Clinical trial results:
A Phase 3, Multicenter, Randomized, Double-blind Study Evaluating the Efficacy and Safety of ABP 654 Compared with Ustekinumab in Subjects With Moderate to Severe Plaque Psoriasis

Summary

EudraCT number	2020-003184-25
Trial protocol	DE LT EE BG HU SK LV
Global end of trial date	03 June 2022

Results information

Result version number	v1 (current)
This version publication date	14 April 2023
First version publication date	14 April 2023

Trial information

Trial identification

Sponsor protocol code	20190232

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT04607980
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	Study Director, Amgen Inc., +1 8665726436, medinfo@amgen.com
Scientific contact	Study Director, Amgen Inc., +1 8665726436, medinfo@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	03 June 2022
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	03 June 2022
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The primary objective of the study was to compare the efficacy of ABP 654 with ustekinumab in participants with moderate to severe plaque psoriasis (Ps).

Protection of trial subjects:

This study was conducted in accordance with International Council for Harmonisation (ICH) Good Clinical Practice (GCP) regulations/guidelines. Essential documents will be retained in accordance with ICH GCP.

Background therapy: -

Evidence for comparator:

Ustekinumab belongs to the pharmacologic class of interleukin (IL)-23 and IL-12 antagonists. In the United States and the European Union, ustekinumab is approved for subcutaneous (SC) administration in the treatment of moderate to severe Ps in adults and pediatric patients (6 years or older).

Actual start date of recruitment	11 November 2020
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: 170
Country: Number of subjects enrolled	Germany: 26
Country: Number of subjects enrolled	Estonia: 22
Country: Number of subjects enrolled	Latvia: 20
Country: Number of subjects enrolled	Lithuania: 18
Country: Number of subjects enrolled	Hungary: 15
Country: Number of subjects enrolled	Canada: 158
Country: Number of subjects enrolled	United States: 134
Worldwide total number of subjects	563
EEA total number of subjects	271

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)	518
From 65 to 84 years	45
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

This study was conducted at 84 centers in Canada, Estonia, Germany, Hungary, Latvia, Lithuania, Poland, and the United States between 11 November 2020 and 03 June 2022.

Pre-assignment

Screening details:

Of the 648 participants screened, 563 participants were enrolled.

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	Treatment Group A (ABP 654)

Arm description:

Participants received SC injection of ABP 654, 45 mg (Baseline body weight [BW] less than or equal to [<=] 100 kg) or 90 mg (Baseline BW greater than [>] 100 kg) at Weeks 0, 4, and 16. From Week 28 participants received ABP 654 (same dose) every 12 weeks (Q12W) at Weeks 28 and 40 or depending on Psoriasis Area and Severity Index (PASI) score, received dose intensification every 8 weeks (Q8W) at Weeks 28, 36, and 44 (as per protocol).

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

Dosage and administration details:

Participants received SC injection of ABP 654.

Arm title	Treatment Group B (Ustekinumab)

Arm description:

Participants received SC injection of ustekinumab, 45 mg (Baseline BW <= 100 kg) or 90 mg (Baseline BW > 100 kg) at Weeks 0, 4, and 16. At Week 28, participants were re-randomized to continue receiving ustekinumab (Treatment group B1), or to receive ABP 654 (Treatment group B2) at Weeks 28 and 40. Depending on PASI score, some participants were not re-randomized and received dose intensification with ustekinumab Q8W at Weeks 28, 36, and 44 (as per protocol).

Arm type	Active comparator
Investigational medicinal product name	Ustekinumab
Investigational medicinal product code	Stelara®
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Participants received SC injection of ustekinumab.

Investigational medicinal product name	ABP 654
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection

Routes of administration	Subcutaneous use

Dosage and administration details:

Participants received SC injection of ABP 654.

Number of subjects in period 1	Treatment Group A (ABP 654)	Treatment Group B (Ustekinumab)
Started	281	282
Treated	280	282
Re-randomized at Week 28	247 [1]	233 [2]
Completed at Week 28	2 [3]	3 [4]
Completed	269	261
Not completed	12	21
Consent withdrawn by subject	2	5
Death	-	1
Adverse event	3	4
Unspecified	3	-
Lost to follow-up	4	8
Protocol deviation	-	3

Notes:

[1] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.
Justification: PASI 50 non-responders were not re-randomized and were considered completed at Week 28 as per protocol.

[2] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.
Justification: PASI 50 non-responders were not re-randomized and were considered completed at Week 28 as per protocol.

[3] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.
Justification: PASI 50 non-responders were not re-randomized and were considered completed at Week 28 as per protocol.

[4] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.
Justification: PASI 50 non-responders were not re-randomized and were considered completed at Week 28 as per protocol.

Baseline characteristics

Reporting groups	
Reporting group title	Treatment Group A (ABP 654)
Reporting group description:	
Participants received SC injection of ABP 654, 45 mg (Baseline body weight [BW] less than or equal to [<=] 100 kg) or 90 mg (Baseline BW greater than [>] 100 kg) at Weeks 0, 4, and 16. From Week 28 participants received ABP 654 (same dose) every 12 weeks (Q12W) at Weeks 28 and 40 or depending on Psoriasis Area and Severity Index (PASI) score, received dose intensification every 8 weeks (Q8W) at Weeks 28, 36, and 44 (as per protocol).	
Reporting group title	Treatment Group B (Ustekinumab)
Reporting group description:	
Participants received SC injection of ustekinumab, 45 mg (Baseline BW <= 100 kg) or 90 mg (Baseline BW > 100 kg) at Weeks 0, 4, and 16. At Week 28, participants were re-randomized to continue receiving ustekinumab (Treatment group B1), or to receive ABP 654 (Treatment group B2) at Weeks 28 and 40. Depending on PASI score, some participants were not re-randomized and received dose intensification with ustekinumab Q8W at Weeks 28, 36, and 44 (as per protocol).	

Reporting group values	Treatment Group A (ABP 654)	Treatment Group B (Ustekinumab)	Total
Number of subjects	281	282	563
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)	257	261	518
From 65-84 years	24	21	45
85 years and over	0	0	0
Age Continuous Units: years			
arithmetic mean	43.7	45.0	
standard deviation	± 14.15	± 12.58	-
Gender Categorical Units: Participants			
Female	104	91	195
Male	177	191	368
Race Units: Subjects			
American Indian or Alaska Native	1	2	3
Asian	20	25	45
Black or African American	4	2	6
Native Hawaiian or other Pacific Islander	0	1	1
White	250	247	497
Multiple	1	0	1
Not allowed to collect	1	0	1
Other	4	5	9

Ethnicity Units: Subjects			
Hispanic or Latino	32	28	60
Not Hispanic or Latino	248	252	500
Not allowed to collect	1	0	1
Unknown	0	2	2
Static Physician Global Assessment of Psoriasis (sPGA)			
The sPGA is a 6-point scale ranging from 0 (clear) to 5 (very severe) used to measure the severity of disease (induration, scaling, and erythema). A sPGA response was defined as a sPGA value of clear (score 0) or almost clear (score 1). Higher scores represent worse symptom severity.			
Units: Subjects			
Score 0 (clear)	0	0	0
Score 1 (almost clear)	0	0	0
Score 2 (mild)	0	0	0
Score 3 (moderate)	130	154	284
Score 4 (severe)	132	114	246
Score 5 (very severe)	19	14	33
PASI			
The PASI is a measure of the average redness (erythema), thickness (induration), and scaliness (scaling; each graded on a 0-4 scale [0 = clear; 1-4 = increasing severity]) of the lesions, weighted by the area of involvement in the four main body areas (i.e., head, arms, trunk to groin, and legs to top of buttocks). The PASI score ranges from 0 to 72. Higher scores represent worse symptom severity.			
Units: Score on a scale			
arithmetic mean	21.50	20.35	
standard deviation	± 8.855	± 7.850	-
Psoriasis Body Surface Area (BSA)			
The percentage of BSA affected was estimated by assuming that the participant's palm, excluding the fingers and thumb, represents roughly 1% of the body's surface.			
Units: Percentage of BSA			
arithmetic mean	26.5	24.9	
standard deviation	± 15.25	± 15.05	-

End points

End points reporting groups

Reporting group title	Treatment Group A (ABP 654)
Reporting group description:	
Participants received SC injection of ABP 654, 45 mg (Baseline body weight [BW] less than or equal to [<=] 100 kg) or 90 mg (Baseline BW greater than [>] 100 kg) at Weeks 0, 4, and 16. From Week 28 participants received ABP 654 (same dose) every 12 weeks (Q12W) at Weeks 28 and 40 or depending on Psoriasis Area and Severity Index (PASI) score, received dose intensification every 8 weeks (Q8W) at Weeks 28, 36, and 44 (as per protocol).	
Reporting group title	Treatment Group B (Ustekinumab)
Reporting group description:	
Participants received SC injection of ustekinumab, 45 mg (Baseline BW <= 100 kg) or 90 mg (Baseline BW > 100 kg) at Weeks 0, 4, and 16. At Week 28, participants were re-randomized to continue receiving ustekinumab (Treatment group B1), or to receive ABP 654 (Treatment group B2) at Weeks 28 and 40. Depending on PASI score, some participants were not re-randomized and received dose intensification with ustekinumab Q8W at Weeks 28, 36, and 44 (as per protocol).	
Subject analysis set title	Through Week 28: ABP 654
Subject analysis set type	Safety analysis
Subject analysis set description:	
All participants who were randomized to receive SC injection of ABP 654, 45 mg (Baseline BW <= 100 kg) or 90 mg (Baseline BW > 100 kg) at Weeks 0, 4, and 16.	
Subject analysis set title	Through Week 28: Ustekinumab
Subject analysis set type	Safety analysis
Subject analysis set description:	
All participants who were randomized to receive SC injection of ustekinumab, 45 mg (Baseline BW <= 100 kg) or 90 mg (Baseline BW > 100 kg) at Weeks 0, 4, and 16.	
Subject analysis set title	Post Week 28: ABP 654/ ABP 654
Subject analysis set type	Safety analysis
Subject analysis set description:	
All participants who were randomized to receive SC injection of ABP 654 at Weeks 0, 4, and 16, followed by ABP 654 (same dose) Q12W at Weeks 28 and 40.	
Subject analysis set title	Post Week 28: Ustekinumab/ ABP 654
Subject analysis set type	Safety analysis
Subject analysis set description:	
All participants who were randomized to receive SC injection of ustekinumab at Weeks 0, 4, and 16. At Week 28, participants were re-randomized to receive ABP 654 (Treatment group B2) at Weeks 28 and 40.	
Subject analysis set title	Post Week 28: Ustekinumab/ Ustekinumab
Subject analysis set type	Safety analysis
Subject analysis set description:	
All participants who were randomized to receive SC injection of ustekinumab at Weeks 0, 4, and 16. At Week 28, participants were re-randomized to continue on ustekinumab (Treatment group B1) at Weeks 28 and 40.	
Subject analysis set title	Post Week 28: ABP 654 Dose Intensification
Subject analysis set type	Safety analysis
Subject analysis set description:	
All participants who were randomized to receive SC injection of ABP 654 at Weeks 0, 4, and 16 with PASI 50 response or better but less than PASI 75 response at Week 28 (as per protocol). Based on the Investigator's discretion, the participants received ABP 654 dose intensification every 8 weeks (Q8W) at Weeks 28, 36, and 44.	
Subject analysis set title	Post Week 28: Ustekinumab Dose Intensification
Subject analysis set type	Safety analysis
Subject analysis set description:	
All participants who were randomized to receive SC injection of ustekinumab at Weeks 0, 4, and 16 with PASI 50 response or better but less than PASI 75 response at Week 28 (as per protocol). Based on the	

Investigator's discretion, the participants received ustekinumab dose intensification Q8W at Weeks 28, 36, and 44.

Primary: PASI Percent Change From Baseline to Week 12

End point title	PASI Percent Change From Baseline to Week 12

End point description:

The PASI is a measure of the average redness (erythema), thickness (induration), and scaliness (scaling; each graded on a 0-4 scale [0 = clear; 1-4 = increasing severity]) of the lesions, weighted by the area of involvement in the four main body areas (i.e., head, arms, trunk to groin, and legs to top of buttocks). The PASI score ranges from 0 to 72. Higher scores represent worse symptom severity.

Results are presented for the Full Analysis Set (FAS) with available data; observed data was used for summary statistics.

End point type	Primary

End point timeframe:

Baseline (Day 1 [Week 0]) and Week 12

End point values	Treatment Group A (ABP 654)	Treatment Group B (Ustekinumab)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	272	276		
Units: Percent Change in PASI score				
arithmetic mean (standard deviation)	81.92 (± 19.872)	81.91 (± 19.611)		

Statistical analyses

Statistical analysis title	Treatment Group A versus Treatment Group B

Statistical analysis description:

Clinical equivalence of the primary endpoint was evaluated by comparing the 2-sided 95% confidence interval (CI) of the mean difference of PASI percent improvement from Baseline to Week 12 between ABP 654 versus (vs) ustekinumab with an equivalence margin of (-15, +15).

Multiple imputation was applied for the point estimate and CI of the mean difference between the 2 groups.

Comparison groups	Treatment Group A (ABP 654) v Treatment Group B (Ustekinumab)
Number of subjects included in analysis	548
Analysis specification	Pre-specified
Analysis type	equivalence
Parameter estimate	Mean difference (final values)
Point estimate	0.14
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.16
upper limit	3.43

Secondary: PASI Percent Change at Other Timepoints

End point title	PASI Percent Change at Other Timepoints

End point description:

The PASI is a measure of the average redness (erythema), thickness (induration), and scaliness (scaling; each graded on a 0-4 scale [0 = clear; 1-4 = increasing severity]) of the lesions, weighted by the area of involvement in the four main body areas (i.e., head, arms, trunk to groin, and legs to top of buttocks). The PASI score ranges from 0 to 72. Higher scores represent worse symptom severity. 999999 = analysis was not pre-specified for this timepoint; N=0.

Through Week 28 results are presented for the FAS with available data; last observation carried forward (LOCF) imputation was used. Post Week 28 results are presented for dose intensification participants with available observed data and re-randomized FAS participants with available data (LOCF imputation was used).

End point type	Secondary

End point timeframe:

Baseline (Day 1 [Week 0]), Weeks 4, 16, 28, 36, 40 (re-randomized FAS only), 44 and Week 52 (End of Study [EOS])

End point values	Treatment Group A (ABP 654)	Treatment Group B (Ustekinumab)	Post Week 28: ABP 654/ ABP 654	Post Week 28: Ustekinumab/ ABP 654
Subject group type	Reporting group	Reporting group	Subject analysis set	Subject analysis set
Number of subjects analysed	280	281	247	117
Units: Percent Change in PASI score				
arithmetic mean (standard deviation)				
Week 4 (N = 280; 281; 0; 0; 0)	44.15 (± 23.587)	42.40 (± 24.536)	999999 (± 999999)	999999 (± 999999)
Week 16 (N = 280; 281; 0; 0; 0)	85.88 (± 18.704)	85.86 (± 19.953)	999999 (± 999999)	999999 (± 999999)
Week 28 (N = 280; 281; 0; 0; 0)	89.41 (± 14.228)	88.18 (± 18.771)	999999 (± 999999)	999999 (± 999999)
Week 36 (N = 25; 34; 0; 0; 0)	75.53 (± 11.038)	74.12 (± 13.826)	999999 (± 999999)	999999 (± 999999)
Week 40 (N = 0; 0; 247; 117; 116)	999999 (± 999999)	999999 (± 999999)	93.60 (± 9.738)	94.22 (± 8.296)
Week 44 (N = 25; 34; 0; 0; 0)	75.33 (± 15.563)	78.42 (± 14.733)	999999 (± 999999)	999999 (± 999999)
Week 52 (N = 25; 34; 247; 117; 116)	77.80 (± 14.760)	77.46 (± 18.109)	92.54 (± 11.808)	93.90 (± 8.987)

End point values	Post Week 28: Ustekinumab/ Ustekinumab			
Subject group type	Subject analysis set			
Number of subjects analysed	116			
Units: Percent Change in PASI score				
arithmetic mean (standard deviation)				
Week 4 (N = 280; 281; 0; 0; 0)	999999 (± 999999)			

Week 16 (N = 280; 281; 0; 0; 0)	999999 (± 999999)			
Week 28 (N = 280; 281; 0; 0; 0)	999999 (± 999999)			
Week 36 (N = 25; 34; 0; 0; 0)	999999 (± 999999)			
Week 40 (N = 0; 0; 247; 117; 116)	95.10 (± 8.529)			
Week 44 (N = 25; 34; 0; 0; 0)	999999 (± 999999)			
Week 52 (N = 25; 34; 247; 117; 116)	93.23 (± 16.029)			

Statistical analyses

Statistical analysis title	Week 4: Treatment Group A vs Treatment Group B

Statistical analysis description:

The mean differences and 95% CIs of PASI percent improvement between the initial randomized groups (ABP 654 vs ustekinumab) at other scheduled visits was estimated using analysis of covariance (ANCOVA) model adjusted for baseline PASI value, and the stratification factors of prior biologic use for psoriasis, baseline BW group, and geographic region.

LOCF imputation was used.

Comparison groups	Treatment Group A (ABP 654) v Treatment Group B (Ustekinumab)
Number of subjects included in analysis	561
Analysis specification	Pre-specified
Analysis type	equivalence
Parameter estimate	Mean difference (final values)
Point estimate	1.95
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.05
upper limit	5.94

Statistical analysis title	Week 28: Treatment Group A vs Treatment Group B

Statistical analysis description:

The mean differences and 95% CIs of PASI percent improvement between the initial randomized groups (ABP 654 vs ustekinumab) at other scheduled visits was estimated using ANCOVA model adjusted for baseline PASI value, and the stratification factors of prior biologic use for psoriasis, baseline BW group, and geographic region.

LOCF imputation was used.

Comparison groups	Treatment Group A (ABP 654) v Treatment Group B (Ustekinumab)

Number of subjects included in analysis	561
Analysis specification	Pre-specified
Analysis type	equivalence
Parameter estimate	Mean difference (final values)
Point estimate	1.34
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.39
upper limit	4.07

Statistical analysis title	Week 36: Treatment Group A vs Treatment Group B

Statistical analysis description:

The mean differences and 95% CIs of PASI percent improvement between the dose intensification groups (ABP 654 vs ustekinumab) at other scheduled visits was estimated using ANCOVA model adjusted for baseline PASI value, and the stratification factors of prior biologic use for psoriasis, baseline BW group, and geographic region.

Observed data was used.

Comparison groups	Treatment Group A (ABP 654) v Treatment Group B (Ustekinumab)
Number of subjects included in analysis	561
Analysis specification	Pre-specified
Analysis type	equivalence
Parameter estimate	Mean difference (final values)
Point estimate	1.26
Confidence interval	
level	95 %
sides	2-sided
lower limit	-5.46
upper limit	7.98

Statistical analysis title	Week 52: ABP 654/Ustekinumab vs Ustekinumab

Statistical analysis description:

The differences for the mean percent change from baseline and the corresponding CIs were for ABP 654/ustekinumab minus ustekinumab/ustekinumab. Estimated using ANCOVA model adjusted for baseline PASI value, and the stratification factors of prior biologic use for psoriasis, baseline BW group, and geographic region.

LOCF imputation was used.

Comparison groups	Post Week 28: Ustekinumab/ ABP 654 v Post Week 28: Ustekinumab/ Ustekinumab
Number of subjects included in analysis	233
Analysis specification	Pre-specified
Analysis type	equivalence
Parameter estimate	Mean difference (final values)
Point estimate	0.7

Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.46
upper limit	3.86

Statistical analysis title	Week 52: Treatment Group A vs Treatment Group B

Statistical analysis description:

The mean differences and 95% CIs of PASI percent improvement between the dose intensification groups (ABP 654 vs ustekinumab) at other scheduled visits was estimated using ANCOVA model adjusted for baseline PASI value, and the stratification factors of prior biologic use for psoriasis, baseline BW group, and geographic region.

Observed data was used.

Comparison groups	Treatment Group A (ABP 654) v Treatment Group B (Ustekinumab)
Number of subjects included in analysis	561
Analysis specification	Pre-specified
Analysis type	equivalence
Parameter estimate	Mean difference (final values)
Point estimate	-0.66
Confidence interval	
level	95 %
sides	2-sided
lower limit	-8.45
upper limit	7.13

Statistical analysis title	Week 40: ABP 654 vs Ustekinumab

Statistical analysis description:

The differences for the mean percent change from baseline and the corresponding CIs were for ABP 654/ABP 654 minus ustekinumab/ustekinumab. Estimated using ANCOVA model adjusted for baseline PASI value, and the stratification factors of prior biologic use for psoriasis, baseline BW group, and geographic region.

LOCF imputation was used.

Comparison groups	Post Week 28: ABP 654/ ABP 654 v Post Week 28: Ustekinumab/ Ustekinumab
Number of subjects included in analysis	363
Analysis specification	Pre-specified
Analysis type	equivalence
Parameter estimate	Mean difference (final values)
Point estimate	-1.41
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.42
upper limit	0.59

Statistical analysis title	Week 40: ABP 654/Ustekinumab vs Ustekinumab

Statistical analysis description:

The differences for the mean percent change from baseline and the corresponding CIs were for ABP 654/ustekinumab minus ustekinumab/ustekinumab. Estimated using ANCOVA model adjusted for baseline PASI value, and the stratification factors of prior biologic use for psoriasis, baseline BW group, and geographic region.

LOCF imputation was used.

Comparison groups	Post Week 28: Ustekinumab/ ABP 654 v Post Week 28: Ustekinumab/ Ustekinumab
Number of subjects included in analysis	233
Analysis specification	Pre-specified
Analysis type	equivalence
Parameter estimate	Mean difference (final values)
Point estimate	-0.85
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.17
upper limit	1.48

Statistical analysis title	Week 52: ABP 654 vs Ustekinumab

Statistical analysis description:

The differences for the mean percent change from baseline and the corresponding CIs were for ABP 654/ABP 654 minus ustekinumab/ustekinumab. Estimated using ANCOVA model adjusted for baseline PASI value, and the stratification factors of prior biologic use for psoriasis, baseline BW group, and geographic region.

LOCF imputation was used.

Comparison groups	Post Week 28: ABP 654/ ABP 654 v Post Week 28: Ustekinumab/ Ustekinumab
Number of subjects included in analysis	363
Analysis specification	Pre-specified
Analysis type	equivalence
Parameter estimate	Mean difference (final values)
Point estimate	-0.56
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.29
upper limit	2.17

Statistical analysis title	Week 16: Treatment Group A vs Treatment Group B

Statistical analysis description:

The mean differences and 95% CIs of PASI percent improvement between the initial randomized groups (ABP 654 vs ustekinumab) at other scheduled visits was estimated using ANCOVA model adjusted for baseline PASI value, and the stratification factors of prior biologic use for psoriasis, baseline BW group,

and geographic region.

LOCF imputation was used.

Comparison groups	Treatment Group A (ABP 654) v Treatment Group B (Ustekinumab)
Number of subjects included in analysis	561
Analysis specification	Pre-specified
Analysis type	equivalence
Parameter estimate	Mean difference (final values)
Point estimate	0.17
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.97
upper limit	3.31

Statistical analysis title	Week 44: Treatment Group A vs Treatment Group B

Statistical analysis description:

The mean differences and 95% CIs of PASI percent improvement between the dose intensification groups (ABP 654 vs ustekinumab) at other scheduled visits was estimated using ANCOVA model adjusted for baseline PASI value, and the stratification factors of prior biologic use for psoriasis, baseline BW group, and geographic region.

Observed data was used.

Comparison groups	Treatment Group A (ABP 654) v Treatment Group B (Ustekinumab)
Number of subjects included in analysis	561
Analysis specification	Pre-specified
Analysis type	equivalence
Parameter estimate	Mean difference (final values)
Point estimate	-3.71
Confidence interval	
level	95 %
sides	2-sided
lower limit	-10.71
upper limit	3.28

Secondary: Percentage of Participants with PASI 75 Response Throughout the Study

End point title	Percentage of Participants with PASI 75 Response Throughout the Study

End point description:

Reduction in disease was measured by PASI score. The PASI 75 response is a 75% or greater improvement (reduction in disease [PASI 75]) from baseline in PASI score. The PASI is a measure of the average redness (erythema), thickness (induration), and scaliness (scaling; each graded on a 0-4 scale [0 = clear; 1-4 = increasing severity]) of the lesions, weighted by the area of involvement in the four main body areas (i.e., head, arms, trunk to groin, and legs to top of buttocks). The PASI score ranges from 0 to 72. Higher scores represent worse symptom severity. 999999 = analysis was not pre-specified for this timepoint; N=0.

Through Week 28 FAS results are presented for the FAS with available data; non-responder imputation (NRI) was used. Post Week 28 results are presented for dose intensification participants with available observed data and re-randomized FAS participants with available data (NRI was used).

End point type	Secondary

End point timeframe:

Baseline (Day 1 [Week 0]), Weeks 4, 16, 28, 36, 40 (re-randomized FAS only), 44 and Week 52 (End of Study [EOS])

End point values	Treatment Group A (ABP 654)	Treatment Group B (Ustekinumab)	Post Week 28: ABP 654/ ABP 654	Post Week 28: Ustekinumab/ ABP 654
Subject group type	Reporting group	Reporting group	Subject analysis set	Subject analysis set
Number of subjects analysed	281	282	247	117
Units: Percentage of participants				
number (confidence interval 95%)				
Week 4 (N = 281; 282; 0; 0; 0)	11.4 (7.67 to 15.10)	10.3 (6.74 to 13.83)	999999 (999999 to 999999)	999999 (999999 to 999999)
Week 12 (N = 281; 282; 0; 0; 0)	69.8 (64.38 to 75.12)	70.2 (64.88 to 75.55)	999999 (999999 to 999999)	999999 (999999 to 999999)
Week 16 (N = 281; 282; 0; 0; 0)	80.8 (76.18 to 85.39)	80.1 (75.49 to 84.80)	999999 (999999 to 999999)	999999 (999999 to 999999)
Week 28 (N = 281; 282; 0; 0; 0)	85.8 (81.68 to 89.85)	82.3 (77.81 to 86.73)	999999 (999999 to 999999)	999999 (999999 to 999999)
Week 36 (N = 25; 34; 0; 0; 0)	52.0 (32.42 to 71.58)	55.9 (39.19 to 72.57)	999999 (999999 to 999999)	999999 (999999 to 999999)
Week 40 (N = 0; 0; 247; 117; 116)	999999 (999999 to 999999)	999999 (999999 to 999999)	94.7 (91.95 to 97.52)	95.7 (92.06 to 99.39)
Week 44 (N = 25; 34; 0; 0; 0)	48.0 (28.42 to 67.58)	64.7 (48.64 to 80.77)	999999 (999999 to 999999)	999999 (999999 to 999999)
Week 52 (N = 25; 34; 247; 117; 116)	64.0 (45.18 to 82.82)	58.8 (42.28 to 75.37)	89.5 (85.65 to 93.30)	92.3 (87.48 to 97.14)

End point values	Post Week 28: Ustekinumab/ Ustekinumab			
Subject group type	Subject analysis set			
Number of subjects analysed	116			
Units: Percentage of participants				
number (confidence interval 95%)				
Week 4 (N = 281; 282; 0; 0; 0)	999999 (999999 to 999999)			
Week 12 (N = 281; 282; 0; 0; 0)	999999 (999999 to 999999)			
Week 16 (N = 281; 282; 0; 0; 0)	999999 (999999 to 999999)			
Week 28 (N = 281; 282; 0; 0; 0)	999999 (999999 to 999999)			

Week 36 (N = 25; 34; 0; 0; 0)	999999 (999999 to 999999)			
Week 40 (N = 0; 0; 247; 117; 116)	94.0 (89.63 to 98.30)			
Week 44 (N = 25; 34; 0; 0; 0)	999999 (999999 to 999999)			
Week 52 (N = 25; 34; 247; 117; 116)	92.2 (87.37 to 97.11)			

Statistical analyses

Statistical analysis title	Week 4: Treatment Group A vs Treatment Group B

Statistical analysis description:

Response difference (ABP 654 – ustekinumab) was estimated by the Mantel-Haenszel estimate, and the 95% CIs were estimated by the stratified Newcombe confidence limits, adjusting for actual stratification factors of prior biologic use for psoriasis, baseline BW group, and geographic region.

NRI was used.

Comparison groups	Treatment Group A (ABP 654) v Treatment Group B (Ustekinumab)
Number of subjects included in analysis	563
Analysis specification	Post-hoc
Analysis type	equivalence
Parameter estimate	Response difference
Point estimate	1.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.02
upper limit	6.42

Statistical analysis title	Week 12: Treatment Group A vs Treatment Group B

Statistical analysis description:

Response difference (ABP 654 – ustekinumab) was estimated by the Mantel-Haenszel estimate, and the 95% CIs were estimated by the stratified Newcombe confidence limits, adjusting for actual stratification factors of prior biologic use for psoriasis, baseline BW group, and geographic region.

NRI was used.

Comparison groups	Treatment Group A (ABP 654) v Treatment Group B (Ustekinumab)
Number of subjects included in analysis	563
Analysis specification	Post-hoc
Analysis type	equivalence
Parameter estimate	Response difference
Point estimate	-0.32

Confidence interval	
level	95 %
sides	2-sided
lower limit	-7.87
upper limit	7.23

Statistical analysis title	Week 16: Treatment Group A vs Treatment Group B

Statistical analysis description:

Response difference (ABP 654 – ustekinumab) was estimated by the Mantel-Haenszel estimate, and the 95% CIs were estimated by the stratified Newcombe confidence limits, adjusting for actual stratification factors of prior biologic use for psoriasis, baseline BW group, and geographic region.

NRI was used.

Comparison groups	Treatment Group A (ABP 654) v Treatment Group B (Ustekinumab)
Number of subjects included in analysis	563
Analysis specification	Post-hoc
Analysis type	equivalence
Parameter estimate	Response difference
Point estimate	0.82
Confidence interval	
level	95 %
sides	2-sided
lower limit	-5.75
upper limit	7.37

Statistical analysis title	Week 28: Treatment Group A vs Treatment Group B

Statistical analysis description:

Response difference (ABP 654 – ustekinumab) was estimated by the Mantel-Haenszel estimate, and the 95% CIs were estimated by the stratified Newcombe confidence limits, adjusting for actual stratification factors of prior biologic use for psoriasis, baseline BW group, and geographic region.

NRI was used.

Comparison groups	Treatment Group A (ABP 654) v Treatment Group B (Ustekinumab)
Number of subjects included in analysis	563
Analysis specification	Post-hoc
Analysis type	equivalence
Parameter estimate	Response difference
Point estimate	3.75
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.37
upper limit	9.84

Statistical analysis title	Week 36: Treatment Group A vs Treatment Group B

Statistical analysis description:

Response difference in dose intensification participants (ABP 654 – ustekinumab) was estimated by the generalized linear model adjusted for the baseline PASI and the stratification factors with an identity link was used to obtain the point estimate and 95% CI for the risk difference of PASI 75 response rate at each scheduled timepoint.

Observed data was used.

Comparison groups	Treatment Group A (ABP 654) v Treatment Group B (Ustekinumab)
Number of subjects included in analysis	563
Analysis specification	Pre-specified
Analysis type	equivalence
Parameter estimate	Response difference
Point estimate	-3.19
Confidence interval	
level	95 %
sides	2-sided
lower limit	-28.15
upper limit	21.76

Statistical analysis title	Week 44: Treatment Group A vs Treatment Group B

Statistical analysis description:

Response difference in dose intensification participants (ABP 654 – ustekinumab) was estimated by the generalized linear model adjusted for the baseline PASI and the stratification factors with an identity link was used to obtain the point estimate and 95% CI for the risk difference of PASI 75 response rate at each scheduled timepoint.

Observed data was used.

Comparison groups	Treatment Group A (ABP 654) v Treatment Group B (Ustekinumab)
Number of subjects included in analysis	563
Analysis specification	Pre-specified
Analysis type	equivalence[1]
Parameter estimate	Response difference
Point estimate	9999
Confidence interval	
level	95 %
sides	2-sided
lower limit	9999
upper limit	9999

Notes:

[1] - If there were less than 25 participants in any of the treatment groups at any visit or any other reason leading to model non-convergence after model check, no statistical modelling could be performed and the results were displayed as 9999.

Statistical analysis title	Week 40: ABP 654 vs Ustekinumab

Statistical analysis description:

Response difference (ABP 654/ABP 654 – ustekinumab/ustekinumab) was estimated by the Mantel-Haenszel estimate, and the 95% CIs were estimated by the stratified Newcombe confidence limits, adjusting for actual stratification factors of prior biologic use for psoriasis, baseline BW group, and geographic region.

NRI was used.

Comparison groups	Post Week 28: ABP 654/ ABP 654 v Post Week 28: Ustekinumab/ Ustekinumab

Number of subjects included in analysis	363
Analysis specification	Post-hoc
Analysis type	equivalence
Parameter estimate	Response difference
Point estimate	1.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.74
upper limit	7.54

Statistical analysis title	Week 52: Treatment Group A vs Treatment Group B

Statistical analysis description:

Response difference in dose intensification participants (ABP 654 – ustekinumab) was estimated by the generalized linear model adjusted for the baseline PASI and the stratification factors with an identity link was used to obtain the point estimate and 95% CI for the risk difference of PASI 75 response rate at each scheduled timepoint.

Observed data was used.

Comparison groups	Treatment Group A (ABP 654) v Treatment Group B (Ustekinumab)
Number of subjects included in analysis	563
Analysis specification	Pre-specified
Analysis type	equivalence[2]
Parameter estimate	Response difference
Point estimate	9999
Confidence interval	
level	95 %
sides	2-sided
lower limit	9999
upper limit	9999

Notes:

[2] - If there were less than 25 participants in any of the treatment groups at any visit or any other reason leading to model non-convergence after model check, no statistical modelling could be performed and the results were displayed as 9999.

Statistical analysis title	Week 52: ABP 654 vs Ustekinumab

Statistical analysis description:

Response difference (ABP 654/ABP 654 – ustekinumab/ustekinumab) was estimated by the Mantel-Haenszel estimate, and the 95% CIs were estimated by the stratified Newcombe confidence limits, adjusting for actual stratification factors of prior biologic use for psoriasis, baseline BW group, and geographic region.

NRI was used.

Comparison groups	Post Week 28: ABP 654/ ABP 654 v Post Week 28: Ustekinumab/ Ustekinumab
Number of subjects included in analysis	363
Analysis specification	Post-hoc
Analysis type	equivalence
Parameter estimate	Response difference
Point estimate	-2.75

Confidence interval	
level	95 %
sides	2-sided
lower limit	-8.61
upper limit	4.41

Statistical analysis title	Week 40: ABP 654/Ustekinumab vs Ustekinumab

Statistical analysis description:

Response difference (ABP 654/ustekinumab – ustekinumab/ustekinumab) was estimated by the Mantel-Haenszel estimate, and the 95% CIs were estimated by the stratified Newcombe confidence limits, adjusting for actual stratification factors of prior biologic use for psoriasis, baseline BW group, and geographic region.

NRI was used.

Comparison groups	Post Week 28: Ustekinumab/ ABP 654 v Post Week 28: Ustekinumab/ Ustekinumab
Number of subjects included in analysis	233
Analysis specification	Post-hoc
Analysis type	equivalence
Parameter estimate	Response difference
Point estimate	1.85
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.89
upper limit	8.39

Statistical analysis title	Week 52: ABP 654/Ustekinumab vs Ustekinumab

Statistical analysis description:

Response difference (ABP 654/ustekinumab – ustekinumab/ustekinumab) was estimated by the Mantel-Haenszel estimate, and the 95% CIs were estimated by the stratified Newcombe confidence limits, adjusting for actual stratification factors of prior biologic use for psoriasis, baseline BW group, and geographic region.

NRI was used.

Comparison groups	Post Week 28: Ustekinumab/ ABP 654 v Post Week 28: Ustekinumab/ Ustekinumab
Number of subjects included in analysis	233
Analysis specification	Post-hoc
Analysis type	equivalence
Parameter estimate	Response difference
Point estimate	0.14
Confidence interval	
level	95 %
sides	2-sided
lower limit	-7.32
upper limit	7.43

Secondary: Percentage of Participants with PASI 100 Response Throughout the Study

End point title	Percentage of Participants with PASI 100 Response Throughout the Study

End point description:

Reduction in disease was measured by PASI score. The PASI 100 response is a 100% improvement (reduction in disease [PASI 100]) from baseline in PASI score. The PASI is a measure of the average redness (erythema), thickness (induration), and scaliness (scaling; each graded on a 0-4 scale [0 = clear; 1-4 = increasing severity]) of the lesions, weighted by the area of involvement in the four main body areas (i.e., head, arms, trunk to groin, and legs to top of buttocks). The PASI score ranges from 0 to 72. Higher scores represent worse symptom severity. -99999 and 99999 = results are not estimable as there were not enough PASI responses. 999999 = analysis was not pre-specified for this timepoint; N=0.

Through Week 28 FAS results are presented for the FAS with available data; NRI was used. Post Week 28 results are presented for dose intensification participants with available observed data and re-randomized FAS participants with available data (NRI was used).

End point type	Secondary

End point timeframe:

Baseline (Day 1 [Week 0]), Weeks 4, 12, 16, 28, 36, 40 (re-randomized FAS only), 44 and Week 52 (EOS)

End point values	Treatment Group A (ABP 654)	Treatment Group B (Ustekinumab)	Post Week 28: ABP 654/ ABP 654	Post Week 28: Ustekinumab/ ABP 654
Subject group type	Reporting group	Reporting group	Subject analysis set	Subject analysis set
Number of subjects analysed	281	282	247	117
Units: Percentage of participants				
number (confidence interval 95%)				
Week 4 (N = 281; 282; 0; 0; 0)	0.4 (0.00 to 1.05)	0.7 (0.00 to 1.69)	999999 (999999 to 999999)	999999 (999999 to 999999)
Week 12 (N = 281; 282; 0; 0; 0)	20.6 (15.91 to 25.37)	19.1 (14.56 to 23.74)	999999 (999999 to 999999)	999999 (999999 to 999999)
Week 16 (N = 281; 282; 0; 0; 0)	29.9 (24.54 to 35.25)	26.2 (21.11 to 31.38)	999999 (999999 to 999999)	999999 (999999 to 999999)
Week 28 (N = 281; 282; 0; 0; 0)	34.5 (28.96 to 40.08)	31.6 (26.14 to 36.98)	999999 (999999 to 999999)	999999 (999999 to 999999)
Week 36 (N = 25; 34; 0; 0; 0)	0 (-99999 to 99999)	0 (-99999 to 99999)	999999 (999999 to 999999)	999999 (999999 to 999999)
Week 40 (N = 0; 0; 247; 117; 116)	999999 (999999 to 999999)	999999 (999999 to 999999)	44.5 (38.34 to 50.73)	41.9 (32.94 to 50.82)
Week 44 (N = 25; 34; 0; 0; 0)	4.0 (0.00 to 11.68)	2.9 (0.00 to 8.62)	999999 (999999 to 999999)	999999 (999999 to 999999)
Week 52 (N = 25; 34; 247; 117; 116)	4.0 (0.00 to 11.68)	14.7 (2.80 to 26.61)	47.0 (40.74 to 53.19)	42.7 (33.77 to 51.70)

End point values	Post Week 28: Ustekinumab/ Ustekinumab			
Subject group type	Subject analysis set			
Number of subjects analysed	116			
Units: Percentage of participants				
number (confidence interval 95%)				
Week 4 (N = 281; 282; 0; 0; 0)	999999 (999999 to 999999)			
Week 12 (N = 281; 282; 0; 0; 0)	999999 (999999 to 999999)			
Week 16 (N = 281; 282; 0; 0; 0)	999999 (999999 to 999999)			
Week 28 (N = 281; 282; 0; 0; 0)	999999 (999999 to 999999)			
Week 36 (N = 25; 34; 0; 0; 0)	999999 (999999 to 999999)			
Week 40 (N = 0; 0; 247; 117; 116)	46.6 (37.47 to 55.63)			
Week 44 (N = 25; 34; 0; 0; 0)	999999 (999999 to 999999)			
Week 52 (N = 25; 34; 247; 117; 116)	44.8 (35.78 to 53.88)			

Statistical analyses

Statistical analysis title	Week 36: Treatment Group A vs Treatment Group B

Statistical analysis description:

Response difference in dose intensification participants (ABP 654 – ustekinumab) was estimated by the Mantel-Haenszel estimate, and the 95% CIs were estimated by the stratified Newcombe confidence limits, adjusting for actual stratification factors of prior biologic use for psoriasis, baseline BW group, and geographic region.

Observed data was used.

Comparison groups	Treatment Group A (ABP 654) v Treatment Group B (Ustekinumab)
Number of subjects included in analysis	563
Analysis specification	Post-hoc
Analysis type	equivalence[3]
Parameter estimate	Response difference
Point estimate	99999
Confidence interval	
level	95 %
sides	2-sided
lower limit	99999
upper limit	99999

Notes:

[3] - 99999 = results are not estimable as there were not enough PASI responses.

Statistical analysis title	Week 28: Treatment Group A vs Treatment Group B

Statistical analysis description:

Response difference (ABP 654 – ustekinumab) was estimated by the Mantel-Haenszel estimate, and the 95% CIs were estimated by the stratified Newcombe confidence limits, adjusting for actual stratification factors of prior biologic use for psoriasis, baseline BW group, and geographic region.

NRI was used.

Comparison groups	Treatment Group A (ABP 654) v Treatment Group B (Ustekinumab)
Number of subjects included in analysis	563
Analysis specification	Post-hoc
Analysis type	equivalence
Parameter estimate	Response difference
Point estimate	3.07
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.68
upper limit	10.78

Statistical analysis title	Week 16: Treatment Group A vs Treatment Group B

Statistical analysis description:

Response difference (ABP 654 – ustekinumab) was estimated by the Mantel-Haenszel estimate, and the 95% CIs were estimated by the stratified Newcombe confidence limits, adjusting for actual stratification factors of prior biologic use for psoriasis, baseline BW group, and geographic region.

NRI was used.

Comparison groups	Treatment Group A (ABP 654) v Treatment Group B (Ustekinumab)
Number of subjects included in analysis	563
Analysis specification	Post-hoc
Analysis type	equivalence
Parameter estimate	Response difference
Point estimate	3.81
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.62
upper limit	11.17

Statistical analysis title	Week 12: Treatment Group A vs Treatment Group B

Statistical analysis description:

Response difference (ABP 654 – ustekinumab) was estimated by the Mantel-Haenszel estimate, and the 95% CIs were estimated by the stratified Newcombe confidence limits, adjusting for actual stratification factors of prior biologic use for psoriasis, baseline BW group, and geographic region.

NRI was used.

Comparison groups	Treatment Group A (ABP 654) v Treatment Group B (Ustekinumab)
Number of subjects included in analysis	563
Analysis specification	Post-hoc
Analysis type	equivalence
Parameter estimate	Response difference
Point estimate	1.58
Confidence interval	
level	95 %
sides	2-sided
lower limit	-5.03
upper limit	8.18

Statistical analysis title	Week 4: Treatment Group A vs Treatment Group B

Statistical analysis description:

Response difference (ABP 654 – ustekinumab) was estimated by the Mantel-Haenszel estimate, and the 95% CIs were estimated by the stratified Newcombe confidence limits, adjusting for actual stratification factors of prior biologic use for psoriasis, baseline BW group, and geographic region.

NRI was used.

Comparison groups	Treatment Group A (ABP 654) v Treatment Group B (Ustekinumab)
Number of subjects included in analysis	563
Analysis specification	Post-hoc
Analysis type	equivalence
Parameter estimate	Response difference
Point estimate	-0.34
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.16
upper limit	3.21

Statistical analysis title	Week 52: ABP 654 vs Ustekinumab

Statistical analysis description:

Response difference (ABP 654/ABP 654 – ustekinumab/ustekinumab) was estimated by the Mantel-Haenszel estimate, and the 95% CIs were estimated by the stratified Newcombe confidence limits, adjusting for actual stratification factors of prior biologic use for psoriasis, baseline BW group, and geographic region.

NRI was used.

Comparison groups	Post Week 28: ABP 654/ ABP 654 v Post Week 28: Ustekinumab/ Ustekinumab
Number of subjects included in analysis	363
Analysis specification	Post-hoc
Analysis type	equivalence
Parameter estimate	Response difference
Point estimate	2.55

Confidence interval	
level	95 %
sides	2-sided
lower limit	-8.42
upper limit	13.3

Statistical analysis title	Week 40: ABP 654/Ustekinumab vs Ustekinumab

Statistical analysis description:

Response difference (ABP 654/ustekinumab - ustekinumab/ustekinumab) was estimated by the Mantel-Haenszel estimate, and the 95% CIs were estimated by the stratified Newcombe confidence limits, adjusting for actual stratification factors of prior biologic use for psoriasis, baseline BW group, and geographic region.

NRI was used.

Comparison groups	Post Week 28: Ustekinumab/ ABP 654 v Post Week 28: Ustekinumab/ Ustekinumab
Number of subjects included in analysis	233
Analysis specification	Post-hoc
Analysis type	equivalence
Parameter estimate	Response difference
Point estimate	-4.93
Confidence interval	
level	95 %
sides	2-sided
lower limit	-17.39
upper limit	7.73

Statistical analysis title	Week 40: ABP 654 vs Ustekinumab

Statistical analysis description:

Response difference (ABP 654/ABP 654 – ustekinumab/ustekinumab) was estimated by the Mantel-Haenszel estimate, and the 95% CIs were estimated by the stratified Newcombe confidence limits, adjusting for actual stratification factors of prior biologic use for psoriasis, baseline BW group, and geographic region.

NRI was used.

Comparison groups	Post Week 28: ABP 654/ ABP 654 v Post Week 28: Ustekinumab/ Ustekinumab
Number of subjects included in analysis	363
Analysis specification	Post-hoc
Analysis type	equivalence
Parameter estimate	Response difference
Point estimate	-1.93
Confidence interval	
level	95 %
sides	2-sided
lower limit	-12.85
upper limit	8.89

Statistical analysis title	Week 52: Treatment Group A vs Treatment Group B

Statistical analysis description:

Response difference in dose intensification participants (ABP 654 – ustekinumab) was estimated by the Mantel-Haenszel estimate, and the 95% CIs were estimated by the stratified Newcombe confidence limits, adjusting for actual stratification factors of prior biologic use for psoriasis, baseline BW group, and geographic region.

Observed data was used.

Comparison groups	Treatment Group A (ABP 654) v Treatment Group B (Ustekinumab)
Number of subjects included in analysis	563
Analysis specification	Post-hoc
Analysis type	equivalence[4]
Parameter estimate	Response difference
Point estimate	99999
Confidence interval	
level	95 %
sides	2-sided
lower limit	99999
upper limit	99999

Notes:

[4] - 99999 = results are not estimable as there were not enough PASI responses.

Statistical analysis title	Week 52: ABP 654/Ustekinumab vs Ustekinumab

Statistical analysis description:

Response difference (ABP 654/ustekinumab – ustekinumab/ustekinumab) was estimated by the Mantel-Haenszel estimate, and the 95% CIs were estimated by the stratified Newcombe confidence limits, adjusting for actual stratification factors of prior biologic use for psoriasis, baseline BW group, and geographic region.

NRI was used.

Comparison groups	Post Week 28: Ustekinumab/ ABP 654 v Post Week 28: Ustekinumab/ Ustekinumab
Number of subjects included in analysis	233
Analysis specification	Post-hoc
Analysis type	equivalence
Parameter estimate	Response difference
Point estimate	-2.41
Confidence interval	
level	95 %
sides	2-sided
lower limit	-14.91
upper limit	10.19

Statistical analysis title	Week 44: Treatment Group A vs Treatment Group B

Statistical analysis description:

Response difference in dose intensification participants (ABP 654 – ustekinumab) was estimated by the Mantel-Haenszel estimate, and the 95% CIs were estimated by the stratified Newcombe confidence limits, adjusting for actual stratification factors of prior biologic use for psoriasis, baseline BW group,

and geographic region.

Observed data was used.

Comparison groups	Treatment Group A (ABP 654) v Treatment Group B (Ustekinumab)
Number of subjects included in analysis	563
Analysis specification	Post-hoc
Analysis type	equivalence[5]
Parameter estimate	Response difference
Point estimate	99999
Confidence interval	
level	95 %
sides	2-sided
lower limit	99999
upper limit	99999

Notes:

[5] - 99999 = results are not estimable as there were not enough PASI responses.

Secondary: Percentage of Participants With sPGA Responses (0/1) at Week 12 and Week 52

End point title	Percentage of Participants With sPGA Responses (0/1) at Week 12 and Week 52

End point description:

The sPGA is a 6-point scale ranging from 0 (clear) to 5 (very severe) used to measure the severity of disease (induration, scaling, and erythema). A sPGA response was defined as a sPGA value of clear (score 0) or almost clear (score 1). Higher scores represent worse symptom severity. 999999 = analysis was not pre-specified for this timepoint; N=0.

Week 12 results are presented for the FAS with available data; NRI was used. Week 52 results are presented for dose intensification participants with available data and re-randomized FAS participants with available data (NRI was used).

End point type	Secondary

End point timeframe:

Week 12 and Week 52 (EOS)

End point values	Treatment Group A (ABP 654)	Treatment Group B (Ustekinumab)	Post Week 28: ABP 654/ ABP 654	Post Week 28: Ustekinumab/ ABP 654
Subject group type	Reporting group	Reporting group	Subject analysis set	Subject analysis set
Number of subjects analysed	281	282	247	117
Units: Percentage of participants				
number (confidence interval 95%)				
Week 12 (N = 281; 282; 0; 0; 0)	55.2 (49.35 to 60.98)	52.8 (47.01 to 58.66)	999999 (999999 to 999999)	999999 (999999 to 999999)
Week 52 (N = 25; 34; 247; 117; 116)	24.0 (7.26 to 40.74)	35.3 (19.23 to 51.36)	71.3 (65.61 to 76.90)	70.9 (62.71 to 79.17)

End point values	Post Week 28: Ustekinumab/ Ustekinumab			

Subject group type	Subject analysis set			
Number of subjects analysed	116			
Units: Percentage of participants				
number (confidence interval 95%)				
Week 12 (N = 281; 282; 0; 0; 0) Week 52 (N = 25; 34; 247; 117; 116)	999999 (999999 to 999999) 78.4 (70.97 to 85.93)			

Statistical analyses

Statistical analysis title	Week 12: Treatment Group A vs Treatment Group B

Statistical analysis description:

Response difference (ABP 654 – ustekinumab) was estimated by the Mantel-Haenszel estimate, and the 95% CIs were estimated by the stratified Newcombe confidence limits, adjusting for actual stratification factors of prior biologic use for psoriasis, baseline BW group, and geographic region.

NRI was used.

Comparison groups	Treatment Group A (ABP 654) v Treatment Group B (Ustekinumab)
Number of subjects included in analysis	563
Analysis specification	Post-hoc
Analysis type	equivalence
Parameter estimate	Response difference
Point estimate	2.55
Confidence interval	
level	95 %
sides	2-sided
lower limit	-5.65
upper limit	10.71

Statistical analysis title	Week 52: Treatment Group A vs Treatment Group B

Statistical analysis description:

Generalized linear model adjusted for the baseline sPGA and the stratification factors with an identity link
was used to obtain the point estimate and 95% CI for the risk difference of sPGA response rate at each scheduled timepoint in dose intensification participants.

Observed data was used.

Comparison groups	Treatment Group A (ABP 654) v Treatment Group B (Ustekinumab)
Number of subjects included in analysis	563
Analysis specification	Post-hoc
Analysis type	equivalence[6]
Parameter estimate	Response difference
Point estimate	9999

Confidence interval	
level	95 %
sides	2-sided
lower limit	9999
upper limit	9999

Notes:

[6] - If there were less than 25 participants in any of the treatment groups at any visit or any other reason leading to model non-convergence after model check, no statistical modelling could be performed and the results were displayed as 9999.

Statistical analysis title	Week 52: ABP 654 vs Ustekinumab

Statistical analysis description:

Response difference (ABP 654/ABP 654 – ustekinumab/ustekinumab) was estimated by the Mantel-Haenszel estimate, and the 95% CIs were estimated by the stratified Newcombe confidence limits, adjusting for actual stratification factors of prior biologic use for psoriasis, baseline BW group, and geographic region.

NRI was used.

Comparison groups	Post Week 28: ABP 654/ ABP 654 v Post Week 28: Ustekinumab/ Ustekinumab
Number of subjects included in analysis	363
Analysis specification	Post-hoc
Analysis type	equivalence
Parameter estimate	Response difference
Point estimate	-6.57
Confidence interval	
level	95 %
sides	2-sided
lower limit	-15.41
upper limit	3.29

Statistical analysis title	Week 52: ABP 654/Ustekinumab vs Ustekinumab

Statistical analysis description:

Response difference (ABP 654/ustekinumab – ustekinumab/ustekinumab) was estimated by the Mantel-Haenszel estimate, and the 95% CIs were estimated by the stratified Newcombe confidence limits, adjusting for actual stratification factors of prior biologic use for psoriasis, baseline BW group, and geographic region.

NRI was used.

Comparison groups	Post Week 28: Ustekinumab/ ABP 654 v Post Week 28: Ustekinumab/ Ustekinumab
Number of subjects included in analysis	233
Analysis specification	Post-hoc
Analysis type	equivalence
Parameter estimate	Response difference
Point estimate	-7.46
Confidence interval	
level	95 %
sides	2-sided
lower limit	-18.41
upper limit	3.74

Secondary: Change From Baseline in Percentage of BSA Affected with Psoriasis at Week 12 and Week 52

End point title	Change From Baseline in Percentage of BSA Affected with Psoriasis at Week 12 and Week 52

End point description:

The percentage of BSA affected was estimated by assuming that the participant's palm, excluding the fingers and thumb, represents roughly 1% of the body's surface. 999999 = analysis was not pre-specified for this timepoint; N=0.

Week 12 results are presented for the FAS with available data; LOCF imputation was used. Week 52 results are presented for dose intensification participants with available observed data and re-randomized FAS participants with available data (LOCF imputation was used).

End point type	Secondary

End point timeframe:

Baseline (Day 1 [Week 0]), Week 12 and Week 52 (EOS)

End point values	Treatment Group A (ABP 654)	Treatment Group B (Ustekinumab)	Post Week 28: ABP 654/ ABP 654	Post Week 28: Ustekinumab/ ABP 654
Subject group type	Reporting group	Reporting group	Subject analysis set	Subject analysis set
Number of subjects analysed	280	281	247	117
Units: Percentage of BSA				
arithmetic mean (standard deviation)				
Week 12 (N = 280; 281; 0; 0; 0)	-17.8 (± 14.32)	-17.2 (± 14.51)	999999 (± 999999)	999999 (± 999999)
Week 52 (N = 25; 34; 247; 117; 116)	-20.6 (± 14.72)	-21.6 (± 16.89)	-24.7 (± 14.81)	-22.8 (± 13.86)

End point values	Post Week 28: Ustekinumab/ Ustekinumab			
Subject group type	Subject analysis set			
Number of subjects analysed	116			
Units: Percentage of BSA				
arithmetic mean (standard deviation)				
Week 12 (N = 280; 281; 0; 0; 0)	999999 (± 999999)			
Week 52 (N = 25; 34; 247; 117; 116)	-22.5 (± 14.11)			

Statistical analyses

Statistical analysis title	Week 12: Treatment Group A vs Treatment Group B

Statistical analysis description:

Mean difference estimated for treatment group A and treatment group B using ANCOVA model adjusted

for baseline BSA value, and the stratification factors of prior biologic use for psoriasis, baseline BW group, and geographic region.

LOCF imputation was used.

Comparison groups	Treatment Group A (ABP 654) v Treatment Group B (Ustekinumab)
Number of subjects included in analysis	561
Analysis specification	Pre-specified
Analysis type	equivalence
Parameter estimate	Mean difference (final values)
Point estimate	0.47
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.15
upper limit	2.1

Statistical analysis title	Week 52: ABP 654/Ustekinumab vs Ustekinumab

Statistical analysis description:

Mean difference estimated for ABP 654/ ustekinumab and ustekinumab/ ustekinumab using ANCOVA model adjusted for baseline BSA value, and the stratification factors of prior biologic use for psoriasis, baseline BW group, and geographic region.

LOCF imputation was used.

Comparison groups	Post Week 28: Ustekinumab/ ABP 654 v Post Week 28: Ustekinumab/ Ustekinumab
Number of subjects included in analysis	233
Analysis specification	Pre-specified
Analysis type	equivalence
Parameter estimate	Mean difference (final values)
Point estimate	0.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.9
upper limit	1.1

Statistical analysis title	Week 52: ABP 654 vs Ustekinumab

Statistical analysis description:

Mean difference estimated for ABP 654/ ABP 654 and ustekinumab/ ustekinumab using ANCOVA model adjusted for baseline BSA value, and the stratification factors of prior biologic use for psoriasis, baseline BW group, and geographic region.

LOCF imputation was used.

Comparison groups	Post Week 28: ABP 654/ ABP 654 v Post Week 28: Ustekinumab/ Ustekinumab

Number of subjects included in analysis	363
Analysis specification	Pre-specified
Analysis type	equivalence
Parameter estimate	Mean difference (final values)
Point estimate	-0.13
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.99
upper limit	0.74

Statistical analysis title	Week 52: Treatment Group A vs Treatment Group B

Statistical analysis description:

Mean difference estimated in dose intensification participants (treatment group A and treatment group B) using ANCOVA model adjusted for baseline BSA value, and the stratification factors of prior biologic use for psoriasis, baseline BW group, and geographic region.

Observed data was used.

Comparison groups	Treatment Group A (ABP 654) v Treatment Group B (Ustekinumab)
Number of subjects included in analysis	561
Analysis specification	Pre-specified
Analysis type	equivalence
Parameter estimate	Mean difference (final values)
Point estimate	1.39
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.9
upper limit	3.67

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

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

End point description:

TEAEs were summarized by actual treatment received. For each category, participants were included only once, even if they experienced multiple events in that category.

Through Week 28 results are presented for the Safety Analysis Set. Post Week 28 results are presented for the re-randomized Safety Analysis Set and the dose intensification participants.

End point type	Secondary

End point timeframe:

Day 1 (Week 0) to Week 28; Week 28 to Week 52 (EOS)

End point values	Through Week 28: ABP 654	Through Week 28: Ustekinumab	Post Week 28: ABP 654/ ABP 654	Post Week 28: Ustekinumab/ ABP 654
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	280	282	247	117
Units: Participants				
Any TEAE	106	99	85	44
Any Serious TEAE	7	5	1	1

End point values	Post Week 28: Ustekinumab/ Ustekinumab	Post Week 28: ABP 654 Dose Intensification	Post Week 28: Ustekinumab Dose Intensification	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	116	25	34	
Units: Participants				
Any TEAE	40	12	9	
Any Serious TEAE	3	1	0	

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants Developing Anti-drug Antibodies (ADAs) to ABP 654

End point title	Number of Participants Developing Anti-drug Antibodies (ADAs) to ABP 654

End point description:

A participant was considered to have developed ADAs if they:
- had a positive post-baseline binding or neutralizing antibody result with a negative or no result at Baseline or
- had a positive post-baseline binding or neutralizing antibody result with a negative or no result prior to the first dose in the post Week 28 study period.

Through Week 28 results are presented for the Safety Analysis Set with available ADA data. Post Week 28 results are presented for the re-randomized Safety Analysis Set with available ADA data.

End point type	Secondary

End point timeframe:

Baseline; Day 1 (Week 0) to Week 28; Week 28 to Week 52 (EOS)

End point values	Through Week 28: ABP 654	Through Week 28: Ustekinumab	Post Week 28: ABP 654/ ABP 654	Post Week 28: Ustekinumab/ ABP 654
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	279	280	246	116
Units: Participants				
Binding antibody	52	104	11	4
Neutralizing antibody	24	50	5	1

End point values	Post Week 28: Ustekinumab/ Ustekinumab	Post Week 28: ABP 654 Dose Intensification	Post Week 28: Ustekinumab Dose Intensification	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	115	25	34	
Units: Participants				
Binding antibody	2	0	2	
Neutralizing antibody	1	0	1	

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants With Events of Interests (EOIs)

End point title	Number of Participants With Events of Interests (EOIs)

End point description:

The EOIs pre-specified 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, serious depression including suicidality, and venous thromboembolism.

Through Week 28 results are presented for the Safety Analysis Set. Post Week 28 results are presented for the re-randomized Safety Analysis Set.

End point type	Secondary

End point timeframe:

Day 1 (Week 0) to Week 28; Week 28 to Week 52 (EOS)

End point values	Through Week 28: ABP 654	Through Week 28: Ustekinumab	Post Week 28: ABP 654/ ABP 654	Post Week 28: Ustekinumab/ ABP 654
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	280	282	247	117
Units: Participants	5	7	3	0

End point values	Post Week 28: Ustekinumab/ Ustekinumab			
Subject group type	Subject analysis set			
Number of subjects analysed	116			
Units: Participants	4			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Day 1 (Week 0) to Week 28; Week 28 to Week 52 (EOS)

Adverse event reporting additional description:

Through Week 28: Safety Analysis Set. Post Week 28: Re-randomized Safety Analysis Set.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	24.1

Reporting groups

Reporting group title	Through Week 28: ABP 654

Reporting group description:

All participants who were randomized to receive SC injection of ABP 654, 45 mg (Baseline BW <= 100 kg) or 90 mg (Baseline BW > 100 kg) at Weeks 0, 4, and 16

Reporting group title	Through Week 28: Ustekinumab

Reporting group description:

All participants who were randomized to receive SC injection of ustekinumab, 45 mg (Baseline BW <= 100 kg) or 90 mg (Baseline BW > 100 kg) at Weeks 0, 4, and 16.

Reporting group title	Post Week 28: ABP 654 / ABP 654

Reporting group description:

All participants who were randomized to receive SC injection of ABP 654 at Weeks 0, 4, and 16, followed by ABP 654 (same dose) Q12W at Weeks 28 and 40.

Reporting group title	Post Week 28: Ustekinumab / ABP654

Reporting group description:

All participants who were randomized to receive SC injection of ustekinumab at Weeks 0, 4, and 16. At Week 28, participants were re-randomized to receive ABP 654 (Treatment group B2) at Weeks 28 and 40.

Reporting group title	Post Week 28: Ustekinumab / Ustekinumab

Reporting group description:

All participants who were randomized to receive SC injection of ustekinumab at Weeks 0, 4, and 16. At Week 28, participants were re-randomized to continue on ustekinumab (Treatment group B1) at Weeks 28 and 40.

Reporting group title	Post Week 28: ABP 654 Dose Intensification

Reporting group description:

All participants who were randomized to receive SC injection of ABP 654 at Weeks 0, 4, and 16 with PASI 50 response or better but less than PASI 75 response at Week 28 (as per protocol). Based on the Investigator's discretion, the participants received ABP 654 dose intensification Q8W at Weeks 28, 36, and 44.

Reporting group title	Post Week 28: Ustekinumab Dose Intensification

Reporting group description:

All participants who were randomized to receive SC injection of ustekinumab at Weeks 0, 4, and 16 with PASI 50 response or better but less than PASI 75 response at Week 28 (as per protocol). Based on the Investigator's discretion, the participants received ustekinumab dose intensification Q8W at Weeks 28, 36, and 44.

Serious adverse events	Through Week 28: ABP 654	Through Week 28: Ustekinumab	Post Week 28: ABP 654 / ABP 654
Total subjects affected by serious adverse events			
subjects affected / exposed	7 / 280 (2.50%)	5 / 282 (1.77%)	1 / 247 (0.40%)
number of deaths (all causes)	0	1	0
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Uterine leiomyoma			
subjects affected / exposed	1 / 280 (0.36%)	0 / 282 (0.00%)	0 / 247 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal neoplasm			
subjects affected / exposed	0 / 280 (0.00%)	1 / 282 (0.35%)	0 / 247 (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
Ovarian cancer			
subjects affected / exposed	0 / 280 (0.00%)	0 / 282 (0.00%)	1 / 247 (0.40%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Invasive lobular breast carcinoma			
subjects affected / exposed	1 / 280 (0.36%)	0 / 282 (0.00%)	0 / 247 (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
Clear cell renal cell carcinoma			
subjects affected / exposed	0 / 280 (0.00%)	1 / 282 (0.35%)	0 / 247 (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
Injury, poisoning and procedural complications			
Femoral neck fracture			
subjects affected / exposed	1 / 280 (0.36%)	0 / 282 (0.00%)	0 / 247 (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
Vascular disorders			
Hypertension			

subjects affected / exposed	1 / 280 (0.36%)	0 / 282 (0.00%)	0 / 247 (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
Congenital, familial and genetic disorders			
Developmental hip dysplasia			
subjects affected / exposed	0 / 280 (0.00%)	0 / 282 (0.00%)	0 / 247 (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			
Acute myocardial infarction			
subjects affected / exposed	0 / 280 (0.00%)	0 / 282 (0.00%)	0 / 247 (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 failure congestive			
subjects affected / exposed	0 / 280 (0.00%)	1 / 282 (0.35%)	0 / 247 (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
Cardiac ventricular thrombosis			
subjects affected / exposed	0 / 280 (0.00%)	1 / 282 (0.35%)	0 / 247 (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
Immune system disorders			
Anaphylactic reaction			
subjects affected / exposed	1 / 280 (0.36%)	0 / 282 (0.00%)	0 / 247 (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
Hepatobiliary disorders			
Cholelithiasis			
subjects affected / exposed	1 / 280 (0.36%)	0 / 282 (0.00%)	0 / 247 (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			
Bipolar I disorder			

subjects affected / exposed	0 / 280 (0.00%)	0 / 282 (0.00%)	0 / 247 (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			
Intervertebral disc disorder			
subjects affected / exposed	0 / 280 (0.00%)	0 / 282 (0.00%)	0 / 247 (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			
COVID-19 pneumonia			
subjects affected / exposed	1 / 280 (0.36%)	0 / 282 (0.00%)	0 / 247 (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
COVID-19			
subjects affected / exposed	0 / 280 (0.00%)	1 / 282 (0.35%)	0 / 247 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Postoperative wound infection			
subjects affected / exposed	0 / 280 (0.00%)	0 / 282 (0.00%)	0 / 247 (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
Sepsis			
subjects affected / exposed	0 / 280 (0.00%)	0 / 282 (0.00%)	0 / 247 (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
Infected cyst			
subjects affected / exposed	0 / 280 (0.00%)	0 / 282 (0.00%)	0 / 247 (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
Cellulitis			
subjects affected / exposed	0 / 280 (0.00%)	1 / 282 (0.35%)	0 / 247 (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

Serious adverse events	Post Week 28: Ustekinumab / ABP654	Post Week 28: Ustekinumab / Ustekinumab	Post Week 28: ABP 654 Dose Intensification
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 117 (0.85%)	3 / 116 (2.59%)	1 / 25 (4.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Uterine leiomyoma			
subjects affected / exposed	0 / 117 (0.00%)	0 / 116 (0.00%)	0 / 25 (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
Renal neoplasm			
subjects affected / exposed	0 / 117 (0.00%)	0 / 116 (0.00%)	0 / 25 (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
Ovarian cancer			
subjects affected / exposed	0 / 117 (0.00%)	0 / 116 (0.00%)	0 / 25 (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
Invasive lobular breast carcinoma			
subjects affected / exposed	0 / 117 (0.00%)	0 / 116 (0.00%)	0 / 25 (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
Clear cell renal cell carcinoma			
subjects affected / exposed	0 / 117 (0.00%)	0 / 116 (0.00%)	0 / 25 (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			
Femoral neck fracture			
subjects affected / exposed	0 / 117 (0.00%)	0 / 116 (0.00%)	0 / 25 (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
Vascular disorders			
Hypertension			

subjects affected / exposed	0 / 117 (0.00%)	0 / 116 (0.00%)	0 / 25 (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
Congenital, familial and genetic disorders			
Developmental hip dysplasia			
subjects affected / exposed	0 / 117 (0.00%)	0 / 116 (0.00%)	1 / 25 (4.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Acute myocardial infarction			
subjects affected / exposed	0 / 117 (0.00%)	1 / 116 (0.86%)	0 / 25 (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
Cardiac failure congestive			
subjects affected / exposed	0 / 117 (0.00%)	0 / 116 (0.00%)	0 / 25 (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 ventricular thrombosis			
subjects affected / exposed	0 / 117 (0.00%)	0 / 116 (0.00%)	0 / 25 (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
Immune system disorders			
Anaphylactic reaction			
subjects affected / exposed	0 / 117 (0.00%)	0 / 116 (0.00%)	0 / 25 (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			
Cholelithiasis			
subjects affected / exposed	0 / 117 (0.00%)	0 / 116 (0.00%)	0 / 25 (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			
Bipolar I disorder			

subjects affected / exposed	0 / 117 (0.00%)	1 / 116 (0.86%)	0 / 25 (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			
Intervertebral disc disorder			
subjects affected / exposed	1 / 117 (0.85%)	0 / 116 (0.00%)	0 / 25 (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			
COVID-19 pneumonia			
subjects affected / exposed	0 / 117 (0.00%)	0 / 116 (0.00%)	0 / 25 (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
COVID-19			
subjects affected / exposed	0 / 117 (0.00%)	1 / 116 (0.86%)	0 / 25 (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
Postoperative wound infection			
subjects affected / exposed	0 / 117 (0.00%)	1 / 116 (0.86%)	0 / 25 (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
Sepsis			
subjects affected / exposed	0 / 117 (0.00%)	1 / 116 (0.86%)	0 / 25 (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
Infected cyst			
subjects affected / exposed	0 / 117 (0.00%)	1 / 116 (0.86%)	0 / 25 (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
Cellulitis			
subjects affected / exposed	0 / 117 (0.00%)	0 / 116 (0.00%)	0 / 25 (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	Post Week 28: Ustekinumab Dose Intensification		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 34 (0.00%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Uterine leiomyoma			
subjects affected / exposed	0 / 34 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Renal neoplasm			
subjects affected / exposed	0 / 34 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Ovarian cancer			
subjects affected / exposed	0 / 34 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Invasive lobular breast carcinoma			
subjects affected / exposed	0 / 34 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Clear cell renal cell carcinoma			
subjects affected / exposed	0 / 34 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Injury, poisoning and procedural complications			
Femoral neck fracture			
subjects affected / exposed	0 / 34 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Vascular disorders			
Hypertension			

subjects affected / exposed	0 / 34 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Congenital, familial and genetic disorders			
Developmental hip dysplasia			
subjects affected / exposed	0 / 34 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cardiac disorders			
Acute myocardial infarction			
subjects affected / exposed	0 / 34 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cardiac failure congestive			
subjects affected / exposed	0 / 34 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cardiac ventricular thrombosis			
subjects affected / exposed	0 / 34 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Immune system disorders			
Anaphylactic reaction			
subjects affected / exposed	0 / 34 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hepatobiliary disorders			
Cholelithiasis			
subjects affected / exposed	0 / 34 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Psychiatric disorders			
Bipolar I disorder			

subjects affected / exposed	0 / 34 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Musculoskeletal and connective tissue disorders			
Intervertebral disc disorder			
subjects affected / exposed	0 / 34 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Infections and infestations			
COVID-19 pneumonia			
subjects affected / exposed	0 / 34 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
COVID-19			
subjects affected / exposed	0 / 34 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Postoperative wound infection			
subjects affected / exposed	0 / 34 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Sepsis			
subjects affected / exposed	0 / 34 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Infected cyst			
subjects affected / exposed	0 / 34 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cellulitis			
subjects affected / exposed	0 / 34 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

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

Non-serious adverse events	Through Week 28: ABP 654	Through Week 28: Ustekinumab	Post Week 28: ABP 654 / ABP 654
Total subjects affected by non-serious adverse events			
subjects affected / exposed	21 / 280 (7.50%)	15 / 282 (5.32%)	36 / 247 (14.57%)
Renal and urinary disorders			
Proteinuria			
subjects affected / exposed	2 / 280 (0.71%)	1 / 282 (0.35%)	1 / 247 (0.40%)
occurrences (all)	2	1	1
Infections and infestations			
COVID-19			
subjects affected / exposed	6 / 280 (2.14%)	4 / 282 (1.42%)	23 / 247 (9.31%)
occurrences (all)	6	4	23
Upper respiratory tract infection			
subjects affected / exposed	6 / 280 (2.14%)	7 / 282 (2.48%)	6 / 247 (2.43%)
occurrences (all)	6	8	6
Nasopharyngitis			
subjects affected / exposed	7 / 280 (2.50%)	3 / 282 (1.06%)	9 / 247 (3.64%)
occurrences (all)	7	3	9

Non-serious adverse events	Post Week 28: Ustekinumab / ABP654	Post Week 28: Ustekinumab / Ustekinumab	Post Week 28: ABP 654 Dose Intensification
Total subjects affected by non-serious adverse events			
subjects affected / exposed	22 / 117 (18.80%)	17 / 116 (14.66%)	9 / 25 (36.00%)
Renal and urinary disorders			
Proteinuria			
subjects affected / exposed	2 / 117 (1.71%)	0 / 116 (0.00%)	2 / 25 (8.00%)
occurrences (all)	2	0	2
Infections and infestations			
COVID-19			
subjects affected / exposed	15 / 117 (12.82%)	10 / 116 (8.62%)	5 / 25 (20.00%)
occurrences (all)	15	10	6
Upper respiratory tract infection			

subjects affected / exposed	6 / 117 (5.13%)	3 / 116 (2.59%)	0 / 25 (0.00%)
occurrences (all)	6	3	0
Nasopharyngitis			
subjects affected / exposed	1 / 117 (0.85%)	7 / 116 (6.03%)	2 / 25 (8.00%)
occurrences (all)	1	7	2

Non-serious adverse events	Post Week 28: Ustekinumab Dose Intensification		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	2 / 34 (5.88%)		
Renal and urinary disorders			
Proteinuria			
subjects affected / exposed	0 / 34 (0.00%)		
occurrences (all)	0		
Infections and infestations			
COVID-19			
subjects affected / exposed	1 / 34 (2.94%)		
occurrences (all)	1		
Upper respiratory tract infection			
subjects affected / exposed	1 / 34 (2.94%)		
occurrences (all)	1		
Nasopharyngitis			
subjects affected / exposed	0 / 34 (0.00%)		
occurrences (all)	0		

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

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

Due to non-convergence of the generalized linear model used for pre-specified analyses, ad hoc analyses were conducted for efficacy endpoints of PASI 75 response, PASI 100 response, and sPGA response.

Notes: