point title	Treatment Satisfaction: Questionnaire for Medication-9 (TSQM-9)

End point description:

Treatment Satisfaction Questionnaire for Medication (TSQM) is a global satisfaction scale used to assess the overall level of participant's (pt) satisfaction or dissatisfaction with their medications (med). In this study, 2-12 years (yrs) (parent as observer), >13 yrs (pt as observer) for TSQM will be analyzed. TSQM-9 is a 9-item, validated, self-administered instrument used to assess pt's satisfaction with med. The 3 domains assessed: effectiveness (E), convenience (C), and global satisfaction (GS). The score of each of the 3 domains is based on an algorithm to create a score of 0 to 100. Higher score=greater satisfaction (sat) in that domain. Full Analysis Set: all enrolled pts who received investigational drug at least once. Number (no) analyzed is the no of pts with data available for analysis at given timepoint. 'n'= no of pts analyzed at specific time point. '999'= mean or SD were 0 and '9999'= SD was not estimable for 1 pt. Change from baseline (CFB), Week (wk). (-)=lesser sat

End point type	Secondary

End point timeframe:

4-Week dosing interval (Week 1, Week 19, and Week 31); 3-Week dosing interval (Week 1, Week 16, and Week 28)

End point values	Epoch 1 and 2			
Subject group type	Subject analysis set			
Number of subjects analysed	16			
Units: score on a scale				
arithmetic mean (standard deviation)				
Week 1, 2-12 yrs, E, 4-week interval (n=3)	64.81 (± 3.208)			
Week 1, 2-12 yrs, E, 3-week interval (n=1)	94.44 (± 9999)			
Week 1, 2-12 yrs, C, 4-week interval (n=3)	44.44 (± 19.245)			
Week 1, 2-12 yrs, C, 3-week interval (n=1)	38.89 (± 9999)			
Week 1, 2-12 yrs, GS, 4-week interval (n=3)	59.52 (± 10.911)			
Week 1, 2-12 yrs, GS, 3-week interval (n=1)	100.00 (± 9999)			
Week 1, ≥13 yrs, E, 4-wk interval (n=6)	64.81 (± 18.812)			
Week 1, ≥ 13 yrs, E, 3-wk interval (n=2)	63.89 (± 3.928)			
Week 1, ≥ 13 yrs, C, 4-wk interval (n=6)	62.04 (± 19.694)			

Week 1, ≥13 yrs, C, 3-week interval (n=2)	44.44 (± 999)			
Week 1, ≥13 yrs, GS, 4-week interval (n=6)	60.71 (± 8.748)			
Week 1, ≥13 yrs, GS, 3-week interval (n=2)	64.29 (± 10.102)			
CFB (EOS/ET), 2-12 yrs, E, 4-wk interval (n=2)	999 (± 999)			
CFB (EOS/ET), 2-12 yrs, E, 3-wk interval (n=1)	-27.78 (± 9999)			
CFB (EOS/ET), 2-12 yrs, C, 4-wk interval (n=2)	13.89 (± 3.928)			
CFB (EOS/ET), 2-12 yrs, C, 3-wk interval (n=1)	999 (± 9999)			
CFB (EOS/ET), 2-12 yrs, GS, 4-wk interval (n=3)	10.71 (± 5.051)			
CFB (EOS/ET), 2-12 yrs, GS, 3-wk interval (n=1)	-28.57 (± 9999)			
CFB (EOS/ET), ≥13 yrs, E, 4-wk interval (n=6)	-12.04 (± 26.156)			
CFB (EOS/ET), ≥13 yrs, E, 3-wk interval (n=2)	2.78 (± 3.928)			
CFB (EOS/ET), ≥13 yrs, C, 4-wk interval (n=6)	-3.70 (± 20.688)			
CFB (EOS/ET), ≥13 yrs, C, 3-wk interval (n=2)	999 (± 7.857)			
CFB (EOS/ET), ≥13 yrs, GS, 4-wk interval (n=6)	-13.10 (± 26.885)			
CFB (EOS/ET), ≥13 yrs, GS, 3-wk interval (n=2)	-3.57 (± 5.051)			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

From the time the informed (e)Consent document is signed until the EOS/Early termination visit (Up to 21 days after the last dose for the 3-week dosing intervals and 28 days after the last dose for 4-week dosing intervals)

Adverse event reporting additional description:

All AEs/SAEs which had been reported until EOS/Early termination visit must be followed to closure (the subject's health has returned to his/her baseline status or all variables have returned to baseline) or until 30 days after EOS/Early termination visit, whichever comes first.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	26

Reporting groups

Reporting group title	Epoch 1: TAK-771 Ramp up Period

Reporting group description:

TAK-771 included IGI 10% and Recombinant Human Hyaluronidase (rHuPH20). Participants received subcutaneous infusion of rHuPH20 solution at a dose of 80 U/g IgG first, followed by SC infusion of 10% IGI within 10 minutes of completion of the infusion of rHuPH20 solution. The dose of 10% IGI was increased from 1/3 of full dose to full dose in 3 weeks for participants who received TAK-771 once every 3 weeks, or from 1/4 of full dose to full dose in 6 weeks for participants who received TAK-771 once every 4 weeks.

Reporting group title	Epoch 2: TAK-771 Full Dose Treatment Period

Reporting group description:

TAK-771 included IGI 10% and rHuPH20. Participants received subcutaneous infusion of rHuPH20 solution at a dose of 80 U/g IgG first, followed by SC infusion of 10% IGI within 10 minutes of completion of the infusion of rHuPH20 solution, every 3, or 4 weeks for up to Week 24.

Serious adverse events	Epoch 1: TAK-771 Ramp up Period	Epoch 2: TAK-771 Full Dose Treatment Period	
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 16 (6.25%)	1 / 16 (6.25%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events			
Respiratory, thoracic and mediastinal disorders			
Upper respiratory tract inflammation			
subjects affected / exposed	0 / 16 (0.00%)	1 / 16 (6.25%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endocrine disorders			
Adrenal insufficiency			

subjects affected / exposed	1 / 16 (6.25%)	0 / 16 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
Gastroenteritis			
subjects affected / exposed	1 / 16 (6.25%)	0 / 16 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

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

Non-serious adverse events	Epoch 1: TAK-771 Ramp up Period	Epoch 2: TAK-771 Full Dose Treatment Period	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	13 / 16 (81.25%)	15 / 16 (93.75%)	
Injury, poisoning and procedural complications			
Joint dislocation			
subjects affected / exposed	0 / 16 (0.00%)	1 / 16 (6.25%)	
occurrences (all)	0	1	
Subcutaneous haematoma			
subjects affected / exposed	0 / 16 (0.00%)	1 / 16 (6.25%)	
occurrences (all)	0	1	
Wound			
subjects affected / exposed	0 / 16 (0.00%)	1 / 16 (6.25%)	
occurrences (all)	0	1	
Nervous system disorders			
Headache			
subjects affected / exposed	2 / 16 (12.50%)	1 / 16 (6.25%)	
occurrences (all)	3	1	
Somnolence			
subjects affected / exposed	0 / 16 (0.00%)	1 / 16 (6.25%)	
occurrences (all)	0	1	
General disorders and administration site conditions			
Administration site pain			

subjects affected / exposed	0 / 16 (0.00%)	1 / 16 (6.25%)	
occurrences (all)	0	1	
Application site erythema			
subjects affected / exposed	1 / 16 (6.25%)	0 / 16 (0.00%)	
occurrences (all)	1	0	
Fatigue			
subjects affected / exposed	1 / 16 (6.25%)	1 / 16 (6.25%)	
occurrences (all)	3	2	
Infusion site erythema			
subjects affected / exposed	2 / 16 (12.50%)	2 / 16 (12.50%)	
occurrences (all)	2	16	
Infusion site pain			
subjects affected / exposed	2 / 16 (12.50%)	0 / 16 (0.00%)	
occurrences (all)	2	0	
Infusion site swelling			
subjects affected / exposed	2 / 16 (12.50%)	1 / 16 (6.25%)	
occurrences (all)	4	2	
Injection site erythema			
subjects affected / exposed	2 / 16 (12.50%)	2 / 16 (12.50%)	
occurrences (all)	4	7	
Injection site induration			
subjects affected / exposed	0 / 16 (0.00%)	1 / 16 (6.25%)	
occurrences (all)	0	5	
Injection site pain			
subjects affected / exposed	0 / 16 (0.00%)	1 / 16 (6.25%)	
occurrences (all)	0	2	
Injection site pruritus			
subjects affected / exposed	1 / 16 (6.25%)	0 / 16 (0.00%)	
occurrences (all)	2	0	
Malaise			
subjects affected / exposed	1 / 16 (6.25%)	1 / 16 (6.25%)	
occurrences (all)	1	1	
Peripheral swelling			
subjects affected / exposed	1 / 16 (6.25%)	0 / 16 (0.00%)	
occurrences (all)	1	0	
Pyrexia			

subjects affected / exposed	5 / 16 (31.25%)	5 / 16 (31.25%)	
occurrences (all)	14	26	
Vaccination site pain			
subjects affected / exposed	0 / 16 (0.00%)	1 / 16 (6.25%)	
occurrences (all)	0	2	
Ear and labyrinth disorders			
Vertigo			
subjects affected / exposed	0 / 16 (0.00%)	1 / 16 (6.25%)	
occurrences (all)	0	1	
Immune system disorders			
Seasonal allergy			
subjects affected / exposed	1 / 16 (6.25%)	1 / 16 (6.25%)	
occurrences (all)	1	1	
Eye disorders			
Conjunctivitis allergic			
subjects affected / exposed	0 / 16 (0.00%)	1 / 16 (6.25%)	
occurrences (all)	0	1	
Ocular hyperaemia			
subjects affected / exposed	0 / 16 (0.00%)	1 / 16 (6.25%)	
occurrences (all)	0	1	
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	0 / 16 (0.00%)	1 / 16 (6.25%)	
occurrences (all)	0	2	
Abdominal pain lower			
subjects affected / exposed	1 / 16 (6.25%)	1 / 16 (6.25%)	
occurrences (all)	1	1	
Aphthous ulcer			
subjects affected / exposed	0 / 16 (0.00%)	1 / 16 (6.25%)	
occurrences (all)	0	1	
Diarrhoea			
subjects affected / exposed	0 / 16 (0.00%)	1 / 16 (6.25%)	
occurrences (all)	0	1	
Faeces soft			
subjects affected / exposed	0 / 16 (0.00%)	1 / 16 (6.25%)	
occurrences (all)	0	1	
Gingival bleeding			

subjects affected / exposed	0 / 16 (0.00%)	1 / 16 (6.25%)	
occurrences (all)	0	1	
Gingival swelling			
subjects affected / exposed	0 / 16 (0.00%)	1 / 16 (6.25%)	
occurrences (all)	0	1	
Vomiting			
subjects affected / exposed	0 / 16 (0.00%)	1 / 16 (6.25%)	
occurrences (all)	0	1	
Reproductive system and breast disorders			
Dysmenorrhoea			
subjects affected / exposed	0 / 16 (0.00%)	1 / 16 (6.25%)	
occurrences (all)	0	1	
Oedema genital			
subjects affected / exposed	1 / 16 (6.25%)	1 / 16 (6.25%)	
occurrences (all)	1	3	
Scrotal oedema			
subjects affected / exposed	0 / 16 (0.00%)	1 / 16 (6.25%)	
occurrences (all)	0	1	
Respiratory, thoracic and mediastinal disorders			
Bronchiectasis			
subjects affected / exposed	0 / 16 (0.00%)	1 / 16 (6.25%)	
occurrences (all)	0	1	
Nasal congestion			
subjects affected / exposed	0 / 16 (0.00%)	1 / 16 (6.25%)	
occurrences (all)	0	1	
Rhinitis allergic			
subjects affected / exposed	0 / 16 (0.00%)	1 / 16 (6.25%)	
occurrences (all)	0	1	
Skin and subcutaneous tissue disorders			
Dermatitis			
subjects affected / exposed	0 / 16 (0.00%)	1 / 16 (6.25%)	
occurrences (all)	0	1	
Pruritus			
subjects affected / exposed	0 / 16 (0.00%)	1 / 16 (6.25%)	
occurrences (all)	0	1	
Rash			

subjects affected / exposed	1 / 16 (6.25%)	0 / 16 (0.00%)	
occurrences (all)	1	0	
Urticaria			
subjects affected / exposed	0 / 16 (0.00%)	2 / 16 (12.50%)	
occurrences (all)	0	2	
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 16 (0.00%)	1 / 16 (6.25%)	
occurrences (all)	0	1	
Back pain			
subjects affected / exposed	0 / 16 (0.00%)	1 / 16 (6.25%)	
occurrences (all)	0	1	
Myalgia			
subjects affected / exposed	0 / 16 (0.00%)	1 / 16 (6.25%)	
occurrences (all)	0	1	
Pain in extremity			
subjects affected / exposed	1 / 16 (6.25%)	1 / 16 (6.25%)	
occurrences (all)	1	2	
Infections and infestations			
Bronchitis			
subjects affected / exposed	1 / 16 (6.25%)	0 / 16 (0.00%)	
occurrences (all)	1	0	
COVID-19			
subjects affected / exposed	0 / 16 (0.00%)	2 / 16 (12.50%)	
occurrences (all)	0	2	
Chronic sinusitis			
subjects affected / exposed	0 / 16 (0.00%)	2 / 16 (12.50%)	
occurrences (all)	0	3	
Conjunctivitis			
subjects affected / exposed	0 / 16 (0.00%)	1 / 16 (6.25%)	
occurrences (all)	0	1	
Cystitis			
subjects affected / exposed	0 / 16 (0.00%)	1 / 16 (6.25%)	
occurrences (all)	0	1	
Nasopharyngitis			

subjects affected / exposed	3 / 16 (18.75%)	3 / 16 (18.75%)	
occurrences (all)	3	8	
Oral herpes			
subjects affected / exposed	1 / 16 (6.25%)	2 / 16 (12.50%)	
occurrences (all)	1	2	
Pneumonia			
subjects affected / exposed	0 / 16 (0.00%)	1 / 16 (6.25%)	
occurrences (all)	0	1	
Upper respiratory tract infection			
subjects affected / exposed	0 / 16 (0.00%)	1 / 16 (6.25%)	
occurrences (all)	0	1	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
19 May 2022	Amendment 1 included the following: - Descriptions of 'Device used in clinical trial' were added. - Infusion rate of 10%IGI was added. - Inclusion criteria 4 and relative description were modified. - Exclusion criteria 9 was modified. - Description in endpoints and analysis for Safety were modified. - HRQoL index for Treatment satisfaction (Life Quality Index) was removed. - Additional items to be summarized descriptively were included. - Analysis for treatment preference was corrected. - Screening visits column for subjects switching from IVIG/cSCIG treatment shown in schedule of activities and clinical laboratory tests were modified. The description in the body was also modified accordingly. - An instruction for dose modification based on weight changes was added. - The timing of specific antibody testing described in the body text was corrected, and it was added that the testing at PK troughs is not required for those who are not in the PK assessment. - Information regarding analysis of antibody titer was added. - Information regarding QoL/treatment satisfaction data capturing was added. The description of SAE reporting was modified.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported