Clinical trial results:
A Multicenter, Randomized, Blinded, Parallel Group, Interchangeability Study in Moderate to Severe Chronic Plaque Psoriasis evaluating Pharmacokinetics, Efficacy, Safety, and Immunogenicity Between Subjects Receiving Humira® Pre-filled syringe (40 mg/0.4 mL) Continuously and Subjects Undergoing Repeated Switches Between Humira® Pre-filled Syringe (40 mg/0.4mL) and Hulio Pre-filled Syringe (40 mg/0.8 mL)

Summary

EudraCT number	2021-006015-29
Trial protocol	CZ EE BG PL
Global end of trial date	19 September 2023

Results information

Result version number	v1 (current)
This version publication date	20 February 2025
First version publication date	20 February 2025

Trial information

Trial identification

Sponsor protocol code	ADA-IJZ-3001

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT05637515
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Biocon Biologics Limited (Study taken over from Mylan)
Sponsor organisation address	Electronic City phase II, , Bangalore, India, 560100
Public contact	Dr. Jayanti Panda, Biocon Biologics Limited, Jayanti.Panda@biocon.com
Scientific contact	Dr. Sarika S Deodhar, Biocon Biologics Limited, Sarika.Deodhar@biocon.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	19 September 2023
Is this the analysis of the primary completion data?	Yes
Primary completion date	19 September 2023
Global end of trial reached?	Yes
Global end of trial date	19 September 2023
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To evaluate interchangeability of Hulio and Humira by examining adalimumab steady-state PK in a switching arm (following 3 switches between Humira and Hulio) as compared to a non-switching arm (receiving only Humira).

Protection of trial subjects:

This study was conducted in accordance with the principles of ICH GCP, applicable regulatory requirements and Sponsor/CRO Standard Operating Procedures. The study followed the recommendations of ICH GCP R2 with quality oversight provided by the sponsor to ensure human subject protection and the reliability of trial results.
Quality was ensured through the designing, conducting, recording, and reporting of the study. The subjects were enrolled in the trial after the informed consent process

Background therapy: -

Evidence for comparator:

Humira(R) is approved product in EU and FDA. Hulio is a monoclonal antibody currently approved as a biosimilar to the European Union approved and United States (US)-Licensed Humira.
The study is designed to confirm the pharmacokinetic equivalence of alternating between the use of Humira and Hulio and Humira without such alternation or switch, in accordance with the US Food and Drug Administration Guidance for Industry, Considerations in Demonstrating Interchangeability with a Reference product . Based on this, Hulio is investigated against Humira as a comparator.

Actual start date of recruitment	05 December 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	Czechia: 62
Country: Number of subjects enrolled	Poland: 212
Country: Number of subjects enrolled	Bulgaria: 91
Country: Number of subjects enrolled	Estonia: 9
Worldwide total number of subjects	374
EEA total number of subjects	374

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37	0

wk	
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	332
From 65 to 84 years	42
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

A total of 386 subjects were enrolled to Runin period at Week 1, all subjects were treated with Humira for 11 weeks. 374 subjects were randomized into randomized interchangeable treatment period which comprised of 2 groups: Group 1(N=193) continued receiving Humira until Week 26; While subjects in Group 2(N=181),went multiple switches until Week 26

Pre-assignment

Screening details:

A total of 479 subjects were screened; 93 were screen failures. The reasons for screen failure were, 66 subjects did not meet eligibility criteria, 16 subjects withdrew consent, 5 subjects were withdrawn based on Sponsor’s decision, and 6 subjects due to other reasons

Period 1

Period 1 title	Overall trial (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Investigator, Monitor, Assessor, Subject

Blinding implementation details:

This was a double-blind randomised trial. except for the designated site monitor responsible for unblinded monitoring, everyone in the trial was blinded until after completion of the trial and the final blinded data review.

Arms

Are arms mutually exclusive?	Yes
Arm title	Humira non-switching treatment arm (Group 1).

Arm description:

Subjects continue to receive Humira (40 mg every other week) until Week 26/Visit 14.

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

Dosage and administration details:

40 mg in 0.4 mL Subcutaneous injection in pre-filled syringe

Arm title	Hulio and Humira switching arm (Group 2)

Arm description:

Subjects undergo repeated switches between Humira and Hulio between week 12 to week26.
- Hulio (40 mg every other week) at Week 12 and Week14
- Humira (40 mg every other week) at Week 16 and Week18, and
- Hulio (40 mg every other week) at Week 20, Week 22,Week 24 and Week26.

Arm type	Active comparator
Investigational medicinal product name	Hulio
Investigational medicinal product code	Adalimumab
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

40 mg in 0.8 mL Subcutaneous injection in pre-filled syringe

Investigational medicinal product name	Humira
Investigational medicinal product code	Adalimumab
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

40 mg in 0.4 mL Subcutaneous injection in pre-filled syringe

Number of subjects in period 1	Humira non-switching treatment arm (Group 1).	Hulio and Humira switching arm (Group 2)
Started	193	181
Completed	176	164
Not completed	17	17
Adverse event, serious fatal	-	1
Physician decision	2	-
Adverse event, non-fatal	1	1
Other reasons	14	15

Baseline characteristics

Reporting groups	
Reporting group title	Humira non-switching treatment arm (Group 1).
Reporting group description:	
Subjects continue to receive Humira (40 mg every other week) until Week 26/Visit 14.	
Reporting group title	Hulio and Humira switching arm (Group 2)
Reporting group description:	
Subjects undergo repeated switches between Humira and Hulio between week 12 to week26. - Hulio (40 mg every other week) at Week 12 and Week14 - Humira (40 mg every other week) at Week 16 and Week18, and - Hulio (40 mg every other week) at Week 20, Week 22,Week 24 and Week26.	

Reporting group values	Humira non-switching treatment arm (Group 1).	Hulio and Humira switching arm (Group 2)	Total
Number of subjects	193	181	374
Age categorical			
the demographic profile was balanced between the treatment groups with respect to age, gender, race, and ethnic origin.			
Units: Subjects			
Adults (18-64 years)	173	157	330
From 65-84 years	20	22	42
<=18 years	0	2	2
Age continuous			
Units: years			
arithmetic mean	46.4	45.7	
standard deviation	± 12.86	± 13.40	-
Gender categorical			
Units: Subjects			
Female	61	69	130
Male	132	112	244

Subject analysis sets	
Subject analysis set title	Full Analysis set
Subject analysis set type	Full analysis
Subject analysis set description:	
Full Analysis set	

Reporting group values	Full Analysis set		
Number of subjects	374		
Age categorical			
the demographic profile was balanced between the treatment groups with respect to age, gender, race, and ethnic origin.			
Units: Subjects			
Adults (18-64 years)	330		
From 65-84 years	42		
<=18 years	2		

Age continuous Units: years			
arithmetic mean	46.0		
standard deviation	±		
Gender categorical Units: Subjects			
Female	130		
Male	244		

End points

End points reporting groups

Reporting group title	Humira non-switching treatment arm (Group 1).
Reporting group description:	
Subjects continue to receive Humira (40 mg every other week) until Week 26/Visit 14.	
Reporting group title	Hulio and Humira switching arm (Group 2)
Reporting group description:	
Subjects undergo repeated switches between Humira and Hulio between week 12 to week26. - Hulio (40 mg every other week) at Week 12 and Week14 - Humira (40 mg every other week) at Week 16 and Week18, and - Hulio (40 mg every other week) at Week 20, Week 22,Week 24 and Week26.	
Subject analysis set title	Full Analysis set
Subject analysis set type	Full analysis
Subject analysis set description:	
Full Analysis set	

Primary: Pharmacokinetics-AUC, Cmax, Cmin

End point title	Pharmacokinetics-AUC, Cmax, Cmin
End point description:	
End point type	Primary
End point timeframe:	
Week 26 - 28	

End point values	Humira non-switching treatment arm (Group 1).	Hulio and Humira switching arm (Group 2)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	166	159		
Units: ug/mL				
arithmetic mean (standard deviation)	7.69 (± 4.96)	8.46 (± 5.42)		

Statistical analyses

Statistical analysis title	Statistical Analysis 1_AUCT, 26-28
Comparison groups	Humira non-switching treatment arm (Group 1). v Hulio and Humira switching arm (Group 2)
Number of subjects included in analysis	325
Analysis specification	Pre-specified
Analysis type	equivalence
Parameter estimate	Mean difference (final values)
Point estimate	104.76

Confidence interval	
level	90 %
sides	2-sided
lower limit	98.23
upper limit	111.74

Statistical analysis title	Statistical Analysis 2_Cmax, 26-28
Comparison groups	Humira non-switching treatment arm (Group 1). v Hulio and Humira switching arm (Group 2)
Number of subjects included in analysis	325
Analysis specification	Pre-specified
Analysis type	equivalence
Parameter estimate	Mean difference (final values)
Point estimate	104.23
Confidence interval	
level	90 %
sides	2-sided
lower limit	95.85
upper limit	113.36

Statistical analysis title	Statistical Analysis Cmin, 26-28
Comparison groups	Hulio and Humira switching arm (Group 2) v Humira non-switching treatment arm (Group 1).
Number of subjects included in analysis	325
Analysis specification	Pre-specified
Analysis type	equivalence
Parameter estimate	Mean difference (final values)
Point estimate	107.85
Confidence interval	
level	90 %
sides	2-sided
lower limit	99.99
upper limit	116.37

Adverse events

Adverse events information	
Timeframe for reporting adverse events: Till 30 Weeks	
Assessment type	Systematic
Dictionary used	
Dictionary name	MedDRA
Dictionary version	26.0
Reporting groups	
Reporting group title	Group 1
Reporting group description: -	
Reporting group title	Group 2
Reporting group description: -	

Serious adverse events	Group 1	Group 2	
Total subjects affected by serious adverse events			
subjects affected / exposed	3 / 193 (1.55%)	3 / 181 (1.66%)	
number of deaths (all causes)	0	1	
number of deaths resulting from adverse events	0	1	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Basal cell carcinoma			
subjects affected / exposed	0 / 193 (0.00%)	1 / 181 (0.55%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Injury, poisoning and procedural complications			
Multiple fractures			
subjects affected / exposed	1 / 193 (0.52%)	0 / 181 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular disorders			
Deep vein thrombosis			
subjects affected / exposed	1 / 193 (0.52%)	0 / 181 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac disorders			
Acute myocardial infarction			

subjects affected / exposed	1 / 193 (0.52%)	0 / 181 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal and connective tissue disorders			
Intervertebral disc protrusion			
subjects affected / exposed	0 / 193 (0.00%)	1 / 181 (0.55%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
COVID-19 pneumonia			
subjects affected / exposed	0 / 193 (0.00%)	1 / 181 (0.55%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Vestibular neuronitis			
subjects affected / exposed	1 / 193 (0.52%)	0 / 181 (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: 0 %

Non-serious adverse events	Group 1	Group 2	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	66 / 193 (34.20%)	54 / 181 (29.83%)	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Skin papilloma			
subjects affected / exposed	0 / 193 (0.00%)	1 / 181 (0.55%)	
occurrences (all)	0	1	
Vascular disorders			
Hypertension			
subjects affected / exposed	4 / 193 (2.07%)	1 / 181 (0.55%)	
occurrences (all)	4	1	
Phlebitis			
subjects affected / exposed	1 / 193 (0.52%)	0 / 181 (0.00%)	
occurrences (all)	1	0	
Surgical and medical procedures			

Intraocular lens implant			
subjects affected / exposed	1 / 193 (0.52%)	0 / 181 (0.00%)	
occurrences (all)	1	0	
General disorders and administration site conditions			
Injection site erythema			
subjects affected / exposed	3 / 193 (1.55%)	3 / 181 (1.66%)	
occurrences (all)	10	4	
Injection site pain			
subjects affected / exposed	4 / 193 (2.07%)	1 / 181 (0.55%)	
occurrences (all)	6	1	
Injection site pruritus			
subjects affected / exposed	2 / 193 (1.04%)	2 / 181 (1.10%)	
occurrences (all)	6	4	
Injection site swelling			
subjects affected / exposed	2 / 193 (1.04%)	2 / 181 (1.10%)	
occurrences (all)	7	2	
Injection site hypersensitivity			
subjects affected / exposed	0 / 193 (0.00%)	2 / 181 (1.10%)	
occurrences (all)	0	2	
Pyrexia			
subjects affected / exposed	1 / 193 (0.52%)	1 / 181 (0.55%)	
occurrences (all)	3	1	
Administration site erythema			
subjects affected / exposed	0 / 193 (0.00%)	1 / 181 (0.55%)	
occurrences (all)	0	1	
Administration site swelling			
subjects affected / exposed	0 / 193 (0.00%)	1 / 181 (0.55%)	
occurrences (all)	0	1	
Fatigue			
subjects affected / exposed	1 / 193 (0.52%)	0 / 181 (0.00%)	
occurrences (all)	1	0	
Injection site bruising			
subjects affected / exposed	1 / 193 (0.52%)	0 / 181 (0.00%)	
occurrences (all)	1	0	
Immune system disorders			

Hypersensitivity			
subjects affected / exposed	1 / 193 (0.52%)	0 / 181 (0.00%)	
occurrences (all)	1	0	
Seasonal allergy			
subjects affected / exposed	1 / 193 (0.52%)	0 / 181 (0.00%)	
occurrences (all)	1	0	
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	0 / 193 (0.00%)	1 / 181 (0.55%)	
occurrences (all)	0	1	
Oropharyngeal pain			
subjects affected / exposed	1 / 193 (0.52%)	0 / 181 (0.00%)	
occurrences (all)	1	0	
Psychiatric disorders			
Depression			
subjects affected / exposed	1 / 193 (0.52%)	0 / 181 (0.00%)	
occurrences (all)	1	0	
Panic attack			
subjects affected / exposed	0 / 193 (0.00%)	1 / 181 (0.55%)	
occurrences (all)	0	1	
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	5 / 193 (2.59%)	3 / 181 (1.66%)	
occurrences (all)	5	4	
Gamma-glutamyltransferase increased			
subjects affected / exposed	3 / 193 (1.55%)	3 / 181 (1.66%)	
occurrences (all)	3	4	
Aspartate aminotransferase increased			
subjects affected / exposed	3 / 193 (1.55%)	2 / 181 (1.10%)	
occurrences (all)	4	2	
Blood glucose increased			
subjects affected / exposed	2 / 193 (1.04%)	0 / 181 (0.00%)	
occurrences (all)	2	0	
Lymphocyte count decreased			

subjects affected / exposed	1 / 193 (0.52%)	0 / 181 (0.00%)	
occurrences (all)	1	0	
Neutrophil count decreased			
subjects affected / exposed	1 / 193 (0.52%)	0 / 181 (0.00%)	
occurrences (all)	1	0	
Monocyte count increased			
subjects affected / exposed	1 / 193 (0.52%)	0 / 181 (0.00%)	
occurrences (all)	1	0	
Injury, poisoning and procedural complications			
Limb injury			
subjects affected / exposed	0 / 193 (0.00%)	1 / 181 (0.55%)	
occurrences (all)	0	2	
Traumatic fracture			
subjects affected / exposed	0 / 193 (0.00%)	1 / 181 (0.55%)	
occurrences (all)	0	1	
Nervous system disorders			
Headache			
subjects affected / exposed	6 / 193 (3.11%)	4 / 181 (2.21%)	
occurrences (all)	8	6	
Sciatica			
subjects affected / exposed	0 / 193 (0.00%)	2 / 181 (1.10%)	
occurrences (all)	0	2	
Blood and lymphatic system disorders			
Haematotoxicity			
subjects affected / exposed	0 / 193 (0.00%)	1 / 181 (0.55%)	
occurrences (all)	0	1	
Leukopenia			
subjects affected / exposed	0 / 193 (0.00%)	1 / 181 (0.55%)	
occurrences (all)	0	1	
Normocytic anaemia			
subjects affected / exposed	0 / 193 (0.00%)	1 / 181 (0.55%)	
occurrences (all)	0	1	
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	2 / 193 (1.04%)	2 / 181 (1.10%)	
occurrences (all)	2	2	

Food poisoning			
subjects affected / exposed	0 / 193 (0.00%)	1 / 181 (0.55%)	
occurrences (all)	0	1	
Toothache			
subjects affected / exposed	1 / 193 (0.52%)	0 / 181 (0.00%)	
occurrences (all)	1	0	
Hepatobiliary disorders			
Fatty liver alcoholic			
subjects affected / exposed	0 / 193 (0.00%)	1 / 181 (0.55%)	
occurrences (all)	0	1	
Hepatic steatosis			
subjects affected / exposed	1 / 193 (0.52%)	0 / 181 (0.00%)	
occurrences (all)	1	0	
Skin and subcutaneous tissue disorders			
Psoriasis			
subjects affected / exposed	3 / 193 (1.55%)	2 / 181 (1.10%)	
occurrences (all)	3	2	
Acne			
subjects affected / exposed	0 / 193 (0.00%)	1 / 181 (0.55%)	
occurrences (all)	0	1	
Dermatitis acneiform			
subjects affected / exposed	1 / 193 (0.52%)	0 / 181 (0.00%)	
occurrences (all)	1	0	
Dermatitis allergic			
subjects affected / exposed	1 / 193 (0.52%)	0 / 181 (0.00%)	
occurrences (all)	1	0	
Dermatitis contact			
subjects affected / exposed	0 / 193 (0.00%)	1 / 181 (0.55%)	
occurrences (all)	0	1	
Palmoplantar pustulosis			
subjects affected / exposed	1 / 193 (0.52%)	0 / 181 (0.00%)	
occurrences (all)	1	0	
Pustular psoriasis			
subjects affected / exposed	0 / 193 (0.00%)	1 / 181 (0.55%)	
occurrences (all)	0	1	
Rash			

subjects affected / exposed	0 / 193 (0.00%)	1 / 181 (0.55%)	
occurrences (all)	0	1	
Skin irritation			
subjects affected / exposed	1 / 193 (0.52%)	0 / 181 (0.00%)	
occurrences (all)	1	0	
Renal and urinary disorders			
Renal colic			
subjects affected / exposed	1 / 193 (0.52%)	1 / 181 (0.55%)	
occurrences (all)	1	1	
Acute kidney injury			
subjects affected / exposed	0 / 193 (0.00%)	1 / 181 (0.55%)	
occurrences (all)	0	1	
Dysuria			
subjects affected / exposed	0 / 193 (0.00%)	1 / 181 (0.55%)	
occurrences (all)	0	1	
Haematuria			
subjects affected / exposed	0 / 193 (0.00%)	1 / 181 (0.55%)	
occurrences (all)	0	1	
Leukocyturia			
subjects affected / exposed	0 / 193 (0.00%)	1 / 181 (0.55%)	
occurrences (all)	0	1	
Proteinuria			
subjects affected / exposed	1 / 193 (0.52%)	0 / 181 (0.00%)	
occurrences (all)	1	0	
Renal cyst			
subjects affected / exposed	1 / 193 (0.52%)	0 / 181 (0.00%)	
occurrences (all)	1	0	
Renal failure			
subjects affected / exposed	0 / 193 (0.00%)	1 / 181 (0.55%)	
occurrences (all)	0	1	
Endocrine disorders			
Hyperthyroidism			
subjects affected / exposed	1 / 193 (0.52%)	0 / 181 (0.00%)	
occurrences (all)	1	0	
Musculoskeletal and connective tissue disorders			

Arthralgia			
subjects affected / exposed	2 / 193 (1.04%)	3 / 181 (1.66%)	
occurrences (all)	2	5	
Back pain			
subjects affected / exposed	1 / 193 (0.52%)	3 / 181 (1.66%)	
occurrences (all)	1	5	
Psoriatic arthropathy			
subjects affected / exposed	0 / 193 (0.00%)	3 / 181 (1.66%)	
occurrences (all)	0	3	
Arthropathy			
subjects affected / exposed	0 / 193 (0.00%)	1 / 181 (0.55%)	
occurrences (all)	0	1	
Intervertebral disc disorder			
subjects affected / exposed	1 / 193 (0.52%)	0 / 181 (0.00%)	
occurrences (all)	1	0	
Pain in extremity			
subjects affected / exposed	0 / 193 (0.00%)	1 / 181 (0.55%)	
occurrences (all)	0	1	
Infections and infestations			
Nasopharyngitis			
subjects affected / exposed	11 / 193 (5.70%)	4 / 181 (2.21%)	
occurrences (all)	11	4	
Upper respiratory tract infection			
subjects affected / exposed	4 / 193 (2.07%)	4 / 181 (2.21%)	
occurrences (all)	4	4	
Pharyngitis			
subjects affected / exposed	4 / 193 (2.07%)	2 / 181 (1.10%)	
occurrences (all)	4	2	
Rhinitis			
subjects affected / exposed	3 / 193 (1.55%)	1 / 181 (0.55%)	
occurrences (all)	3	1	
Tonsillitis			
subjects affected / exposed	2 / 193 (1.04%)	2 / 181 (1.10%)	
occurrences (all)	2	2	
Urinary tract infection			

subjects affected / exposed	2 / 193 (1.04%)	2 / 181 (1.10%)	
occurrences (all)	2	2	
Influenza			
subjects affected / exposed	1 / 193 (0.52%)	2 / 181 (1.10%)	
occurrences (all)	1	2	
Sinusitis			
subjects affected / exposed	2 / 193 (1.04%)	1 / 181 (0.55%)	
occurrences (all)	2	1	
Oral herpes			
subjects affected / exposed	2 / 193 (1.04%)	0 / 181 (0.00%)	
occurrences (all)	2	0	
Pulpitis dental			
subjects affected / exposed	2 / 193 (1.04%)	0 / 181 (0.00%)	
occurrences (all)	2	0	
Bacteriuria			
subjects affected / exposed	0 / 193 (0.00%)	1 / 181 (0.55%)	
occurrences (all)	0	1	
Bronchitis			
subjects affected / exposed	1 / 193 (0.52%)	0 / 181 (0.00%)	
occurrences (all)	1	0	
COVID-19 pneumonia			
subjects affected / exposed	0 / 193 (0.00%)	1 / 181 (0.55%)	
occurrences (all)	0	1	
Folliculitis			
subjects affected / exposed	0 / 193 (0.00%)	1 / 181 (0.55%)	
occurrences (all)	0	1	
Gastroenteritis			
subjects affected / exposed	0 / 193 (0.00%)	1 / 181 (0.55%)	
occurrences (all)	0	1	
Gastrointestinal infection			
subjects affected / exposed	0 / 193 (0.00%)	1 / 181 (0.55%)	
occurrences (all)	0	1	
Gastrointestinal viral infection			
subjects affected / exposed	0 / 193 (0.00%)	1 / 181 (0.55%)	
occurrences (all)	0	1	
Helicobacter infection			

subjects affected / exposed	1 / 193 (0.52%)	0 / 181 (0.00%)	
occurrences (all)	1	0	
Lyme disease			
subjects affected / exposed	1 / 193 (0.52%)	0 / 181 (0.00%)	
occurrences (all)	1	0	
Oral candidiasis			
subjects affected / exposed	1 / 193 (0.52%)	0 / 181 (0.00%)	
occurrences (all)	1	0	
Pharyngitis streptococcal			
subjects affected / exposed	0 / 193 (0.00%)	1 / 181 (0.55%)	
occurrences (all)	0	1	
Pseudomonas infection			
subjects affected / exposed	0 / 193 (0.00%)	1 / 181 (0.55%)	
occurrences (all)	0	1	
Varicella zoster virus infection			
subjects affected / exposed	1 / 193 (0.52%)	0 / 181 (0.00%)	
occurrences (all)	1	0	
Skin candida			
subjects affected / exposed	1 / 193 (0.52%)	0 / 181 (0.00%)	
occurrences (all)	1	0	
Vulvovaginal candidiasis			
subjects affected / exposed	1 / 193 (0.52%)	0 / 181 (0.00%)	
occurrences (all)	1	0	
Urinary casts			
subjects affected / exposed	1 / 193 (0.52%)	0 / 181 (0.00%)	
occurrences (all)	1	0	
Metabolism and nutrition disorders			
Dyslipidaemia			
subjects affected / exposed	1 / 193 (0.52%)	0 / 181 (0.00%)	
occurrences (all)	1	0	
Hypercalcaemia			
subjects affected / exposed	1 / 193 (0.52%)	0 / 181 (0.00%)	
occurrences (all)	1	0	
Hyperlipidaemia			
subjects affected / exposed	1 / 193 (0.52%)	0 / 181 (0.00%)	
occurrences (all)	1	0	

Obesity subjects affected / exposed occurrences (all)	1 / 193 (0.52%) 1	0 / 181 (0.00%) 0	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
24 August 2022	ADA-IJZ-3001 - Protocol v2.0 dated 24 August 2022

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

Limitations of the trial such as small numbers of subjects analysed or technical problems leading to unreliable data.

Not applicable

Notes: