Clinical trial results:
A Multicenter, Randomized, Double-blind Study Evaluating the Pharmacokinetics, Efficacy, Safety, and Immunogenicity of Multiple Switches Between Humira (adalimumab [US]) and ABP 501 Compared With Continued Use of Adalimumab in Subjects With Moderate to Severe Plaque Psoriasis

Summary

EudraCT number	2021-000542-18
Trial protocol	DE LV
Global end of trial date	19 December 2022

Results information

Result version number	v1 (current)
This version publication date	04 January 2024
First version publication date	04 January 2024

Trial information

Trial identification

Sponsor protocol code	20200497

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Amgen Inc.
Sponsor organisation address	One Amgen Center Drive, Thousand Oaks, CA, United States,
Public contact	IHQ Medical Info-Clinical Trials, Amgen (EUROPE) GmbH, MedInfoInternational@amgen.com
Scientific contact	IHQ Medical Info-Clinical Trials, Amgen (EUROPE) GmbH, MedInfoInternational@amgen.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 December 2022
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	19 December 2022
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The main objective of the study is to demonstrate similarity of pharmacokinetics (PK) in participants after multiple switches between adalimumab (Humira®) 100 mg/mL and ABP 501 100 mg/mL, compared to participants receiving continued use of adalimumab 100 mg/mL.

Protection of trial subjects:

This study was conducted in accordance with International Council for Harmonisation (ICH) Good Clinical Practice (GCP) Guideline E6 (R1)/Integrated Addendum E6 (R2); 21 Code of Federal Regulations Parts 50, 56, and 312; requirements for the conduct of clinical studies as provided in the European Union (EU) Directive 2001/20/EC; the consensus ethical principles derived from international guidelines including the Declaration of Helsinki and Council for International Organizations of Medical Sciences International Ethical Guidelines; and all applicable laws and regulatory requirements.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	04 October 2021
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Poland: 143
Country: Number of subjects enrolled	Germany: 38
Country: Number of subjects enrolled	Latvia: 14
Country: Number of subjects enrolled	Estonia: 9
Country: Number of subjects enrolled	United States: 151
Country: Number of subjects enrolled	Canada: 70
Worldwide total number of subjects	425
EEA total number of subjects	204

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0

Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	384
From 65 to 84 years	41
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

A total of 425 participants were enrolled in the study at 83 centers across 6 countries (Canada, Estonia, Germany, Latvia, Poland, and the US) between October 2021 and December 2022.

Pre-assignment

Screening details:

Participants were enrolled into period 1 of the study (Lead-in Period) and received adalimumab subcutaneously (SC) during 12 week. Participants who responded to treatment during Period 1 (achieving PASI ≥ 50) were randomized to Period 2 to either the Continued-use Group or the Switching Group. Period 2 lasted 20 weeks from Week 12 to Week 32.

Period 1

Period 1 title	Period 1 (Lead-in period)
Is this the baseline period?	No
Allocation method	Non-randomised - controlled
Blinding used	Double blind
Roles blinded	Investigator, Subject

Arms

Arm title	Period 1 (Lead-in period)

Arm description:

Participants with plaque psoriasis (Ps) received adalimumab 100 mg/mL SC from Week 1 to Week 12 for a total of 6 doses (Week 1/Day 1 [80 mg], Week 2/Day 8 [40 mg], Week 4, Week 6, Week 8, and Week 10 [40 mg]) during the Lead-in Period.

Arm type	No intervention

No investigational medicinal product assigned in this arm

Number of subjects in period 1	Period 1 (Lead-in period)
Started	425
Completed	380
Not completed	45
Adverse event, serious fatal	1
Consent withdrawn by subject	6
Adverse event, non-fatal	6
Not indicated	1
Lost to follow-up	3
Lack of efficacy	23
Protocol deviation	5

Period 2

Period 2 title	Period 2
Is this the baseline period?	Yes[1]
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator

Arms

Are arms mutually exclusive?	Yes
Arm title	Period 2 (Switching Group)

Arm description:

Participants with Ps who responded to treatment (achieving PASI ≥ 50) in Period 1, were randomised to the Switching Group from Week 12 to Week 32 in Period 2 of the study. Participants received ABP 501 Q2W (Week 12 and Week 14 [40 mg]), adalimumab Q2W (Week 16 and Week 18 [40 mg]), and again ABP 501 Q2W (Week 20, Week 22, Week 24, Week 26, Week 28 [40 mg]).

Arm type	Experimental
Investigational medicinal product name	ABP 501
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Subcutaneous use

Dosage and administration details:

40 mg Q2W at Week 12, Week 14, Week 20, Week 22, Week 24, Week 26, and Week 28

Investigational medicinal product name	Adalimumab
Investigational medicinal product code	
Other name	Humira
Pharmaceutical forms	Suspension for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

40 mg Q2W at Week 16 and Week 18

Arm title	Period 2 (Continued-use Group)

Arm description:

Participants with Ps who responded to treatment achieving PASI ≥ 50 in Period 1, were randomised to the Continued-use Group from Week 12 to Week 32 in Period 2 of the study. Participants continued receiving adalimumab 40 mg Q2W.

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

Dosage and administration details:

40 mg Q2W from Week 12 to Week 28

Notes:

[1] - Period 1 is not the baseline period. It is expected that period 1 will be the baseline period.

Justification: Baseline characteristics are presented for participants who responded to treatment during Period 1 (achieving PASI ≥ 50) and were randomized in Period 2.

Number of subjects in period 2[2]	Period 2 (Switching Group)	Period 2 (Continued-use Group)
Started	186	194
Completed	174	173
Not completed	12	21
Consent withdrawn by subject	4	9
Adverse event, non-fatal	3	6
Lost to follow-up	5	5
Protocol deviation	-	1

Notes:

[2] - The number of subjects reported to be in the baseline period are not the same as the worldwide number enrolled in the trial. It is expected that these numbers will be the same.
Justification: Baseline characteristics are presented for participants who responded to treatment during Period 1 (achieving PASI ≥ 50) and were randomized in Period 2. The worldwide number enrolled in the study includes participants in the Lead-in Period.

Baseline characteristics

Reporting groups	
Reporting group title	Period 2 (Switching Group)
Reporting group description:	
Participants with Ps who responded to treatment (achieving PASI ≥ 50) in Period 1, were randomised to the Switching Group from Week 12 to Week 32 in Period 2 of the study. Participants received ABP 501 Q2W (Week 12 and Week 14 [40 mg]), adalimumab Q2W (Week 16 and Week 18 [40 mg]), and again ABP 501 Q2W (Week 20, Week 22, Week 24, Week 26, Week 28 [40 mg]).	
Reporting group title	Period 2 (Continued-use Group)
Reporting group description:	
Participants with Ps who responded to treatment achieving PASI ≥ 50 in Period 1, were randomised to the Continued-use Group from Week 12 to Week 32 in Period 2 of the study. Participants continued receiving adalimumab 40 mg Q2W.	

Reporting group values	Period 2 (Switching Group)	Period 2 (Continued-use Group)	Total
Number of subjects	186	194	380
Age categorical Units: Participants			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	171	173	344
From 65-84 years	15	21	36
85 years and over	0	0	0
Age Continuous Units: years			
arithmetic mean	44.9	44.3	
standard deviation	± 13.27	± 13.91	-
Sex: Female, Male Units: Participants			
Female	56	63	119
Male	130	131	261
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	2	2	4
Asian	14	10	24
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	4	4	8
White	162	172	334
More than one race	1	0	1
Unknown or Not Reported	3	6	9
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	27	36	63

Not Hispanic or Latino	158	158	316
Unknown or Not Reported	1	0	1

End points

End points reporting groups

Reporting group title	Period 1 (Lead-in period)
Reporting group description:	
Participants with plaque psoriasis (Ps) received adalimumab 100 mg/mL SC from Week 1 to Week 12 for a total of 6 doses (Week 1/Day 1 [80 mg], Week 2/Day 8 [40 mg], Week 4, Week 6, Week 8, and Week 10 [40 mg]) during the Lead-in Period.	
Reporting group title	Period 2 (Switching Group)
Reporting group description:	
Participants with Ps who responded to treatment (achieving PASI ≥ 50) in Period 1, were randomised to the Switching Group from Week 12 to Week 32 in Period 2 of the study. Participants received ABP 501 Q2W (Week 12 and Week 14 [40 mg]), adalimumab Q2W (Week 16 and Week 18 [40 mg]), and again ABP 501 Q2W (Week 20, Week 22, Week 24, Week 26, Week 28 [40 mg]).	
Reporting group title	Period 2 (Continued-use Group)
Reporting group description:	
Participants with Ps who responded to treatment achieving PASI ≥ 50 in Period 1, were randomised to the Continued-use Group from Week 12 to Week 32 in Period 2 of the study. Participants continued receiving adalimumab 40 mg Q2W.	

Primary: Area Under the Curve From Time 0 Over the Dosing Interval (AUCtau) of ABP 501 (Switching Group) and Adalimumab (Continued-use Group)

End point title	Area Under the Curve From Time 0 Over the Dosing Interval (AUCtau) of ABP 501 (Switching Group) and Adalimumab (Continued-use Group)
End point description:	
Data collected from the PK Parameter Analysis Set which consisted of all randomized participants who receive at least one dose post-randomization and who have an evaluable ABP 501 or adalimumab serum concentration-time profile between weeks 28 and 30. This analysis set was used for the primary analysis of the primary and secondary PK endpoints and was analyzed according to actual treatment received.	
End point type	Primary
End point timeframe:	
Week 28 pre-dose and 1hour, 1 day, 3 days, 4 days, 7 days, 11 days, and 14 days post Week 28 dose	

End point values	Period 2 (Switching Group)	Period 2 (Continued-use Group)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	146	145		
Units: hr*µg/mL				
geometric mean (geometric coefficient of variation)	1458.03 (± 156.6)	1472.68 (± 174.9)		

Statistical analyses

Statistical analysis title	AUCtau
Comparison groups	Period 2 (Continued-use Group) v Period 2 (Switching Group)

Number of subjects included in analysis	291
Analysis specification	Pre-specified
Analysis type	equivalence[1]
Parameter estimate	Ratio Geometric Least Square Mean (GMR)
Point estimate	1.0516
Confidence interval	
level	90 %
sides	2-sided
lower limit	0.901
upper limit	1.2273

Notes:

[1] - The pre-specified similarity margin was 0.8 to 1.25.

Primary: Maximum Serum Concentration (Cmax) of ABP 501 (Switching Group) and Adalimumab (Continued-use Group)

End point title	Maximum Serum Concentration (Cmax) of ABP 501 (Switching Group) and Adalimumab (Continued-use Group)

End point description:

Data collected from the PK Parameter Analysis Set which consisted of all randomized participants who receive at least one dose post-randomization and who have an evaluable ABP 501 or adalimumab serum concentration-time profile between weeks 28 and 30. This analysis set was used for the primary analysis of the primary and secondary PK endpoints and was analyzed according to actual treatment received.

End point type	Primary

End point timeframe:

Week 28 pre-dose and 1hour, 1 day, 3 days, 4 days, 7 days, 11 days, and 14 days post Week 28 dose

End point values	Period 2 (Switching Group)	Period 2 (Continued-use Group)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	153	153		
Units: µg/mL				
geometric mean (geometric coefficient of variation)	4.91 (± 153.6)	5.01 (± 160.4)		

Statistical analyses

Statistical analysis title	Cmax
Comparison groups	Period 2 (Switching Group) v Period 2 (Continued-use Group)
Number of subjects included in analysis	306
Analysis specification	Pre-specified
Analysis type	equivalence[2]
Parameter estimate	GMR
Point estimate	1.0044

Confidence interval	
level	90 %
sides	2-sided
lower limit	0.8717
upper limit	1.1574

Notes:

[2] - The pre-specified similarity margin was 0.8 to 1.25.

Secondary: Time to Reach Maximum Serum Concentration (tmax) of ABP 501 (Switching Group) and Adalimumab (Continued-use Group)

End point title	Time to Reach Maximum Serum Concentration (tmax) of ABP 501 (Switching Group) and Adalimumab (Continued-use Group)

End point description:

Data collected from the PK Parameter Analysis Set which consisted of all randomized participants who receive at least one dose post-randomization and who have an evaluable ABP 501 or adalimumab serum concentration-time profile between weeks 28 and 30. This analysis set was used for the primary analysis of the primary and secondary PK endpoints and was analyzed according to actual treatment received.

End point type	Secondary

End point timeframe:

Week 28 pre-dose and 1hour, 1 day, 3 days, 4 days, 7 days, 11 days, and 14 days post Week 28 dose

End point values	Period 2 (Switching Group)	Period 2 (Continued-use Group)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	162	160		
Units: Hours				
median (full range (min-max))	72.30 (0 to 266.5)	72.35 (0 to 334.9)		

Statistical analyses

No statistical analyses for this end point

Secondary: Trough Concentration (Ctrough) of ABP 501 (Switching Group) and Adalimumab (Continued-use Group)

End point title	Trough Concentration (Ctrough) of ABP 501 (Switching Group) and Adalimumab (Continued-use Group)

End point description:

Data collected between Week 14 and Week 28

End point type	Secondary

End point timeframe:

Week 12, Week 16, Week 20 and Week 28

End point values	Period 2 (Switching Group)	Period 2 (Continued-use Group)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	162	160		
Units: ng/mL				
geometric mean (geometric coefficient of variation)				
Week 12	4528.7316 (± 88.9)	4072.5556 (± 119.0)		
Week 16	4046.3069 (± 144.1)	3682.0016 (± 188.1)		
Week 20	4113.0839 (± 160.8)	4332.1272 (± 148.9)		
Week 28	3736.9917 (± 182.1)	4014.4980 (± 193.5)		

Statistical analyses

No statistical analyses for this end point

Secondary: PASI Percent Improvement From Baseline (Day 1) to Week 30

End point title	PASI Percent Improvement From Baseline (Day 1) to Week 30

End point description:

The PASI measures the average redness (erythema), thickness (induration), and scaliness (each graded on a 0 to 4 scale) of psoriasis lesions, weighted by the area of involvement in the four main body areas (i.e., head and neck, trunk, upper extremities, and lower extremities). PASI scores can range from 0.0 to 72.0, with higher scores indicating greater severity and/or more extensive psoriasis. Percent improvement from baseline was calculated as (value at baseline - value at post-baseline visit) × 100 / (value at baseline). Results are presented for the per-protocol efficacy analysis set as observed, which consisted of all participants who were randomized and received all assigned doses post randomization and who had not experienced an important protocol deviation that could affect the efficacy endpoints.

End point type	Secondary

End point timeframe:

Baseline (Day 1), Week 30

End point values	Period 2 (Switching Group)	Period 2 (Continued-use Group)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	151	151		
Units: Percentage change				
arithmetic mean (confidence interval 95%)	88.56 (86.07 to 91.05)	91.01 (88.76 to 93.26)		

Statistical analyses

Statistical analysis title	PASI Percentage Change
Comparison groups	Period 2 (Switching Group) v Period 2 (Continued-use Group)

Number of subjects included in analysis	302
Analysis specification	Pre-specified
Analysis type	equivalence[3]
Parameter estimate	Mean difference (final values)
Point estimate	-2.47
Confidence interval	
level	90 %
sides	2-sided
lower limit	-5.23
upper limit	0.29

Notes:

[3] - The pre-specified similarity margin was 0.8 to 1.25.

Secondary: Number of Participants Achieving PASI 75 Response at Week 30

End point title	Number of Participants Achieving PASI 75 Response at Week 30

End point description:

A PASI 75 response is a 75% or greater improvement (reduction) from baseline in PASI score. The PASI measures the average redness (erythema), thickness (induration), and scaliness (each graded on a 0 to 4 scale) of psoriasis lesions, weighted by the area of involvement in the four main body areas (i.e., head and neck, trunk, upper extremities, and lower extremities). PASI scores can range from 0.0 to 72.0, with higher scores indicating greater severity and/or more extensive psoriasis. Results are presented for the per-protocol efficacy analysis set, which consisted of all participants who were randomized and received all assigned doses post randomization and who had not experienced an important protocol deviation that could affect the efficacy endpoints.

End point type	Secondary

End point timeframe:

Baseline (Day 1) and Week 30

End point values	Period 2 (Switching Group)	Period 2 (Continued-use Group)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	151	151		
Units: Participants	131	134		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants Achieving PASI 100 Response at Week 30

End point title	Number of Participants Achieving PASI 100 Response at Week 30

End point description:

A PASI 100 response is a 100% improvement (reduction) from baseline in PASI score. The PASI measures the average redness (erythema), thickness (induration), and scaliness (each graded on a 0 to 4 scale) of psoriasis lesions, weighted by the area of involvement in the four main body areas (i.e., head and neck, trunk, upper extremities, and lower extremities). PASI scores can range from 0.0 to 72.0, with higher scores indicating greater severity and/or more extensive psoriasis. Results are presented for the per-protocol efficacy analysis set, which consisted of all participants who were randomized and

received all assigned doses post randomization and who had not experienced an important protocol deviation that could affect the efficacy endpoints.

End point type	Secondary

End point timeframe:

Baseline (Day 1) and Week 30

End point values	Period 2 (Switching Group)	Period 2 (Continued-use Group)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	151	151		
Units: Participants	52	61		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants Achieving PASI 90 Response at Week 30

End point title	Number of Participants Achieving PASI 90 Response at Week 30

End point description:

A PASI 90 response is a 90% or greater improvement (reduction) from baseline in PASI score. The PASI measures the average redness (erythema), thickness (induration), and scaliness (each graded on a 0 to 4 scale) of psoriasis lesions, weighted by the area of involvement in the four main body areas (i.e., head and neck, trunk, upper extremities, and lower extremities). PASI scores can range from 0.0 to 72.0, with higher scores indicating greater severity and/or more extensive psoriasis. Results are presented for the per-protocol efficacy analysis set, which consisted of all participants who were randomized and received all assigned doses post randomization and who had not experienced an important protocol deviation that could affect the efficacy endpoints.

End point type	Secondary

End point timeframe:

Baseline (Day 1) and Week 30

End point values	Period 2 (Switching Group)	Period 2 (Continued-use Group)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	151	151		
Units: Participants	92	108		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants Experiencing Events of Interest (EOI)

End point title	Number of Participants Experiencing Events of Interest (EOI)

End point description:

An EOI is defined as a noteworthy event for a particular product or class of products that a sponsor may wish to monitor carefully. It could be serious or non-serious and could include events that might be potential precursors or prodromes for more serious medical conditions in susceptible individuals.

End point type	Secondary

End point timeframe:

Baseline up to Week 32

End point values	Period 2 (Switching Group)	Period 2 (Continued-use Group)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	186	194		
Units: Participants	13	17		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants Experiencing Treatment-emergent Adverse Events (TEAE)

End point title	Number of Participants Experiencing Treatment-emergent Adverse Events (TEAE)

End point description:

TEAEs are any event that occurred after the participant received study treatment. Any clinically significant changes in vital signs, electrocardiograms, and clinical laboratory tests that occurred after study treatment administration were recorded as TEAEs. A serious TEAE is any untoward medical occurrence in a clinical study participant after first dose irrespective of a causal relationship with the study treatment(s) that resulted in death, was immediately life threatening, required in-patient hospitalization or prolongation of existing hospitalization, resulted in persistent or significant disability/incapacity, a congenital anomaly/birth defect, or another medically important serious event.

End point type	Secondary

End point timeframe:

Baseline up to Week 32

End point values	Period 2 (Switching Group)	Period 2 (Continued-use Group)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	186	194		
Units: Participants				
TEAE	97	106		
Serious TEAE	3	4		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants With Anti-drug Antibodies (ADA) Expression Post Randomization

End point title	Number of Participants With Anti-drug Antibodies (ADA) Expression Post Randomization

End point description:

Ab = antibody
Trans = transient

End point type	Secondary

End point timeframe:

Week 16, Week 20, Week 28, Week 30, and Week 32

End point values	Period 2 (Switching Group)	Period 2 (Continued-use Group)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	186	194		
Units: Participants				
Subjects with a post-randomization result	186	194		
Binding Ab negative or no result	25	18		
Binding Ab positive post randomization	16	10		
Trans binding Ab positive post randomization	3	2		
Neutralizing Ab negative or no result	174	182		
Neutralizing Ab positive	21	27		
Trans neutralizing Ab positive post randomization	2	3		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

32 weeks

Adverse event reporting additional description:

All-cause mortality is reported for all participants enrolled/randomized in the study. Serious adverse events and other adverse events are reported for all participants who received at least one dose of study drug.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	25.1

Reporting groups

Reporting group title	Period 1 (Lead-in period)

Reporting group description:

Participants with Ps received adalimumab 100 mg/mL SC from Week 1 to Week 12 for a total of 6 doses (Week 1/D1 [80 mg], Week 2/D8 [40 mg], Week 4, Week 6, Week 8, and Week 10 [40 mg]) during the Lead-in Period.

Reporting group title	Period 2 (Switching Group)

Reporting group description:

Participants with Ps who responded to treatment achieving PASI ≥ 50 in Period 1, were randomised to the Switching Group from Week 12 to Week 32 in Period 2 of the study. Participants received ABP 501 Q2W (Week 12 and Week 14 [40 mg]), adalimumab Q2W (Week 16 and Week 18 [40 mg]), and again ABP 501 Q2W (Week 20, Week 22, Week 24, Week 26, Week 28 [40 mg]).

Reporting group title	Period 2 (Continued-use Group)

Reporting group description:

Participants with Ps who responded to treatment achieving PASI ≥ 50 in Period 1, were randomized to the Continued-use Group from Week 12 to Week 32 in Period 2 of the study. Participants continued receiving adalimumab 40 mg Q2W.

Serious adverse events	Period 1 (Lead-in period)	Period 2 (Switching Group)	Period 2 (Continued-use Group)
Total subjects affected by serious adverse events			
subjects affected / exposed	5 / 425 (1.18%)	3 / 186 (1.61%)	4 / 194 (2.06%)
number of deaths (all causes)	1	0	0
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Metastases to lymph nodes			
subjects affected / exposed	1 / 425 (0.24%)	0 / 186 (0.00%)	0 / 194 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Breast cancer			

subjects affected / exposed	1 / 425 (0.24%)	0 / 186 (0.00%)	0 / 194 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Trigeminal nerve disorder			
subjects affected / exposed	1 / 425 (0.24%)	0 / 186 (0.00%)	0 / 194 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Facial paralysis			
subjects affected / exposed	1 / 425 (0.24%)	0 / 186 (0.00%)	0 / 194 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Central nervous system lesion			
subjects affected / exposed	1 / 425 (0.24%)	0 / 186 (0.00%)	0 / 194 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pregnancy, puerperium and perinatal conditions			
Abortion spontaneous			
subjects affected / exposed	0 / 425 (0.00%)	0 / 186 (0.00%)	1 / 194 (0.52%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Death			
subjects affected / exposed	1 / 425 (0.24%)	0 / 186 (0.00%)	0 / 194 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Gastrointestinal disorders			
Alcoholic pancreatitis			
subjects affected / exposed	0 / 425 (0.00%)	1 / 186 (0.54%)	0 / 194 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal pain			

subjects affected / exposed	1 / 425 (0.24%)	0 / 186 (0.00%)	0 / 194 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colitis			
subjects affected / exposed	0 / 425 (0.00%)	0 / 186 (0.00%)	1 / 194 (0.52%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Diabetic foot			
subjects affected / exposed	0 / 425 (0.00%)	1 / 186 (0.54%)	0 / 194 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Osteoarthritis			
subjects affected / exposed	1 / 425 (0.24%)	0 / 186 (0.00%)	0 / 194 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Tuberculosis			
subjects affected / exposed	0 / 425 (0.00%)	0 / 186 (0.00%)	1 / 194 (0.52%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diverticulitis intestinal perforated			
subjects affected / exposed	0 / 425 (0.00%)	0 / 186 (0.00%)	1 / 194 (0.52%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Hyperglycaemia			
subjects affected / exposed	0 / 425 (0.00%)	1 / 186 (0.54%)	0 / 194 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

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

Non-serious adverse events	Period 1 (Lead-in period)	Period 2 (Switching Group)	Period 2 (Continued-use Group)
Total subjects affected by non-serious adverse events			
subjects affected / exposed	38 / 425 (8.94%)	26 / 186 (13.98%)	28 / 194 (14.43%)
Nervous system disorders			
Headache			
subjects affected / exposed	16 / 425 (3.76%)	4 / 186 (2.15%)	13 / 194 (6.70%)
occurrences (all)	19	4	15
Infections and infestations			
COVID-19			
subjects affected / exposed	14 / 425 (3.29%)	13 / 186 (6.99%)	7 / 194 (3.61%)
occurrences (all)	14	13	7
Nasopharyngitis			
subjects affected / exposed	12 / 425 (2.82%)	13 / 186 (6.99%)	11 / 194 (5.67%)
occurrences (all)	13	14	16

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported