



Clinical trial results:

A Multicenter, Randomized, Double-blinded Study Evaluating the Pharmacokinetics, Efficacy and Safety of Multiple Switches Between Ustekinumab and ABP 654 Compared with Continued Use of Ustekinumab in Subjects with Moderate to Severe Plaque Psoriasis Summary

EudraCT number	2020-005205-42
Trial protocol	DE HU LV EE ES
Global end of trial date	28 February 2023

Results information

Result version number	v1 (current)
This version publication date	28 December 2023
First version publication date	28 December 2023

Trial information

Trial identification

Sponsor protocol code	20200417
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT04761627
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	28 February 2023
Is this the analysis of the primary completion data?	No

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

Notes:

General information about the trial

Main objective of the trial:

The primary objective was to demonstrate similarity of pharmacokinetics (PK) in participants with multiple switches between ustekinumab RP and ABP 654 compared to participants receiving continued use of ustekinumab RP.

Protection of trial subjects:

This study was conducted in accordance with International Council for Harmonisation Good Clinical Practice 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 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	24 March 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	Canada: 88
Country: Number of subjects enrolled	Estonia: 14
Country: Number of subjects enrolled	Georgia: 6
Country: Number of subjects enrolled	Germany: 64
Country: Number of subjects enrolled	Hungary: 29
Country: Number of subjects enrolled	Latvia: 12
Country: Number of subjects enrolled	Poland: 121
Country: Number of subjects enrolled	United States: 160
Worldwide total number of subjects	494
EEA total number of subjects	240

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)	431
From 65 to 84 years	63
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Participants were enrolled at 87 study centers in 8 countries, including Canada, Estonia, Georgia, Germany, Hungary, Latvia, Poland, and the United States, and participated from 24 March 2021 to 28 February 2023.

Pre-assignment

Screening details:

Participants with plaque psoriasis were randomized at week 28 to 1 of 2 treatment groups following a run-in period. Randomization was stratified by prior biologic use for psoriasis at baseline, geographic region, and body weight group at baseline. Dosage was weight-based to ensure similar concentration by body weight received.

Period 1

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

Arms

Arm title	Run-in: Ustekinumab Reference Product (RP)
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Arm description:

Participants received ustekinumab RP 45 mg (baseline body weight $\leq$ 100 kg) or 90 mg (baseline body weight $>$ 100 kg) on day 1 (week 0), week 4, and week 16. At week 28, eligible participants with a 50% improvement in Psoriasis Area and Severity Index (PASI 50) response or better were randomized to the continued-use group (ustekinumab RP) or the switching group (ustekinumab RP and ABP 654).

Arm type	Experimental
Investigational medicinal product name	Ustekinumab RP
Investigational medicinal product code	
Other name	Stelara®
Pharmaceutical forms	Solution for injection in pre-filled syringe
Routes of administration	Subcutaneous use

Dosage and administration details:

Participants received ustekinumab RP 45 mg (baseline body weight $\leq$ 100 kg) or 90 mg (baseline body weight $>$ 100 kg) on day 1 (week 0), week 4, and week 16 in the run-in period.

Number of subjects in period 1	Run-in: Ustekinumab Reference Product (RP)
Started	494
Completed	453
Not completed	41
Adverse event, serious fatal	1
Consent withdrawn by subject	7
Abnormal liver function	1
Study site closure	2
Adverse event, non-fatal	6

Pregnancy	2
Did not meet PASI 50	15
Lost to follow-up	2
Required alternative therapy	2
Protocol deviation	3

Period 2

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

Arms

Are arms mutually exclusive?	Yes
Arm title	Post-randomization Switching: Ustekinumab RP and ABP 654

Arm description:

At week 28, eligible participants with a PASI 50 response or better were randomized to the switching group and received ABP 654 at week 28, ustekinumab RP at week 40, and ABP 654 at week 52. Ustekinumab RP and ABP 654 (45 mg [baseline body weight ≤ 100 kg] or 90 mg [baseline body weight > 100 kg]) were administered by SC injection using a pre-filled syringe.

Arm type	Experimental
Investigational medicinal product name	ABP 654
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection in pre-filled syringe
Routes of administration	Subcutaneous use

Dosage and administration details:

Participants received ABP 654 45 mg (baseline body weight ≤ 100 kg) or 90 mg (baseline body weight > 100 kg) at weeks 28 and 52 in the post-randomization period.

Investigational medicinal product name	Ustekinumab RP
Investigational medicinal product code	
Other name	Stelara®
Pharmaceutical forms	Solution for injection in pre-filled syringe
Routes of administration	Subcutaneous use

Dosage and administration details:

Participants received ustekinumab RP 45 mg (baseline body weight ≤ 100 kg) or 90 mg (baseline body weight > 100 kg) at week 40 in the post-randomization period.

Arm title	Post-randomization Continued-use: Ustekinumab RP
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Arm description:

At week 28, eligible participants with a PASI 50 response or better were randomized to the continued-use group to receive ustekinumab RP 45 mg (baseline body weight ≤ 100 kg) or 90 mg (baseline body weight > 100 kg) at weeks 28, 40, and 52. Ustekinumab RP was administered by SC injection using a pre-filled syringe.

Arm type	Experimental
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Investigational medicinal product name	Ustekinumab RP
Investigational medicinal product code	
Other name	Stelara®
Pharmaceutical forms	Solution for injection in pre-filled syringe
Routes of administration	Subcutaneous use

Dosage and administration details:

Participants received ustekinumab RP 45 mg (baseline body weight ≤ 100 kg) or 90 mg (baseline body weight > 100 kg) at weeks 28, 40, and 52 in the post-randomization period.

Notes:

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

Justification: In Period 2, eligible participants were randomized to treatment and this was considered the baseline period.

Number of subjects in period 2^[2]	Post-randomization Switching: Ustekinumab RP and ABP 654	Post-randomization Continued-use: Ustekinumab RP
Started	228	225
Full analysis set	228	225
Safety analysis set	228	224
Completed	209	209
Not completed	19	16
Consent withdrawn by subject	7	6
Study site closure	-	1
Adverse event, non-fatal	4	2
Family planning	1	-
Military service	1	-
Pregnancy	-	1
Lost to follow-up	6	6

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: The number of participants included in the worldwide number enrolled aligns with the number of participants who entered the run-in period.

Baseline characteristics

Reporting groups

Reporting group title	Post-randomization Switching: Ustekinumab RP and ABP 654
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Reporting group description:

At week 28, eligible participants with a PASI 50 response or better were randomized to the switching group and received ABP 654 at week 28, ustekinumab RP at week 40, and ABP 654 at week 52. Ustekinumab RP and ABP 654 (45 mg [baseline body weight ≤ 100 kg] or 90 mg [baseline body weight > 100 kg]) were administered by SC injection using a pre-filled syringe.

Reporting group title	Post-randomization Continued-use: Ustekinumab RP
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Reporting group description:

At week 28, eligible participants with a PASI 50 response or better were randomized to the continued-use group to receive ustekinumab RP 45 mg (baseline body weight ≤ 100 kg) or 90 mg (baseline body weight > 100 kg) at weeks 28, 40, and 52. Ustekinumab RP was administered by SC injection using a pre-filled syringe.

Reporting group values	Post-randomization Switching: Ustekinumab RP and ABP 654	Post-randomization Continued-use: Ustekinumab RP	Total
Number of subjects	228	225	453
Age Categorical Units: Subjects			
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)	203	190	393
From 65-84 years	25	35	60
85 years and over	0	0	0
Age Continuous Units: years			
arithmetic mean	46.9	48.1	
standard deviation	± 13.36	± 13.48	-
Gender Categorical Units: Subjects			
Female	64	83	147
Male	164	142	306
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	26	23	49
Not Hispanic or Latino	202	201	403
Unknown or Not Reported	0	1	1
Race/Ethnicity, Customized Units: Subjects			
White	207	214	421
Asian	9	3	12
Black or African American	7	1	8

Other	3	2	5
American Indian or Alaska Native	1	2	3
Native Hawaiian or other Pacific Islander	1	2	3
Not allowed to collect	0	1	1

End points

End points reporting groups

Reporting group title	Run-in: Ustekinumab Reference Product (RP)
Reporting group description: Participants received ustekinumab RP 45 mg (baseline body weight $\leq$ 100 kg) or 90 mg (baseline body weight $>$ 100 kg) on day 1 (week 0), week 4, and week 16. At week 28, eligible participants with a 50% improvement in Psoriasis Area and Severity Index (PASI 50) response or better were randomized to the continued-use group (ustekinumab RP) or the switching group (ustekinumab RP and ABP 654).	
Reporting group title	Post-randomization Switching: Ustekinumab RP and ABP 654
Reporting group description: At week 28, eligible participants with a PASI 50 response or better were randomized to the switching group and received ABP 654 at week 28, ustekinumab RP at week 40, and ABP 654 at week 52. Ustekinumab RP and ABP 654 (45 mg [baseline body weight $\leq$ 100 kg] or 90 mg [baseline body weight $>$ 100 kg]) were administered by SC injection using a pre-filled syringe.	
Reporting group title	Post-randomization Continued-use: Ustekinumab RP
Reporting group description: At week 28, eligible participants with a PASI 50 response or better were randomized to the continued-use group to receive ustekinumab RP 45 mg (baseline body weight $\leq$ 100 kg) or 90 mg (baseline body weight $>$ 100 kg) at weeks 28, 40, and 52. Ustekinumab RP was administered by SC injection using a pre-filled syringe.	
Subject analysis set title	Switching: Ustekinumab RP and ABP 654
Subject analysis set type	Safety analysis
Subject analysis set description: Participants were randomized to the switching group at week 28 and completed all planned doses of ABP 654 and ustekinumab RP up to week 52, including ABP 654 at week 28, ustekinumab RP at week 40, and ABP 654 at week 52.	
Subject analysis set title	Continued-use: Ustekinumab RP
Subject analysis set type	Safety analysis
Subject analysis set description: Participants were randomized to the continued-use group at week 28 and completed all planned doses of ustekinumab RP up to week 52, including 3 doses at weeks 28, 40, and 52.	
Subject analysis set title	Switching: ABP 654/Ustekinumab RP/Missing
Subject analysis set type	Safety analysis
Subject analysis set description: Participants were randomized to the switching group at week 28 and received ABP 654 at week 28 and ustekinumab RP at week 40 but did not receive the planned dose of ABP 654 at week 52.	
Subject analysis set title	Continued-use: Ustekinumab RP/Ustekinumab RP/Missing
Subject analysis set type	Safety analysis
Subject analysis set description: Participants were randomized to the continued-use group at week 28 and received ustekinumab RP at week 28 and week 40 but did not receive the planned dose of ustekinumab RP at week 52.	
Subject analysis set title	Switching: ABP 654/Missing/Missing
Subject analysis set type	Safety analysis
Subject analysis set description: Participants were randomized to the switching group at week 28 and received ABP 654 at week 28 and did not receive the planned doses of ustekinumab RP at week 40 and ABP 654 at week 52.	
Subject analysis set title	Continued-use: Ustekinumab RP/Missing/Missing
Subject analysis set type	Safety analysis
Subject analysis set description: Participants were randomized to the continued-use group at week 28 and received ustekinumab RP at week 28 but did not receive the planned doses of ustekinumab RP at week 40 and week 52.	

Primary: Area Under the Plasma Concentration Time Curve (AUC) Over the Dosing Interval (AUCtau) Between Week 52 and Week 64

End point title	Area Under the Plasma Concentration Time Curve (AUC) Over the Dosing Interval (AUCtau) Between Week 52 and Week 64
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End point description:

AUCtau from time 0 (week 52) over the dosing interval up to week 64 is presented. PK parameters are based on ABP 654 in the switching group and on ustekinumab in the continued use group.

The PK parameter analysis set consisted of all randomized participants who received all 3 doses of the assigned investigational product (IP) between week 28 and week 52 and who had an evaluable ABP 654 or ustekinumab serum concentration-time profile between week 52 and week 64. Participants with data available are presented.

End point type	Primary
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End point timeframe:

Blood samples were taken pre-dose week 52; and at 2 days, 7 days, 10 days, 2 weeks, 4 weeks, 8 weeks, and 12 weeks after the week 52 dose

End point values	Post-randomization Switching: Ustekinumab RP and ABP 654	Post-randomization Continued-use: Ustekinumab RP		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	199	204		
Units: hour*mcg/mL				
geometric mean (geometric coefficient of variation)	5144.40 ($\pm$ 45.3)	5768.45 ($\pm$ 50.4)		

Statistical analyses

Statistical analysis title	AUCtau: Switching group versus Continued-use group
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Statistical analysis description:

The geometric least squares (LS) mean, ratio of geometric LS means, and 90% confidence intervals (CIs) were estimated using the analysis of covariance (ANCOVA) model adjusted for the actual stratification factors if prior biologic use for psoriasis, baseline body weight group, geographic region, and PK trough concentration at week 28.

Comparison groups	Post-randomization Continued-use: Ustekinumab RP v Post-randomization Switching: Ustekinumab RP and ABP 654
Number of subjects included in analysis	403
Analysis specification	Pre-specified
Analysis type	equivalence ^[1]
Parameter estimate	Geometric LS mean ratio
Point estimate	0.9325
Confidence interval	
level	90 %
sides	2-sided
lower limit	0.8874
upper limit	0.9799

Notes:

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

Primary: Maximum Observed Serum Concentration (Cmax) Between Week 52 and Week 64

End point title	Maximum Observed Serum Concentration (Cmax) Between Week 52 and Week 64
End point description: Cmax between week 52 and week 64 is presented. PK parameters are based on ABP 654 in the switching group and on ustekinumab in the continued use group. The PK parameter analysis set consisted of all randomized participants who received all 3 doses of the assigned IP between week 28 and week 52 and who had an evaluable ABP 654 or ustekinumab serum concentration-time profile between week 52 and week 64. Participants with data available are presented.	
End point type	Primary
End point timeframe: Blood samples were taken pre-dose week 52; and at 2 days, 7 days, 10 days, 2 weeks, 4 weeks, 8 weeks, and 12 weeks after the week 52 dose	

End point values	Post-randomization Switching: Ustekinumab RP and ABP 654	Post-randomization Continued-use: Ustekinumab RP		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	204	205		
Units: mcg/mL				
geometric mean (geometric coefficient of variation)	5.78 (± 41.4)	6.31 (± 46.8)		

Statistical analyses

Statistical analysis title	Cmax: Switching group versus Continued-use group
Statistical analysis description: The geometric LS mean, ratio of geometric LS means, and 90% CIs were estimated using the ANCOVA model adjusted for the actual stratification factors if prior biologic use for psoriasis, baseline body weight group, geographic region, and PK trough concentration at week 28.	
Comparison groups	Post-randomization Switching: Ustekinumab RP and ABP 654 v Post-randomization Continued-use: Ustekinumab RP
Number of subjects included in analysis	409
Analysis specification	Pre-specified
Analysis type	equivalence ^[2]
Parameter estimate	Geometric LS mean ratio
Point estimate	0.9483
Confidence interval	
level	90 %
sides	2-sided
lower limit	0.8977
upper limit	1.0018

Notes:

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

Secondary: Time of Maximum Serum Concentration (tmax) Between Week 52 and Week 64

End point title	Time of Maximum Serum Concentration (tmax) Between Week 52 and Week 64
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End point description:

Tmax between week 52 and week 64 is presented. PK parameters are based on ABP 654 in the switching group and on ustekinumab in the continued-use group.

The PK parameter analysis set consisted of all randomized participants who received all 3 doses of the assigned IP between week 28 and week 52 and who had an evaluable ABP 654 or ustekinumab serum concentration-time profile between week 52 and week 64. Participants with data available are presented.

End point type	Secondary
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End point timeframe:

Blood samples were taken pre-dose week 52; and at 2 days, 7 days, 10 days, 2 weeks, 4 weeks, 8 weeks, and 12 weeks after the week 52 dose

End point values	Post-randomization Switching: Ustekinumab RP and ABP 654	Post-randomization Continued-use: Ustekinumab RP		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	204	205		
Units: hours				
median (full range (min-max))	167.80 (41.4 to 355.2)	168.93 (43.6 to 407.6)		

Statistical analyses

No statistical analyses for this end point

Secondary: Serum Trough Concentration at Steady-state (C_{trough,ss}) at Week 28, Week 40, and Week 52

End point title	Serum Trough Concentration at Steady-state (C _{trough,ss}) at Week 28, Week 40, and Week 52
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End point description:

C_{trough,ss} at weeks 28, 40, and 52 are presented. PK parameters are based on ABP 654 in the switching group and on ustekinumab in the continued-use group.

The PK parameter analysis set consisted of all randomized participants who received all 3 doses of the assigned IP between week 28 and week 52 and who had an evaluable ABP 654 or ustekinumab serum concentration-time profile between week 52 and week 64. Participants with data available are presented.

End point type	Secondary
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End point timeframe:

Blood samples were taken pre-dose week 28, week 40, and week 52

End point values	Post-randomization Switching: Ustekinumab RP and ABP 654	Post-randomization Continued-use: Ustekinumab RP		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	204	205		
Units: ng/mL				
geometric mean (geometric coefficient of variation)				
Week 28 (n=194, 198)	570.46 ($\pm$ 105.9)	595.86 ($\pm$ 110.0)		
Week 40 (n=193, 200)	537.52 ($\pm$ 96.4)	590.61 ($\pm$ 103.9)		
Week 52 (n=196, 201)	562.51 ($\pm$ 114.0)	599.11 ($\pm$ 108.5)		

Statistical analyses

Statistical analysis title	Week 28 Ctrough,ss: Switching versus Continued-use
Statistical analysis description:	
Geometric LS means, ratio of Geometric LS means, and 90% CIs for Ctrough,ss at week 28 were estimated based on an ANCOVA model adjusted for the actual stratification factors of prior biologic use for psoriasis, baseline body weight group, and geographic region.	
Comparison groups	Post-randomization Switching: Ustekinumab RP and ABP 654 v Post-randomization Continued-use: Ustekinumab RP
Number of subjects included in analysis	409
Analysis specification	Pre-specified
Analysis type	equivalence ^[3]
Parameter estimate	Geometric LS mean ratio
Point estimate	0.9617
Confidence interval	
level	90 %
sides	2-sided
lower limit	0.8319
upper limit	1.1119

Notes:

[3] - At week 28 a total of 392 participants were included in this analysis. The prespecified similarity margin was 0.8 to 1.25.

Statistical analysis title	Week 52 Ctrough,ss: Switching versus Continued-use
Statistical analysis description:	
Geometric LS means, ratio of geometric LS means, and 90% CIs for Ctrough,ss at week 40 and week 52 between the 2 treatment groups were estimated using an ANCOVA model adjusting for stratification factors and PK trough concentration at week 28.	
Comparison groups	Post-randomization Switching: Ustekinumab RP and ABP 654 v Post-randomization Continued-use: Ustekinumab RP

Number of subjects included in analysis	409
Analysis specification	Pre-specified
Analysis type	equivalence ^[4]
Parameter estimate	Geometric LS mean ratio
Point estimate	0.9806
Confidence interval	
level	90 %
sides	2-sided
lower limit	0.8916
upper limit	1.0785

Notes:

[4] - At week 52 a total of 397 participants were included in this analysis. The prespecified similarity margin was 0.8 to 1.25.

Statistical analysis title	Week 40 Ctrough,ss: Switching versus Continued-use
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Statistical analysis description:

Geometric LS means, ratio of geometric LS means, and 90% CIs for Ctrough,ss at week 40 and week 52 between the 2 treatment groups were estimated using an ANCOVA model adjusting for stratification factors and PK trough concentration at week 28.

Comparison groups	Post-randomization Switching: Ustekinumab RP and ABP 654 v Post-randomization Continued-use: Ustekinumab RP
Number of subjects included in analysis	409
Analysis specification	Pre-specified
Analysis type	equivalence ^[5]
Parameter estimate	Geometric LS mean ratio
Point estimate	0.9662
Confidence interval	
level	90 %
sides	2-sided
lower limit	0.8879
upper limit	1.0515

Notes:

[5] - At week 40 a total of 393 participants were included in this analysis. The prespecified similarity margin was 0.8 to 1.25.

Secondary: PASI Percent Improvement From Baseline at Week 64

End point title	PASI Percent Improvement From Baseline at Week 64
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End point description:

The PASI is a measure of the average redness, thickness, and scaliness, each graded on a 0 to 4 scale, weighted by the area of involvement. PASI combines the assessment of the severity and the area affected into a single score in the range 0 (no disease) to 72 (maximal disease). PASI percent improvement is defined as $100 \times (\text{value at baseline} - \text{value at post-baseline visit}) / \text{value at baseline}$. A positive value indicates PASI improvement. Baseline data were derived based on observed data and at week 64 were derived based on multiple imputation (MI) data. Baseline was the last non-missing assessment prior to the first dose of IP. The per-protocol efficacy analysis set included all participants who were randomized and received all 3 doses of the assigned IP between week 28 and week 52 and did not experience an important protocol deviation that could affect the evaluation of the efficacy endpoints. The participants analyzed includes those imputed by MI as well as those with observed data.

End point type	Secondary
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End point timeframe:

Baseline (day 1) and week 64

End point values	Post-randomization Switching: Ustekinumab RP and ABP 654	Post-randomization Continued-use: Ustekinumab RP		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	216	215		
Units: Percentage change				
arithmetic mean (standard deviation)	88.80 (± 18.066)	88.72 (± 16.128)		

Statistical analyses

Statistical analysis title	Mean difference PASI Percent Improvement
Statistical analysis description:	
Switching group - Continued-use group. Multiple imputation was applied for the point estimate and CI of the mean difference between the switching and continued-use groups. Missing PASI scores at the week 64 visit were imputed by MI.	
Comparison groups	Post-randomization Switching: Ustekinumab RP and ABP 654 v Post-randomization Continued-use: Ustekinumab RP
Number of subjects included in analysis	431
Analysis specification	Pre-specified
Analysis type	equivalence ^[6]
Parameter estimate	Mean difference
Point estimate	0.07
Confidence interval	
level	90 %
sides	2-sided
lower limit	-2.62
upper limit	2.77

Notes:

[6] - The prespecified similarity margin was 0.8 to 1.25.

Secondary: PASI 100 Response at Week 64

End point title	PASI 100 Response at Week 64
End point description:	
The PASI is a measure of the average redness, thickness, and scaliness, each graded on a 0 to 4 scale, weighted by area of involvement. PASI combines assessment of the severity and the area affected into a single score in the range 0 (no disease) to 72 (maximal disease). PASI response was defined as a participant meeting/surpassing a pre-specified threshold for percent improvement in PASI score compared to baseline. A participant with ≥ 100% improvement was a PASI 100 responder. Missing PASI 100 responses at week 64 were imputed by NRI. Baseline was the last non-missing assessment taken prior to the first dose of IP. The per-protocol efficacy analysis set included all participants who were randomized and received all 3 doses of assigned IP between week 28 and week 52 and who did not experience an important protocol deviation during the study that could affect the evaluation of the efficacy endpoints. The participants analyzed include those imputed by NRI and those with observed data.	
End point type	Secondary
End point timeframe:	
Baseline (day 1) and week 64	

End point values	Post-randomization Switching: Ustekinumab RP and ABP 654	Post-randomization Continued-use: Ustekinumab RP		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	216	215		
Units: Percentage of responders				
number (confidence interval 95%)	36.1 (29.7 to 42.5)	35.8 (29.4 to 42.2)		

Statistical analyses

Statistical analysis title	Difference in PASI 100 Response at Week 64
Statistical analysis description:	
Switching group - Continued-use group. Response difference was estimated by the Mantel-Haenszel estimate, and the 90% CIs were estimated by the stratified Newcombe confidence limits, adjusting for the prior biologic use of psoriasis, baseline body weight group, geographic region. Missing post-baseline binary response data were imputed by NRI.	
Comparison groups	Post-randomization Switching: Ustekinumab RP and ABP 654 v Post-randomization Continued-use: Ustekinumab RP
Number of subjects included in analysis	431
Analysis specification	Pre-specified
Analysis type	equivalence ^[7]
Parameter estimate	Response difference
Point estimate	0.2
Confidence interval	
level	90 %
sides	2-sided
lower limit	-7.4
upper limit	7.8

Notes:

[7] - The prespecified similarity margin was 0.8 to 1.25.

Secondary: PASI 75 Response at Week 64

End point title	PASI 75 Response at Week 64
End point description:	
The PASI is a measure of the average redness, thickness, and scaliness, each graded on a 0 to 4 scale, weighted by the area of involvement. PASI combines the assessment of the severity and the area affected into a single score in the range 0 (no disease) to 72 (maximal disease). PASI response was defined as a participant meeting/surpassing a pre-specified threshold for percent improvement in PASI score compared to baseline. A participant with $\geq 75\%$ improvement was a PASI 75 responder. Missing PASI 75 responses at week 64 were imputed by non-responder imputation (NRI). Baseline was the last non-missing assessment prior to first dose of IP. The per-protocol efficacy analysis set included all participants who were randomized and received all 3 doses of the assigned IP between week 28 and week 52 and did not experience an important protocol deviation that could affect the evaluation of the efficacy endpoints. The participants analyzed include those imputed by NRI and those with observed.	
End point type	Secondary

End point timeframe:

Baseline (day 1) and week 64

End point values	Post-randomization Switching: Ustekinumab RP and ABP 654	Post-randomization Continued-use: Ustekinumab RP		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	216	215		
Units: Percentage of responders				
number (confidence interval 95%)	83.3 (78.4 to 88.3)	82.8 (77.8 to 87.8)		

Statistical analyses

Statistical analysis title	Difference in PASI 75 Response at Week 64
Statistical analysis description:	
Switching group - Continued-use group. Response difference was estimated by the Mantel-Haenszel estimate, and the 90% CIs were estimated by the stratified Newcombe confidence limits, adjusting for the prior biologic use of psoriasis, baseline body weight group, geographic region. Missing post-baseline binary response data were imputed by NRI.	
Comparison groups	Post-randomization Switching: Ustekinumab RP and ABP 654 v Post-randomization Continued-use: Ustekinumab RP
Number of subjects included in analysis	431
Analysis specification	Pre-specified
Analysis type	equivalence ^[8]
Parameter estimate	Response difference
Point estimate	0.2
Confidence interval	
level	90 %
sides	2-sided
lower limit	-5.7
upper limit	6.2

Notes:

[8] - The prespecified similarity margin was 0.8 to 1.25.

Secondary: Number of Participants with Treatment-emergent Adverse Events (TEAEs): Post-randomization Period

End point title	Number of Participants with Treatment-emergent Adverse Events (TEAEs): Post-randomization Period
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End point description:

TEAEs during the post-randomization period were defined as AEs that started on or after the first dose of investigational product post-randomization and prior to the end of study. The number of participants who experienced any TEAE, and who experienced a serious TEAE are presented. A serious TEAE was defined as any untoward medical occurrence that meets at least 1 of the following serious criteria: resulted in death (fatal), was life-threatening, required inpatient hospitalization or prolongation of existing hospitalization, resulted in persistent or significant disability/incapacity, congenital anomaly/birth defect, or other medically important serious event. Participants in the safety analysis set who completed all planned doses of investigational product in the post-randomization period up to week

52. The safety analysis set included all randomized participant who received at least 1 dose of investigational product post randomization.

End point type	Secondary
End point timeframe:	
Week 28 to week 64	

End point values	Switching: Ustekinumab RP and ABP 654	Continued-use: Ustekinumab RP	Switching: ABP 654/Ustekinumab RP/Missing	Continued-use: Ustekinumab RP/Ustekinumab RP/Missing
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	217	216	8	5
Units: participants				
Any TEAE	97	108	4	1
Any serious TEAE	3	2	0	0

End point values	Switching: ABP 654/Missing/Missing	Continued-use: Ustekinumab RP/Missing/Missing		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	3	3		
Units: participants				
Any TEAE	3	0		
Any serious TEAE	0	0		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants with Events of Interest (EOI): Post-randomization Period

End point title	Number of Participants with Events of Interest (EOI): Post-randomization Period
End point description:	
The treatment-emergent EOIs prespecified for this study included serious systemic hypersensitivity reactions, facial palsy, pustular psoriasis, erythrodermic psoriasis, serious infections (including mycobacterial and salmonella infections), malignancy, cardiovascular events, reversible posterior leukoencephalopathy syndrome (RPLS), serious depression including suicidality, and venous thromboembolism. The safety analysis set included all randomized participant who received at least 1 dose of investigational product post randomization.	
End point type	Secondary
End point timeframe:	
Week 28 to week 64	

End point values	Switching: Ustekinumab RP and ABP 654	Continued-use: Ustekinumab RP		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	217	216		
Units: participants				
Any EOI	6	7		
Cardiovascular events	2	3		
RPLS	2	0		
Serious infections	1	2		
Malignancy	1	1		
Serious depression	0	1		
Serious systemic hypersensitivity reactions	0	0		
Facial palsy	0	0		
Pustular psoriasis	0	0		
Erythrodermic psoriasis	0	0		
Venous thromboembolism	0	0		

Statistical analyses

Statistical analysis title	Risk difference for any EOI
Statistical analysis description:	
Switching group - Continued-use group. Risk difference and CIs were estimated by Wald asymptotic confidence limits, or exact confidence limits if n < 25 for either treatment.	
Comparison groups	Switching: Ustekinumab RP and ABP 654 v Continued-use: Ustekinumab RP
Number of subjects included in analysis	433
Analysis specification	Pre-specified
Analysis type	equivalence ^[9]
Parameter estimate	Risk difference (RD)
Point estimate	-0.48
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.17
upper limit	3.1

Notes:

[9] - The prespecified similarity margin was 0.8 to 1.25.

Secondary: Number of Participants with Antidrug Antibodies (ADAs): Post-randomization Period

End point title	Number of Participants with Antidrug Antibodies (ADAs): Post-randomization Period
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End point description:

The number of participants developing binding or neutralizing ADAs during the post-randomization period is defined as the number of participants in the safety analysis set who had a positive result post-

randomization and had never tested positive (i.e., negative or no results) prior to the first dose of post-randomization investigational product and who had at least one ADA result post-randomization. A transient antibody result was defined as a positive result during the post-randomization period with a negative result at the participant's last visit tested within the respective study period. Baseline was defined as the last non-missing assessment taken prior to the first dose of IP for the study. The safety analysis set included all randomized participants who received at least 1 dose of IP post randomization. PB=post-baseline; PR=post-randomization; bAb= binding antibody; nAb=neutralizing antibody; t= transient; +ve=positive; -ve=negative

End point type	Secondary
End point timeframe:	
Baseline (pre-dose day 1), week 4, week 16, week 28, week 40, week 52 and week 64	

End point values	Switching: Ustekinumab RP and ABP 654	Continued-use: Ustekinumab RP	Switching: ABP 654/Ustekinumab RP/Missing	Continued-use: Ustekinumab RP/Ustekinumab RP/Missing
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	217	216	8	5
Units: participants				
Participants with PB result PR	217	216	8	5
BAb -ve/no result prior first dose PR	136	134	5	4
BAb +ve PR; -ve/no result prior to first dose PR	7	11	0	1
T bAb +ve PR; -ve/no result prior first dose PR	4	5	0	0
NAb -ve/no result prior to first dose PR	190	188	6	5
Nab +ve PR; -ve/no results prior to first dose PR	8	6	0	1
T nAb +ve PR; -ve/no result prior first dose PR	6	1	0	0

End point values	Switching: ABP 654/Missing/Missing	Continued-use: Ustekinumab RP/Missing/Missing		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	3	3		
Units: participants				
Participants with PB result PR	3	1		
BAb -ve/no result prior first dose PR	3	1		
BAb +ve PR; -ve/no result prior to first dose PR	1	0		
T bAb +ve PR; -ve/no result prior first dose PR	0	0		
NAb -ve/no result prior to first dose PR	3	1		
Nab +ve PR; -ve/no results prior to first dose PR	0	0		
T nAb +ve PR; -ve/no result prior first dose PR	0	0		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

All-cause mortality was collected from enrollment to the end of study visit, up to approximately 68 weeks. Adverse events were collected from Day 1 to end of study, up to 64 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
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Dictionary used

Dictionary name	MedDRA
Dictionary version	25.1

Reporting groups

Reporting group title	Run-in: Ustekinumab RP
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Reporting group description:

Participants received ustekinumab RP 45 mg (baseline body weight $\leq$ 100 kg) or 90 mg (baseline body weight $>$ 100 kg) on day 1 (week 0), week 4, and week 16.

Reporting group title	Switching: Ustekinumab RP and ABP 654
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Reporting group description:

Participants were randomized to the switching group at week 28 and completed all planned doses of ABP 654 and ustekinumab RP up to week 52, including ABP 654 at week 28, ustekinumab RP at week 40, and ABP 654 at week 52.

Reporting group title	Continued-use: Ustekinumab RP
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Reporting group description:

Participants were randomized to the continued-use group at week 28 and completed all planned doses of ustekinumab RP up to week 52, including 3 doses at weeks 28, 40, and 52.

Reporting group title	Continued-use: Ustekinumab RP/Missing/Missing
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Reporting group description:

Participants were randomized to the continued-use group at week 28 and received ustekinumab RP at week 28 but did not receive the planned doses of ustekinumab RP at week 40 and week 52.

Reporting group title	Continued-use: Ustekinumab RP/Ustekinumab RP/Missing
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Reporting group description:

Participants were randomized to the continued-use group at week 28 and received ustekinumab RP at week 28 and week 40 but did not receive the planned dose of ustekinumab RP at week 52.

Reporting group title	Switching: ABP 654/Missing/Missing
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Reporting group description:

Participants were randomized to the switching group at week 28 and received ABP 654 at week 28 and did not receive the planned doses of ustekinumab RP at week 40 and ABP 654 at week 52.

Reporting group title	Switching: ABP 654/Ustekinumab RP/Missing
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Reporting group description:

Participants were randomized to the switching group at week 28 and received ABP 654 at week 28 and ustekinumab RP at week 40 but did not receive the planned dose of ABP 654 at week 52.

Serious adverse events	Run-in: Ustekinumab RP	Switching: Ustekinumab RP and ABP 654	Continued-use: Ustekinumab RP
Total subjects affected by serious adverse events			
subjects affected / exposed	14 / 494 (2.83%)	3 / 217 (1.38%)	2 / 216 (0.93%)
number of deaths (all causes)	2	0	0

number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Papillary thyroid cancer			
subjects affected / exposed	0 / 494 (0.00%)	0 / 217 (0.00%)	1 / 216 (0.46%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colon cancer			
subjects affected / exposed	0 / 494 (0.00%)	1 / 217 (0.46%)	0 / 216 (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
General disorders and administration site conditions			
Death			
subjects affected / exposed	2 / 494 (0.40%)	0 / 217 (0.00%)	0 / 216 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 2	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Nasal turbinate hypertrophy			
subjects affected / exposed	1 / 494 (0.20%)	0 / 217 (0.00%)	0 / 216 (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
Nasal septum deviation			
subjects affected / exposed	1 / 494 (0.20%)	0 / 217 (0.00%)	0 / 216 (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
Nasal obstruction			
subjects affected / exposed	1 / 494 (0.20%)	0 / 217 (0.00%)	0 / 216 (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
Psychiatric disorders			
Dermatillomania			
subjects affected / exposed	0 / 494 (0.00%)	0 / 217 (0.00%)	1 / 216 (0.46%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural			

complications			
Fibula fracture			
subjects affected / exposed	1 / 494 (0.20%)	0 / 217 (0.00%)	0 / 216 (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
Tibia fracture			
subjects affected / exposed	1 / 494 (0.20%)	0 / 217 (0.00%)	0 / 216 (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
Cardiac disorders			
Atrial fibrillation			
subjects affected / exposed	1 / 494 (0.20%)	0 / 217 (0.00%)	0 / 216 (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
Supraventricular tachycardia			
subjects affected / exposed	1 / 494 (0.20%)	0 / 217 (0.00%)	0 / 216 (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			
Cerebrovascular accident			
subjects affected / exposed	0 / 494 (0.00%)	1 / 217 (0.46%)	0 / 216 (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
Facial paralysis			
subjects affected / exposed	1 / 494 (0.20%)	0 / 217 (0.00%)	0 / 216 (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
Eye disorders			
Vision blurred			
subjects affected / exposed	1 / 494 (0.20%)	0 / 217 (0.00%)	0 / 216 (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
Gastrointestinal disorders			
Pancreatitis acute			

subjects affected / exposed	1 / 494 (0.20%)	1 / 217 (0.46%)	0 / 216 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Cholecystitis acute			
subjects affected / exposed	1 / 494 (0.20%)	0 / 217 (0.00%)	0 / 216 (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
Cholelithiasis			
subjects affected / exposed	1 / 494 (0.20%)	0 / 217 (0.00%)	0 / 216 (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
Cholecystitis			
subjects affected / exposed	0 / 494 (0.00%)	1 / 217 (0.46%)	0 / 216 (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
Skin and subcutaneous tissue disorders			
Erythrodermic psoriasis			
subjects affected / exposed	1 / 494 (0.20%)	0 / 217 (0.00%)	0 / 216 (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
Pustular psoriasis			
subjects affected / exposed	1 / 494 (0.20%)	0 / 217 (0.00%)	0 / 216 (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
Musculoskeletal and connective tissue disorders			
Osteoarthritis			
subjects affected / exposed	1 / 494 (0.20%)	0 / 217 (0.00%)	0 / 216 (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
Cervical spinal stenosis			
subjects affected / exposed	1 / 494 (0.20%)	0 / 217 (0.00%)	0 / 216 (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			
Otitis media chronic			
subjects affected / exposed	1 / 494 (0.20%)	0 / 217 (0.00%)	0 / 216 (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
Pneumonia viral			
subjects affected / exposed	1 / 494 (0.20%)	0 / 217 (0.00%)	0 / 216 (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

Serious adverse events	Continued-use: Ustekinumab RP/Missing/Missing	Continued-use: Ustekinumab RP/Ustekinumab RP/Missing	Switching: ABP 654/Missing/Missing
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Papillary thyroid cancer			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colon cancer			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Death			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Nasal turbinate hypertrophy			

subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nasal septum deviation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nasal obstruction			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Dermatillomania			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Fibula fracture			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tibia fracture			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Atrial fibrillation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Supraventricular tachycardia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Nervous system disorders			
Cerebrovascular accident			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Facial paralysis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
Vision blurred			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Pancreatitis acute			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Cholecystitis acute			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholelithiasis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholecystitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Erythrodermic psoriasis			

subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pustular psoriasis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Osteoarthritis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cervical spinal stenosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Otitis media chronic			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia viral			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Switching: ABP 654/Ustekinumab RP/Missing		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 8 (0.00%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Papillary thyroid cancer			

subjects affected / exposed	0 / 8 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Colon cancer			
subjects affected / exposed	0 / 8 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
General disorders and administration site conditions			
Death			
subjects affected / exposed	0 / 8 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Respiratory, thoracic and mediastinal disorders			
Nasal turbinate hypertrophy			
subjects affected / exposed	0 / 8 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Nasal septum deviation			
subjects affected / exposed	0 / 8 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Nasal obstruction			
subjects affected / exposed	0 / 8 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Psychiatric disorders			
Dermatillomania			
subjects affected / exposed	0 / 8 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Injury, poisoning and procedural complications			
Fibula fracture			

subjects affected / exposed	0 / 8 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Tibia fracture			
subjects affected / exposed	0 / 8 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cardiac disorders			
Atrial fibrillation			
subjects affected / exposed	0 / 8 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Supraventricular tachycardia			
subjects affected / exposed	0 / 8 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Nervous system disorders			
Cerebrovascular accident			
subjects affected / exposed	0 / 8 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Facial paralysis			
subjects affected / exposed	0 / 8 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Eye disorders			
Vision blurred			
subjects affected / exposed	0 / 8 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal disorders			
Pancreatitis acute			

subjects affected / exposed	0 / 8 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hepatobiliary disorders			
Cholecystitis acute			
subjects affected / exposed	0 / 8 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cholelithiasis			
subjects affected / exposed	0 / 8 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cholecystitis			
subjects affected / exposed	0 / 8 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Skin and subcutaneous tissue disorders			
Erythrodermic psoriasis			
subjects affected / exposed	0 / 8 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pustular psoriasis			
subjects affected / exposed	0 / 8 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Musculoskeletal and connective tissue disorders			
Osteoarthritis			
subjects affected / exposed	0 / 8 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cervical spinal stenosis			
subjects affected / exposed	0 / 8 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

Infections and infestations Otitis media chronic subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 8 (0.00%) 0 / 0 0 / 0		
Pneumonia viral subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 8 (0.00%) 0 / 0 0 / 0		

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

Non-serious adverse events	Run-in: Ustekinumab RP	Switching: Ustekinumab RP and ABP 654	Continued-use: Ustekinumab RP
Total subjects affected by non-serious adverse events			
subjects affected / exposed	116 / 494 (23.48%)	55 / 217 (25.35%)	58 / 216 (26.85%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Brain neoplasm benign			
subjects affected / exposed	0 / 494 (0.00%)	0 / 217 (0.00%)	0 / 216 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Abdominal wall wound			
subjects affected / exposed	0 / 494 (0.00%)	0 / 217 (0.00%)	0 / 216 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Headache			
subjects affected / exposed	9 / 494 (1.82%)	5 / 217 (2.30%)	1 / 216 (0.46%)
occurrences (all)	12	6	1
Skin and subcutaneous tissue disorders			
Scleroedema			
subjects affected / exposed	0 / 494 (0.00%)	0 / 217 (0.00%)	0 / 216 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Psoriatic arthropathy			
subjects affected / exposed	1 / 494 (0.20%)	1 / 217 (0.46%)	2 / 216 (0.93%)
occurrences (all)	1	1	2

Infections and infestations Sinusitis subjects affected / exposed occurrences (all)	6 / 494 (1.21%) 7	1 / 217 (0.46%) 1	3 / 216 (1.39%) 3
Nasopharyngitis subjects affected / exposed occurrences (all)	27 / 494 (5.47%) 28	12 / 217 (5.53%) 16	16 / 216 (7.41%) 19
COVID-19 subjects affected / exposed occurrences (all)	65 / 494 (13.16%) 65	27 / 217 (12.44%) 27	25 / 216 (11.57%) 25
Upper respiratory tract infection subjects affected / exposed occurrences (all)	18 / 494 (3.64%) 20	14 / 217 (6.45%) 15	14 / 216 (6.48%) 15
Metabolism and nutrition disorders Type 2 diabetes mellitus subjects affected / exposed occurrences (all)	1 / 494 (0.20%) 1	2 / 217 (0.92%) 2	2 / 216 (0.93%) 2

Non-serious adverse events	Continued-use: Ustekinumab RP/Missing/Missing	Continued-use: Ustekinumab RP/Ustekinumab RP/Missing	Switching: ABP 654/Missing/Missing
Total subjects affected by non-serious adverse events subjects affected / exposed	0 / 3 (0.00%)	1 / 5 (20.00%)	3 / 3 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps) Brain neoplasm benign subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 5 (0.00%) 0	1 / 3 (33.33%) 1
Injury, poisoning and procedural complications Abdominal wall wound subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 5 (0.00%) 0	0 / 3 (0.00%) 0
Nervous system disorders Headache subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	1 / 5 (20.00%) 1	0 / 3 (0.00%) 0
Skin and subcutaneous tissue disorders Scleroedema			

subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 5 (0.00%) 0	0 / 3 (0.00%) 0
Musculoskeletal and connective tissue disorders Psoriatic arthropathy subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	1 / 5 (20.00%) 1	1 / 3 (33.33%) 1
Infections and infestations Sinusitis subjects affected / exposed occurrences (all) Nasopharyngitis subjects affected / exposed occurrences (all) COVID-19 subjects affected / exposed occurrences (all) Upper respiratory tract infection subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0 0 / 3 (0.00%) 0 0 / 3 (0.00%) 0 0 / 3 (0.00%) 0	0 / 5 (0.00%) 0 0 / 5 (0.00%) 0 0 / 5 (0.00%) 0 0 / 5 (0.00%) 0	0 / 3 (0.00%) 0 0 / 3 (0.00%) 0 2 / 3 (66.67%) 2 0 / 3 (0.00%) 0
Metabolism and nutrition disorders Type 2 diabetes mellitus subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 5 (0.00%) 0	0 / 3 (0.00%) 0

Non-serious adverse events	Switching: ABP 654/Ustekinumab RP/Missing		
Total subjects affected by non-serious adverse events subjects affected / exposed	4 / 8 (50.00%)		
Neoplasms benign, malignant and unspecified (incl cysts and polyps) Brain neoplasm benign subjects affected / exposed occurrences (all)	0 / 8 (0.00%) 0		
Injury, poisoning and procedural complications Abdominal wall wound subjects affected / exposed occurrences (all)	1 / 8 (12.50%) 1		
Nervous system disorders			

Headache subjects affected / exposed occurrences (all)	0 / 8 (0.00%) 0		
Skin and subcutaneous tissue disorders Scleroedema subjects affected / exposed occurrences (all)	1 / 8 (12.50%) 1		
Musculoskeletal and connective tissue disorders Psoriatic arthropathy subjects affected / exposed occurrences (all)	0 / 8 (0.00%) 0		
Infections and infestations Sinusitis subjects affected / exposed occurrences (all) Nasopharyngitis subjects affected / exposed occurrences (all) COVID-19 subjects affected / exposed occurrences (all) Upper respiratory tract infection subjects affected / exposed occurrences (all)	1 / 8 (12.50%) 1 0 / 8 (0.00%) 0 2 / 8 (25.00%) 2 0 / 8 (0.00%) 0		
Metabolism and nutrition disorders Type 2 diabetes mellitus subjects affected / exposed occurrences (all)	1 / 8 (12.50%) 1		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
02 June 2021	- change of sample size from 352 to 480 enrolled participants - updated verbiage of bioequivalence and PK equivalence to similarity and PK similarity - updated similarity margin from (0.77, 1.3) to (0.8, 1.25) - changed method for handling missing values for the PASI endpoint from last observation carried forward method to multiple imputation method - included PK and ADA samples at week 4 - clarified tolerance windows for PK sample collection times - included human immunodeficiency virus serology at screening and electrocardiogram at baseline and weeks 16, 28, 40, and 52 - updated inclusion/exclusion criteria - included electrocardiogram data analysis descriptive summary for the number of abnormal electrocardiograms - clarified that the concomitant medication for the run-in treated set was for the Run-in Period

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported