



Clinical trial results:

A Phase 3, Open-label, Non-controlled, Extension Study to Evaluate the Long-term Safety of TAK-771 in Japanese Patients with Primary Immunodeficiency Disease (PID)

Summary

EudraCT number	2022-003621-21
Trial protocol	Outside EU/EEA
Global end of trial date	30 October 2025

Results information

Result version number	v1 (current)
This version publication date	09 May 2026
First version publication date	09 May 2026

Trial information

Trial identification

Sponsor protocol code	TAK-771-3005
-----------------------	--------------

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT05513586
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Takeda
Sponsor organisation address	95 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?	Yes

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	30 October 2025
Is this the analysis of the primary completion data?	No
Global end of trial reached?	Yes
Global end of trial date	30 October 2025
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The main purpose of the trial is to evaluate the long-term safety of TAK-771 in Japanese participants with PID.

Protection of trial subjects:

Participant signed an informed consent form (ICF) before participating in the study.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	13 September 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: 15
Worldwide total number of subjects	15
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)	10
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

A total of 15 participants with primary immunodeficiency diseases (PID) took part in the study in Japan from 13 Sep 2022 to 30 Oct 2025.

Pre-assignment

Screening details:

Participants who completed the study TAK-771-3004 (NCT05150340) were enrolled in this extension study and continued to receive TAK-771.

Period 1

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

Arms

Arm title	TAK-771
-----------	---------

Arm description:

Participants continued TAK-771 (Immune Globulin Infusion [IGI] 10% + Recombinant Human Hyaluronidase [rHuPH20]) administration at the same dose and frequency they had in the Study TAK-771-3004 (NCT05150340) with dosing intervals of either 3 or 4 weeks, until the commercial TAK-771 becomes available at each study site or study termination. Participants received subcutaneous (SC) infusion of rHuPH20 solution first at a dose of 80 units per gram (U/g), followed by SC infusion of 10 percentage (%) IGI within 10 minutes of completion of the infusion of rHuPH20 solution. The dose of TAK-771 was adjusted to maintain the target immunoglobulin G (IgG) trough level of greater than or equal to ($\geq$) 5 gram per litre (g/L).

Arm type	Experimental
Investigational medicinal product name	TAK-771 [IGI + rHuPH20]
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Subcutaneous use

Dosage and administration details:

TAK-771 SC infusion.

Number of subjects in period 1	TAK-771
Started	15
Completed	12
Not completed	3
Consent withdrawn by subject	2
Adverse event, non-fatal	1

Baseline characteristics

Reporting groups

Reporting group title	TAK-771
-----------------------	---------

Reporting group description:

Participants continued TAK-771 (Immune Globulin Infusion [IGI] 10% + Recombinant Human Hyaluronidase [rHuPH20]) administration at the same dose and frequency they had in the Study TAK-771-3004 (NCT05150340) with dosing intervals of either 3 or 4 weeks, until the commercial TAK-771 becomes available at each study site or study termination. Participants received subcutaneous (SC) infusion of rHuPH20 solution first at a dose of 80 units per gram (U/g), followed by SC infusion of 10 percentage (%) IGI within 10 minutes of completion of the infusion of rHuPH20 solution. The dose of TAK-771 was adjusted to maintain the target immunoglobulin G (IgG) trough level of greater than or equal to ($\geq$) 5 gram per litre (g/L).

Reporting group values	TAK-771	Total	
Number of subjects	15	15	
Age Categorical			
Units: Subjects			

Age continuous			
Units: years			
arithmetic mean	22.7		
standard deviation	± 14.19	-	
Gender categorical			
Units: Subjects			
Female	5	5	
Male	10	10	
Race (NIH/OMB)			
Units: Subjects			
American Indian or Alaska Native	0	0	
Asian	15	15	
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	
Ethnicity (NIH/OMB)			
Units: Subjects			
Hispanic or Latino	0	0	
Not Hispanic or Latino	15	15	
Unknown or Not Reported	0	0	

End points

End points reporting groups

Reporting group title	TAK-771
Reporting group description:	
Participants continued TAK-771 (Immune Globulin Infusion [IGI] 10% + Recombinant Human Hyaluronidase [rHuPH20]) administration at the same dose and frequency they had in the Study TAK-771-3004 (NCT05150340) with dosing intervals of either 3 or 4 weeks, until the commercial TAK-771 becomes available at each study site or study termination. Participants received subcutaneous (SC) infusion of rHuPH20 solution first at a dose of 80 units per gram (U/g), followed by SC infusion of 10 percentage (%) IGI within 10 minutes of completion of the infusion of rHuPH20 solution. The dose of TAK-771 was adjusted to maintain the target immunoglobulin G (IgG) trough level of greater than or equal to ($\geq$) 5 gram per litre (g/L).	

Primary: Percentage of Participants with Treatment-Emergent Adverse Events (TEAEs)

End point title	Percentage of Participants with Treatment-Emergent Adverse Events (TEAEs) ^[1]
End point description:	
An Adverse event (AE) was any untoward medical occurrence in a clinical investigation participant administered a pharmaceutical product that does not necessarily have a causal relationship with this treatment. An AE can therefore be any unfavorable and unintended sign (including a clinically significant laboratory finding), symptom, or disease temporally associated with the use of a investigational product, whether or not causality is suspected. A TEAE was defined as any event emerging or manifesting at or after the initiation of treatment with an investigational product or medicinal product or any existing event that worsened in either intensity or frequency following exposure to the investigational product. EXSAS included all enrolled participants who received investigational drug in Study TAK-771-3005 at least once.	
End point type	Primary
End point timeframe:	
From start of study drug administration up to end of study (up to 3.1 years)	

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: All analysis was descriptive only and no formal hypothesis testing was done.

End point values	TAK-771			
Subject group type	Reporting group			
Number of subjects analysed	15			
Units: percentage of participants				
number (not applicable)	100			

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Participants who Developed Anti-rHuPH20 Binding Antibody Titers of $\geq$ 1:160 and Neutralizing Antibodies to rHuPH20

End point title	Percentage of Participants who Developed Anti-rHuPH20 Binding Antibody Titers of $\geq$ 1:160 and Neutralizing Antibodies to rHuPH20 ^[2]
-----------------	---

End point description:

Participants who developed anti-rHuPH20 binding antibody titers of $\geq 1:160$ and neutralizing antibodies to rHuPH20 was reported. EXSAS included all enrolled participants who received investigational drug in Study TAK-771-3005 at least once.

End point type	Primary
----------------	---------

End point timeframe:

From start of study drug administration up to end of study (up to 3.1 years)

Notes:

[2] - 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: All analysis was descriptive only and no formal hypothesis testing was done.

End point values	TAK-771			
Subject group type	Reporting group			
Number of subjects analysed	15			
Units: percentage of participants				
number (not applicable)				
Anti-rHuPH20 Binding Antibody Titers of $\geq 1:160$	0			
Neutralizing Antibodies	0			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

From start of study drug administration up to end of study (up to 3.1 years)

Adverse event reporting additional description:

EXSAS included all enrolled participants who received investigational drug in Study TAK-771-3005 at least once.

Assessment type	Systematic
-----------------	------------

Dictionary used

Dictionary name	MedDRA
-----------------	--------

Dictionary version	28.1
--------------------	------

Reporting groups

Reporting group title	TAK-771
-----------------------	---------

Reporting group description:

Participants continued TAK-771 (IGI 10% + rHuPH20) administration at the same dose and frequency they had in the Study TAK-771-3004 (NCT05150340) with dosing intervals of either 3 or 4 weeks, until the commercial TAK-771 becomes available at each study site or study termination. Participants received SC infusion of rHuPH20 solution first at a dose of 80 U/g, followed by SC infusion of 10% IGI within 10 minutes of completion of the infusion of rHuPH20 solution. The dose of TAK-771 was adjusted to maintain the target IgG trough level of ≥ 5 g/L.

Serious adverse events	TAK-771		
Total subjects affected by serious adverse events			
subjects affected / exposed	6 / 15 (40.00%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		
Injury, poisoning and procedural complications			
Joint dislocation			
subjects affected / exposed	1 / 15 (6.67%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Eye disorders			
Eyelid ptosis			
subjects affected / exposed	1 / 15 (6.67%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal disorders			
Diarrhoea			

subjects affected / exposed	1 / 15 (6.67%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Inflammatory bowel disease			
subjects affected / exposed	1 / 15 (6.67%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Vomiting			
subjects affected / exposed	1 / 15 (6.67%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Endocrine disorders			
Adrenal insufficiency			
subjects affected / exposed	1 / 15 (6.67%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 0		
Infections and infestations			
COVID-19			
subjects affected / exposed	1 / 15 (6.67%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pneumonia			
subjects affected / exposed	1 / 15 (6.67%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Metabolism and nutrition disorders			
Hypoglycaemia			
subjects affected / exposed	1 / 15 (6.67%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		

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

Non-serious adverse events	TAK-771		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	15 / 15 (100.00%)		
General disorders and administration site conditions			
Administration site erythema			
subjects affected / exposed	1 / 15 (6.67%)		
occurrences (all)	2		
Infusion site erythema			
subjects affected / exposed	2 / 15 (13.33%)		
occurrences (all)	27		
Administration site pruritus			
subjects affected / exposed	1 / 15 (6.67%)		
occurrences (all)	1		
Infusion site swelling			
subjects affected / exposed	2 / 15 (13.33%)		
occurrences (all)	14		
Injection site erythema			
subjects affected / exposed	4 / 15 (26.67%)		
occurrences (all)	23		
Injection site induration			
subjects affected / exposed	1 / 15 (6.67%)		
occurrences (all)	24		
Injection site reaction			
subjects affected / exposed	1 / 15 (6.67%)		
occurrences (all)	1		
Injection site pruritus			
subjects affected / exposed	1 / 15 (6.67%)		
occurrences (all)	1		
Injection site pain			
subjects affected / exposed	4 / 15 (26.67%)		
occurrences (all)	44		
Injection site swelling			
subjects affected / exposed	1 / 15 (6.67%)		
occurrences (all)	1		
Malaise			

subjects affected / exposed occurrences (all) Pyrexia subjects affected / exposed occurrences (all) Thirst subjects affected / exposed occurrences (all)	1 / 15 (6.67%) 1 7 / 15 (46.67%) 26 1 / 15 (6.67%) 11		
Immune system disorders Seasonal allergy subjects affected / exposed occurrences (all)	2 / 15 (13.33%) 2		
Reproductive system and breast disorders Oedema genital subjects affected / exposed occurrences (all)	1 / 15 (6.67%) 1		
Respiratory, thoracic and mediastinal disorders Cough subjects affected / exposed occurrences (all) Bronchiectasis subjects affected / exposed occurrences (all) Asthma subjects affected / exposed occurrences (all) Nasal congestion subjects affected / exposed occurrences (all) Oropharyngeal pain subjects affected / exposed occurrences (all) Rhinorrhoea subjects affected / exposed occurrences (all) Upper respiratory tract inflammation	1 / 15 (6.67%) 1 1 / 15 (6.67%) 4 1 / 15 (6.67%) 1 1 / 15 (6.67%) 1 1 / 15 (6.67%) 1 1 / 15 (6.67%) 2		

subjects affected / exposed occurrences (all)	2 / 15 (13.33%) 3		
Psychiatric disorders Anxiety disorder subjects affected / exposed occurrences (all)	1 / 15 (6.67%) 1		
Investigations Liver function test increased subjects affected / exposed occurrences (all)	1 / 15 (6.67%) 1		
Injury, poisoning and procedural complications Arthropod bite subjects affected / exposed occurrences (all) Contusion subjects affected / exposed occurrences (all) Joint dislocation subjects affected / exposed occurrences (all) Scratch subjects affected / exposed occurrences (all) Procedural pain subjects affected / exposed occurrences (all)	2 / 15 (13.33%) 2 1 / 15 (6.67%) 2 1 / 15 (6.67%) 1 1 / 15 (6.67%) 1 1 / 15 (6.67%) 1		
Nervous system disorders Sensory disturbance subjects affected / exposed occurrences (all) Headache subjects affected / exposed occurrences (all) Dizziness subjects affected / exposed occurrences (all)	1 / 15 (6.67%) 1 3 / 15 (20.00%) 4 1 / 15 (6.67%) 1		

Blood and lymphatic system disorders	Anaemia		
	subjects affected / exposed	1 / 15 (6.67%)	
	occurrences (all)	1	
	Iron deficiency anaemia		
Ear and labyrinth disorders	subjects affected / exposed	1 / 15 (6.67%)	
	occurrences (all)	1	
	Deafness neurosensory		
	subjects affected / exposed	1 / 15 (6.67%)	
Eye disorders	occurrences (all)	1	
	Conjunctivitis allergic		
	subjects affected / exposed	1 / 15 (6.67%)	
	occurrences (all)	1	
Gastrointestinal disorders	Keratitis interstitial		
	subjects affected / exposed	1 / 15 (6.67%)	
	occurrences (all)	1	
	Abdominal discomfort		
	subjects affected / exposed	1 / 15 (6.67%)	
	occurrences (all)	1	
	Constipation		
	subjects affected / exposed	1 / 15 (6.67%)	
	occurrences (all)	2	
	Dental caries		
	subjects affected / exposed	2 / 15 (13.33%)	
	occurrences (all)	5	
	Diarrhoea		
	subjects affected / exposed	1 / 15 (6.67%)	
	occurrences (all)	1	
	Dyspepsia		
	subjects affected / exposed	1 / 15 (6.67%)	
	occurrences (all)	1	
	Enteritis		
	subjects affected / exposed	1 / 15 (6.67%)	
	occurrences (all)	1	

Gastric polyps			
subjects affected / exposed	1 / 15 (6.67%)		
occurrences (all)	1		
Gastroesophageal reflux disease			
subjects affected / exposed	1 / 15 (6.67%)		
occurrences (all)	1		
Gingival pain			
subjects affected / exposed	1 / 15 (6.67%)		
occurrences (all)	3		
Hiatus hernia			
subjects affected / exposed	1 / 15 (6.67%)		
occurrences (all)	1		
Inflammatory bowel disease			
subjects affected / exposed	1 / 15 (6.67%)		
occurrences (all)	2		
Large intestine polyp			
subjects affected / exposed	1 / 15 (6.67%)		
occurrences (all)	1		
Lip dry			
subjects affected / exposed	1 / 15 (6.67%)		
occurrences (all)	1		
Nausea			
subjects affected / exposed	2 / 15 (13.33%)		
occurrences (all)	3		
Vomiting			
subjects affected / exposed	1 / 15 (6.67%)		
occurrences (all)	1		
Stomatitis			
subjects affected / exposed	2 / 15 (13.33%)		
occurrences (all)	2		
Skin and subcutaneous tissue disorders			
Drug eruption			
subjects affected / exposed	1 / 15 (6.67%)		
occurrences (all)	1		
Erythema			

subjects affected / exposed	1 / 15 (6.67%)		
occurrences (all)	1		
Pruritus			
subjects affected / exposed	1 / 15 (6.67%)		
occurrences (all)	1		
Hand dermatitis			
subjects affected / exposed	1 / 15 (6.67%)		
occurrences (all)	1		
Rash			
subjects affected / exposed	2 / 15 (13.33%)		
occurrences (all)	2		
Vitiligo			
subjects affected / exposed	1 / 15 (6.67%)		
occurrences (all)	1		
Endocrine disorders			
Autoimmune thyroiditis			
subjects affected / exposed	1 / 15 (6.67%)		
occurrences (all)	1		
Musculoskeletal and connective tissue disorders			
Back pain			
subjects affected / exposed	1 / 15 (6.67%)		
occurrences (all)	1		
Arthralgia			
subjects affected / exposed	2 / 15 (13.33%)		
occurrences (all)	4		
Musculoskeletal pain			
subjects affected / exposed	1 / 15 (6.67%)		
occurrences (all)	2		
Myalgia			
subjects affected / exposed	1 / 15 (6.67%)		
occurrences (all)	1		
Neck pain			
subjects affected / exposed	1 / 15 (6.67%)		
occurrences (all)	2		
Infections and infestations			

Gastroenteritis			
subjects affected / exposed	1 / 15 (6.67%)		
occurrences (all)	1		
Conjunctivitis			
subjects affected / exposed	1 / 15 (6.67%)		
occurrences (all)	1		
COVID-19			
subjects affected / exposed	6 / 15 (40.00%)		
occurrences (all)	6		
Hordeolum			
subjects affected / exposed	1 / 15 (6.67%)		
occurrences (all)	1		
Influenza			
subjects affected / exposed	4 / 15 (26.67%)		
occurrences (all)	5		
Nasopharyngitis			
subjects affected / exposed	9 / 15 (60.00%)		
occurrences (all)	26		
Oral herpes			
subjects affected / exposed	1 / 15 (6.67%)		
occurrences (all)	3		
Otitis externa			
subjects affected / exposed	1 / 15 (6.67%)		
occurrences (all)	1		
Pharyngitis			
subjects affected / exposed	1 / 15 (6.67%)		
occurrences (all)	1		
Pneumonia			
subjects affected / exposed	2 / 15 (13.33%)		
occurrences (all)	2		
Respiratory syncytial virus infection			
subjects affected / exposed	1 / 15 (6.67%)		
occurrences (all)	1		
Rhinitis			
subjects affected / exposed	2 / 15 (13.33%)		
occurrences (all)	2		

Sinusitis			
subjects affected / exposed	2 / 15 (13.33%)		
occurrences (all)	2		
Tinea versicolour			
subjects affected / exposed	1 / 15 (6.67%)		
occurrences (all)	1		
Upper respiratory tract infection			
subjects affected / exposed	3 / 15 (20.00%)		
occurrences (all)	10		
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	1 / 15 (6.67%)		
occurrences (all)	1		
Hypokalaemia			
subjects affected / exposed	1 / 15 (6.67%)		
occurrences (all)	1		
Hypoglycaemia			
subjects affected / exposed	1 / 15 (6.67%)		
occurrences (all)	1		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
24 May 2022	The following updates were made: Assessments of serum trough concentrations of IgG subclasses were removed and description regarding delivery of study drugs from the site to participants home address was added.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported