



Clinical trial results:

A Phase 2b/3 Randomized, Double-Blind, Placebo-Controlled, Dose-Ranging Study to Investigate the Efficacy and Safety of PF-06651600 in Adult and Adolescent Alopecia Areata (AA) Subjects With 50% or Greater Scalp Hair Loss

Summary

EudraCT number	2018-001714-14
Trial protocol	GB DE HU CZ PL ES
Global end of trial date	24 June 2021

Results information

Result version number	v1 (current)
This version publication date	11 January 2022
First version publication date	11 January 2022

Trial information

Trial identification

Sponsor protocol code	B7981015
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT03732807
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Pfizer Inc.
Sponsor organisation address	235 E 42nd Street, New York, United States, NY 10017
Public contact	Pfizer ClinicalTrials.gov Call Center, Pfizer Inc., 001 18007181021, ClinicalTrials.gov_Inquiries@pfizer.com
Scientific contact	Pfizer ClinicalTrials.gov Call Center, Pfizer Inc., 001 18007181021, ClinicalTrials.gov_Inquiries@pfizer.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?	Yes
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	10 July 2021
Is this the analysis of the primary completion data?	No
Global end of trial reached?	Yes
Global end of trial date	24 June 2021
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To evaluate the efficacy of PF-06651600 compared to placebo in adult and adolescent alopecia areata (AA) subjects with 50% or greater scalp hair loss on regrowth of lost hair (measured by an absolute severity of alopecia tool (SALT) Score ≤ 20) at week 24.

To evaluate the efficacy of PF-06651600 compared to placebo in adult and adolescent AA subjects with 50% or greater scalp hair loss on regrowth of lost hair (as measured by an absolute SALT Score ≤ 10) at Week 24 (this objective was utilized as the primary objective for the European Medicines Agency and competent authorities in the Voluntary Harmonisation Procedure countries).

Protection of trial subjects:

The study was in compliance with the ethical principles derived from the Declaration of Helsinki and in compliance with all International Council for Harmonization (ICH) Good Clinical Practice (GCP) Guidelines. All the local regulatory requirements pertinent to safety of trial subjects were followed.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	03 December 2018
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	Argentina: 5
Country: Number of subjects enrolled	Australia: 67
Country: Number of subjects enrolled	Canada: 98
Country: Number of subjects enrolled	Chile: 44
Country: Number of subjects enrolled	China: 81
Country: Number of subjects enrolled	Colombia: 3
Country: Number of subjects enrolled	Czechia: 20
Country: Number of subjects enrolled	Denmark: 31
Country: Number of subjects enrolled	Spain: 17
Country: Number of subjects enrolled	Georgia: 23
Country: Number of subjects enrolled	Hungary: 1
Country: Number of subjects enrolled	Japan: 47
Country: Number of subjects enrolled	Korea, Republic of: 7
Country: Number of subjects enrolled	Mexico: 1
Country: Number of subjects enrolled	Poland: 53
Country: Number of subjects enrolled	Russian Federation: 14
Country: Number of subjects enrolled	Taiwan: 11

Country: Number of subjects enrolled	United States: 195
Worldwide total number of subjects	718
EEA total number of subjects	122

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)	105
Adults (18-64 years)	593
From 65 to 84 years	20
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

The study was conducted in 18 countries from 03 December 2018 to 24 June 2021. A total of 718 subjects were enrolled.

Pre-assignment

Screening details:

Total 1097 subjects signed the informed consent form. Out of which 379 subjects were screen failures, 718 actually enrolled into the study and were assigned to study treatments.

Period 1

Period 1 title	Treatment Phase (up to Week 24)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator

Arms

Are arms mutually exclusive?	Yes
Arm title	Ritlecitinib (PF-06651600) 200 mg then 50 mg

Arm description:

Subjects aged 12 years or above with moderate to severe AA with greater than or equal to (\geq) 50 percent (%) hair loss of the scalp were randomised to receive Ritlecitinib 4 of 50 milligram (mg) tablet once daily for 4 weeks (loading phase) and then 50 mg tablet once daily for next 20 weeks (maintenance phase). Subjects then entered into extension phase of 24 weeks and continued to receive 50 mg tablet once daily. Subjects were followed up to maximum of 5 weeks after the last dose of study drug .

Arm type	Experimental
Investigational medicinal product name	Ritlecitinib
Investigational medicinal product code	PF-06651600
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Subjects received 4 of 50 mg tablet of Ritlecitinib once daily for 4 weeks and then 50 mg tablet once daily for next 44 weeks.

Arm title	Ritlecitinib (PF-06651600) 200 mg then 30 mg
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Arm description:

Subjects aged 12 years or above with moderate to severe AA with $\geq 50\%$ hair loss of the scalp were randomised to receive Ritlecitinib 4 of 50 mg tablet once daily for 4 weeks (loading phase) and then 3 of 10 mg tablet once daily for next 20 weeks (maintenance phase). Subjects then entered into extension phase of 24 weeks and continued to receive 3 of 10 mg tablet once daily. Subjects were followed up to maximum of 5 weeks after the last dose of study drug.

Arm type	Experimental
Investigational medicinal product name	Ritlecitinib
Investigational medicinal product code	PF-06651600
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Subjects received 4 of 50 mg tablet of Ritlecitinib once daily for 4 weeks and then 3 of 10 mg tablet once daily for next 44 weeks.

Arm title	Ritlecitinib (PF-06651600) 50 mg
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Arm description:

Subjects aged 12 years or above with moderate to severe AA with $\geq 50\%$ hair loss of the scalp were randomised to receive Ritlecitinib 50 mg tablet once daily for 4 weeks (loading phase). Subjects then continued to receive 50 mg tablet once daily in maintenance phase of 20 weeks and extension phase of 24 weeks. Subjects were followed up to maximum of 5 weeks after the last dose of study drug.

Arm type	Experimental
Investigational medicinal product name	Ritlecitinib
Investigational medicinal product code	PF-06651600
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Subjects received 50 mg tablet of Ritlecitinib once daily for 48 weeks.

Arm title	Ritlecitinib (PF-06651600) 30 mg
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Arm description:

Subjects aged 12 years or above with moderate to severe AA with $\geq 50\%$ hair loss of the scalp were randomised to receive Ritlecitinib 3 of 10 mg tablet once daily for 4 weeks (loading phase). Subjects then continued to receive 3 of 10 mg tablet once daily in maintenance phase of 20 weeks and extension phase of 24 weeks. Subjects were followed up to maximum of 5 weeks after the last dose of study drug.

Arm type	Experimental
Investigational medicinal product name	Ritlecitinib
Investigational medicinal product code	PF-06651600
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Subjects received 3 of 10 mg tablet of Ritlecitinib once daily for 48 weeks.

Arm title	Ritlecitinib (PF-06651600) 10 mg
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Arm description:

Subjects aged 12 years or above with moderate to severe AA with $\geq 50\%$ hair loss of the scalp were randomised to receive Ritlecitinib 10 mg tablet once daily for 4 weeks (loading phase). Subjects then continued to receive 10 mg tablet once daily in maintenance phase of 20 weeks and extension phase of 24 weeks. Subjects were followed up to maximum of 5 weeks after the last dose of study drug.

Arm type	Experimental
Investigational medicinal product name	Ritlecitinib
Investigational medicinal product code	PF-06651600
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Subjects received 10 mg tablet of Ritlecitinib once daily for 48 weeks.

Arm title	Placebo, Ritlecitinib (PF-06651600) 200 mg then 50 mg
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Arm description:

Subjects aged 12 years or above with moderate to severe AA with $\geq 50\%$ hair loss of the scalp were randomised to receive placebo once daily for 4 weeks (loading phase) and then continued placebo once daily for next 20 weeks (maintenance phase). Subjects then entered into extension phase of 24 weeks and received 4 of 50 mg tablet once daily for 4 weeks and then 50 mg tablet once daily for 20 weeks. Subjects were followed up to maximum of 5 weeks after the last dose of study drug.

Arm type	Placebo
Investigational medicinal product name	Placebo, Ritlecitinib
Investigational medicinal product code	PF-06651600
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Subjects received placebo once daily for 24 weeks and then 4 of 50 mg tablet of Ritlecitinib once daily for 4 weeks followed by 50 mg tablet of Ritlecitinib once daily for next 20 weeks.

Arm title	Placebo, Ritlecitinib (PF-06651600) 50 mg
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Arm description:

Subjects aged 12 years or above with moderate to severe AA with $\geq 50\%$ hair loss of the scalp were randomised to receive placebo once daily for 4 weeks (loading phase) and then continued to receive placebo once daily for next 20 weeks (maintenance phase). Subjects then entered into extension phase of 24 weeks and receive 50 mg tablet once daily. Subjects were followed up to maximum of 5 weeks after the last dose of study drug.

Arm type	Placebo
Investigational medicinal product name	Placebo, Ritlecitinib
Investigational medicinal product code	PF-06651600
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Subjects received placebo once daily for 24 weeks and then 50 mg tablet of Ritlecitinib once daily for next 24 weeks.

Number of subjects in period 1	Ritlecitinib (PF-06651600) 200 mg then 50 mg	Ritlecitinib (PF-06651600) 200 mg then 30 mg	Ritlecitinib (PF-06651600) 50 mg
Started	132	130	130
Completed	122	124	121
Not completed	10	6	9
Physician decision	-	1	2
Pregnancy	1	-	-
Adverse event	3	-	2
Lost to follow-up	1	-	1
Protocol deviation	1	1	-
Withdrawal by subject	4	4	4
Lack of efficacy	-	-	-

Number of subjects in period 1	Ritlecitinib (PF-06651600) 30 mg	Ritlecitinib (PF-06651600) 10 mg	Placebo, Ritlecitinib (PF-06651600) 200 mg then 50 mg
Started	132	63	65
Completed	117	58	63
Not completed	15	5	2
Physician decision	5	-	-
Pregnancy	-	1	-
Adverse event	4	2	-
Lost to follow-up	2	1	-
Protocol deviation	-	-	-

Withdrawal by subject	4	1	1
Lack of efficacy	-	-	1

Number of subjects in period 1	Placebo, Ritlecitinib (PF-06651600) 50 mg
Started	66
Completed	61
Not completed	5
Physician decision	1
Pregnancy	1
Adverse event	1
Lost to follow-up	-
Protocol deviation	-
Withdrawal by subject	2
Lack of efficacy	-

Period 2

Period 2 title	Treatment Extension (Week 25 up to 48)
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator

Arms

Are arms mutually exclusive?	Yes
Arm title	Ritlecitinib (PF-06651600) 200 mg then 50 mg

Arm description:

Subjects aged 12 years or above with moderate to severe AA with $\geq 50\%$ hair loss of the scalp were randomised to receive Ritlecitinib 4 of 50 mg tablet once daily for 4 weeks (loading phase) and then 50 mg tablet once daily for next 20 weeks (maintenance phase). Subjects then entered into extension phase of 24 weeks and continued to receive 50 mg tablet once daily. Subjects were followed up to maximum of 5 weeks after the last dose of study drug .

Arm type	Experimental
Investigational medicinal product name	Ritlecitinib
Investigational medicinal product code	PF-06651600
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Subjects received 4 of 50 mg tablet of Ritlecitinib once daily for 4 weeks and then 50 mg tablet once daily for next 44 weeks.

Arm title	Ritlecitinib (PF-06651600) 200 mg then 30 mg
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Arm description:

Subjects aged 12 years or above with moderate to severe AA with $\geq 50\%$ hair loss of the scalp were randomised to receive Ritlecitinib 4 of 50 mg tablet once daily for 4 weeks (loading phase) and then 3 of 10 mg tablet once daily for next 20 weeks (maintenance phase). Subjects then entered into extension phase of 24 weeks and continued to receive 3 of 10 mg tablet once daily. Subjects were followed up to

maximum of 5 weeks after the last dose of study drug.

Arm type	Experimental
Investigational medicinal product name	Ritlecitinib
Investigational medicinal product code	PF-06651600
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Subjects received 4 of 50 mg tablet of Ritlecitinib once daily for 4 weeks and then 3 of 10 mg tablet once daily for next 44 weeks.

Arm title	Ritlecitinib (PF-06651600) 50 mg
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Arm description:

Subjects aged 12 years or above with moderate to severe AA with $\geq 50\%$ hair loss of the scalp were randomised to receive Ritlecitinib 50 mg tablet once daily for 4 weeks (loading phase). Subjects then continued to receive 50 mg tablet once daily in maintenance phase of 20 weeks and extension phase of 24 weeks. Subjects were followed up to maximum of 5 weeks after the last dose of study drug.

Arm type	Experimental
Investigational medicinal product name	Ritlecitinib
Investigational medicinal product code	PF-06651600
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Subjects received 50 mg tablet of Ritlecitinib once daily for 48 weeks.

Arm title	Ritlecitinib (PF-06651600) 30 mg
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Arm description:

Subjects aged 12 years or above with moderate to severe AA with $\geq 50\%$ hair loss of the scalp were randomised to receive Ritlecitinib 3 of 10 mg tablet once daily for 4 weeks (loading phase). Subjects then continued to receive 3 of 10 mg tablet once daily in maintenance phase of 20 weeks and extension phase of 24 weeks. Subjects were followed up to maximum of 5 weeks after the last dose of study drug.

Arm type	Experimental
Investigational medicinal product name	Ritlecitinib
Investigational medicinal product code	PF-06651600
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Subjects received 3 of 10 mg tablet of Ritlecitinib once daily for 48 weeks.

Arm title	Ritlecitinib (PF-06651600) 10 mg
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Arm description:

Subjects aged 12 years or above with moderate to severe AA with $\geq 50\%$ hair loss of the scalp were randomised to receive Ritlecitinib 10 mg tablet once daily for 4 weeks (loading phase). Subjects then continued to receive 10 mg tablet once daily in maintenance phase of 20 weeks and extension phase of 24 weeks. Subjects were followed up to maximum of 5 weeks after the last dose of study drug.

Arm type	Experimental
Investigational medicinal product name	Ritlecitinib
Investigational medicinal product code	PF-06651600
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Subjects received 10 mg tablet of Ritlecitinib once daily for 48 weeks.

Arm title	Placebo, Ritlecitinib (PF-06651600) 200 mg then 50 mg
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Arm description:

Subjects aged 12 years or above with moderate to severe AA with $\geq 50\%$ hair loss of the scalp were randomised to receive placebo once daily for 4 weeks (loading phase) and then continued placebo once daily for next 20 weeks (maintenance phase). Subjects then entered into extension phase of 24 weeks and received 4 of 50 mg tablet once daily for 4 weeks and then 50 mg tablet once daily for 20 weeks. Subjects were followed up to maximum of 5 weeks after the last dose of study drug.

Arm type	Placebo
Investigational medicinal product name	Placebo, Ritlecitinib
Investigational medicinal product code	PF-06651600
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Subjects received placebo once daily for 24 weeks and then 4 of 50 mg tablet of Ritlecitinib once daily for 4 weeks followed by 50 mg tablet of Ritlecitinib once daily for next 20 weeks.

Arm title	Placebo, Ritlecitinib (PF-06651600) 50 mg
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Arm description:

Subjects aged 12 years or above with moderate to severe AA with $\geq 50\%$ hair loss of the scalp were randomised to receive placebo once daily for 4 weeks (loading phase) and then continued to receive placebo once daily for next 20 weeks (maintenance phase). Subjects then entered into extension phase of 24 weeks and receive 50 mg tablet once daily. Subjects were followed up to maximum of 5 weeks after the last dose of study drug.

Arm type	Placebo
Investigational medicinal product name	Placebo, Ritlecitinib
Investigational medicinal product code	PF-06651600
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Subjects received placebo once daily for 24 weeks and then 50 mg tablet of Ritlecitinib once daily for next 24 weeks.

Number of subjects in period 2	Ritlecitinib (PF-06651600) 200 mg then 50 mg	Ritlecitinib (PF-06651600) 200 mg then 30 mg	Ritlecitinib (PF-06651600) 50 mg
Started	122	124	121
Completed	126	119	125
Not completed	6	11	5
Physician decision	-	1	-
Adverse event	-	2	2
Unspecified	1	4	-
Lost to follow-up	-	-	2
Non-Compliant with study drug	-	1	-
Lack of efficacy	2	1	-
Withdrawal by subject	3	2	1
Joined	10	6	9
Other	10	6	9

Number of subjects in period 2	Ritlecitinib (PF-06651600) 30 mg	Ritlecitinib (PF-06651600) 10 mg	Placebo, Ritlecitinib (PF-06651600) 200 mg then 50 mg
Started	117	58	63
Completed	123	58	62
Not completed	9	5	3
Physician decision	1	1	-
Adverse event	1	-	-
Unspecified	2	-	-
Lost to follow-up	1	1	2
Non-Compliant with study drug	-	-	-
Lack of efficacy	3	3	-
Withdrawal by subject	1	-	1
Joined	15	5	2
Other	15	5	2

Number of subjects in period 2	Placebo, Ritlecitinib (PF-06651600) 50 mg
Started	61
Completed	62
Not completed	4
Physician decision	-
Adverse event	2
Unspecified	-
Lost to follow-up	-
Non-Compliant with study drug	-
Lack of efficacy	1
Withdrawal by subject	1
Joined	5
Other	5

Baseline characteristics

Reporting groups

Reporting group title	Ritlecitinib (PF-06651600) 200 mg then 50 mg
Reporting group description:	
Subjects aged 12 years or above with moderate to severe AA with greater than or equal to (\geq) 50 percent (%) hair loss of the scalp were randomised to receive Ritlecitinib 4 of 50 milligram (mg) tablet once daily for 4 weeks (loading phase) and then 50 mg tablet once daily for next 20 weeks (maintenance phase). Subjects then entered into extension phase of 24 weeks and continued to receive 50 mg tablet once daily. Subjects were followed up to maximum of 5 weeks after the last dose of study drug .	
Reporting group title	Ritlecitinib (PF-06651600) 200 mg then 30 mg
Reporting group description:	
Subjects aged 12 years or above with moderate to severe AA with \geq 50% hair loss of the scalp were randomised to receive Ritlecitinib 4 of 50 mg tablet once daily for 4 weeks (loading phase) and then 3 of 10 mg tablet once daily for next 20 weeks (maintenance phase). Subjects then entered into extension phase of 24 weeks and continued to receive 3 of 10 mg tablet once daily. Subjects were followed up to maximum of 5 weeks after the last dose of study drug.	
Reporting group title	Ritlecitinib (PF-06651600) 50 mg
Reporting group description:	
Subjects aged 12 years or above with moderate to severe AA with \geq 50% hair loss of the scalp were randomised to receive Ritlecitinib 50 mg tablet once daily for 4 weeks (loading phase). Subjects then continued to receive 50 mg tablet once daily in maintenance phase of 20 weeks and extension phase of 24 weeks. Subjects were followed up to maximum of 5 weeks after the last dose of study drug.	
Reporting group title	Ritlecitinib (PF-06651600) 30 mg
Reporting group description:	
Subjects aged 12 years or above with moderate to severe AA with \geq 50% hair loss of the scalp were randomised to receive Ritlecitinib 3 of 10 mg tablet once daily for 4 weeks (loading phase). Subjects then continued to receive 3 of 10 mg tablet once daily in maintenance phase of 20 weeks and extension phase of 24 weeks. Subjects were followed up to maximum of 5 weeks after the last dose of study drug.	
Reporting group title	Ritlecitinib (PF-06651600) 10 mg
Reporting group description:	
Subjects aged 12 years or above with moderate to severe AA with \geq 50% hair loss of the scalp were randomised to receive Ritlecitinib 10 mg tablet once daily for 4 weeks (loading phase). Subjects then continued to receive 10 mg tablet once daily in maintenance phase of 20 weeks and extension phase of 24 weeks. Subjects were followed up to maximum of 5 weeks after the last dose of study drug.	
Reporting group title	Placebo, Ritlecitinib (PF-06651600) 200 mg then 50 mg
Reporting group description:	
Subjects aged 12 years or above with moderate to severe AA with \geq 50% hair loss of the scalp were randomised to receive placebo once daily for 4 weeks (loading phase) and then continued placebo once daily for next 20 weeks (maintenance phase). Subjects then entered into extension phase of 24 weeks and received 4 of 50 mg tablet once daily for 4 weeks and then 50 mg tablet once daily for 20 weeks. Subjects were followed up to maximum of 5 weeks after the last dose of study drug.	
Reporting group title	Placebo, Ritlecitinib (PF-06651600) 50 mg
Reporting group description:	
Subjects aged 12 years or above with moderate to severe AA with \geq 50% hair loss of the scalp were randomised to receive placebo once daily for 4 weeks (loading phase) and then continued to receive placebo once daily for next 20 weeks (maintenance phase). Subjects then entered into extension phase of 24 weeks and receive 50 mg tablet once daily. Subjects were followed up to maximum of 5 weeks after the last dose of study drug.	

Reporting group values	Ritlecitinib (PF-06651600) 200 mg then 50 mg	Ritlecitinib (PF-06651600) 200 mg then 30 mg	Ritlecitinib (PF-06651600) 50 mg
Number of subjects	132	130	130

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)	20	19	18
Adults (18-64 years)	108	110	109
From 65-84 years	4	1	3
85 years and over	0	0	0
Age Continuous Units: Years			
arithmetic mean	34.5	33.7	32.4
standard deviation	± 14.98	± 13.75	± 13.36
Sex: Female, Male Units: Subjects			
Female	81	85	71
Male	51	45	59
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	0	1	0
Asian	33	28	43
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	6	7	5
White	92	90	79
More than one race	0	3	1
Unknown or Not Reported	1	1	2
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	18	16	11
Not Hispanic or Latino	113	114	116
Unknown or Not Reported	1	0	3

Reporting group values	Ritlecitinib (PF-06651600) 30 mg	Ritlecitinib (PF-06651600) 10 mg	Placebo, Ritlecitinib (PF-06651600) 200 mg then 50 mg
Number of subjects	132	63	65
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)	20	9	10
Adults (18-64 years)	105	54	53
From 65-84 years	7	0	2
85 years and over	0	0	0

Age Continuous Units: Years arithmetic mean standard deviation	33.7 ± 14.83	34.3 ± 13.88	33.0 ± 14.01
Sex: Female, Male Units: Subjects			
Female	80	43	46
Male	52	20	19
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	2	0	0
Asian	34	17	14
Native Hawaiian or Other Pacific Islander	0	1	0
Black or African American	3	2	2
White	91	42	47
More than one race	2	0	2
Unknown or Not Reported	0	1	0
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	23	8	7
Not Hispanic or Latino	109	55	58
Unknown or Not Reported	0	0	0

Reporting group values	Placebo, Ritlecitinib (PF-06651600) 50 mg	Total	
Number of subjects	66	718	
Age categorical Units: Subjects			
In utero	0	0	
Preterm newborn infants (gestational age < 37 wks)	0	0	
Newborns (0-27 days)	0	0	
Infants and toddlers (28 days-23 months)	0	0	
Children (2-11 years)	0	0	
Adolescents (12-17 years)	9	105	
Adults (18-64 years)	54	593	
From 65-84 years	3	20	
85 years and over	0	0	
Age Continuous Units: Years arithmetic mean standard deviation	35.0 ± 15.89	-	
Sex: Female, Male Units: Subjects			
Female	40	446	
Male	26	272	
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	0	3	
Asian	17	186	

Native Hawaiian or Other Pacific Islander	0	1	
Black or African American	2	27	
White	47	488	
More than one race	0	8	
Unknown or Not Reported	0	5	
Ethnicity (NIH/OMB)			
Units: Subjects			
Hispanic or Latino	4	87	
Not Hispanic or Latino	61	626	
Unknown or Not Reported	1	5	

Subject analysis sets

Subject analysis set title	Placebo
Subject analysis set type	Full analysis

Subject analysis set description:

Subjects aged 12 years or above with moderate to severe AA with $\geq 50\%$ hair loss of the scalp were randomised to receive placebo once daily for 4 weeks (loading phase) and then continued placebo once daily for next 20 weeks (maintenance phase). Subjects then entered into extension phase of 24 weeks and received either 4 of 50 mg tablet once daily for 4 weeks followed by 50 mg tablet once daily for next 20 weeks or 50 mg tablet once daily for next 24 weeks. Subjects were followed up to maximum of 5 weeks after the last dose of study drug.

Reporting group values	Placebo		
Number of subjects	131		
Age categorical			
Units: Subjects			
In utero	0		
Preterm newborn infants (gestational age < 37 wks)	0		
Newborns (0-27 days)	0		
Infants and toddlers (28 days-23 months)	0		
Children (2-11 years)	0		
Adolescents (12-17 years)	19		
Adults (18-64 years)	107		
From 65-84 years	5		
85 years and over	0		
Age Continuous			
Units: Years			
arithmetic mean	34.0		
standard deviation	± 14.96		
Sex: Female, Male			
Units: Subjects			
Female	86		
Male	45		
Race (NIH/OMB)			
Units: Subjects			
American Indian or Alaska Native	0		
Asian	31		
Native Hawaiian or Other Pacific Islander	0		
Black or African American	4		

White	94		
More than one race	2		
Unknown or Not Reported	0		
Ethnicity (NIH/OMB)			
Units: Subjects			
Hispanic or Latino	11		
Not Hispanic or Latino	119		
Unknown or Not Reported	1		

End points

End points reporting groups

Reporting group title	Ritlecitinib (PF-06651600) 200 mg then 50 mg
Reporting group description: Subjects aged 12 years or above with moderate to severe AA with greater than or equal to (\geq) 50 percent (%) hair loss of the scalp were randomised to receive Ritlecitinib 4 of 50 milligram (mg) tablet once daily for 4 weeks (loading phase) and then 50 mg tablet once daily for next 20 weeks (maintenance phase). Subjects then entered into extension phase of 24 weeks and continued to receive 50 mg tablet once daily. Subjects were followed up to maximum of 5 weeks after the last dose of study drug .	
Reporting group title	Ritlecitinib (PF-06651600) 200 mg then 30 mg
Reporting group description: Subjects aged 12 years or above with moderate to severe AA with \geq 50% hair loss of the scalp were randomised to receive Ritlecitinib 4 of 50 mg tablet once daily for 4 weeks (loading phase) and then 3 of 10 mg tablet once daily for next 20 weeks (maintenance phase). Subjects then entered into extension phase of 24 weeks and continued to receive 3 of 10 mg tablet once daily. Subjects were followed up to maximum of 5 weeks after the last dose of study drug.	
Reporting group title	Ritlecitinib (PF-06651600) 50 mg
Reporting group description: Subjects aged 12 years or above with moderate to severe AA with \geq 50% hair loss of the scalp were randomised to receive Ritlecitinib 50 mg tablet once daily for 4 weeks (loading phase). Subjects then continued to receive 50 mg tablet once daily in maintenance phase of 20 weeks and extension phase of 24 weeks. Subjects were followed up to maximum of 5 weeks after the last dose of study drug.	
Reporting group title	Ritlecitinib (PF-06651600) 30 mg
Reporting group description: Subjects aged 12 years or above with moderate to severe AA with \geq 50% hair loss of the scalp were randomised to receive Ritlecitinib 3 of 10 mg tablet once daily for 4 weeks (loading phase). Subjects then continued to receive 3 of 10 mg tablet once daily in maintenance phase of 20 weeks and extension phase of 24 weeks. Subjects were followed up to maximum of 5 weeks after the last dose of study drug.	
Reporting group title	Ritlecitinib (PF-06651600) 10 mg
Reporting group description: Subjects aged 12 years or above with moderate to severe AA with \geq 50% hair loss of the scalp were randomised to receive Ritlecitinib 10 mg tablet once daily for 4 weeks (loading phase). Subjects then continued to receive 10 mg tablet once daily in maintenance phase of 20 weeks and extension phase of 24 weeks. Subjects were followed up to maximum of 5 weeks after the last dose of study drug.	
Reporting group title	Placebo, Ritlecitinib (PF-06651600) 200 mg then 50 mg
Reporting group description: Subjects aged 12 years or above with moderate to severe AA with \geq 50% hair loss of the scalp were randomised to receive placebo once daily for 4 weeks (loading phase) and then continued placebo once daily for next 20 weeks (maintenance phase). Subjects then entered into extension phase of 24 weeks and received 4 of 50 mg tablet once daily for 4 weeks and then 50 mg tablet once daily for 20 weeks. Subjects were followed up to maximum of 5 weeks after the last dose of study drug.	
Reporting group title	Placebo, Ritlecitinib (PF-06651600) 50 mg
Reporting group description: Subjects aged 12 years or above with moderate to severe AA with \geq 50% hair loss of the scalp were randomised to receive placebo once daily for 4 weeks (loading phase) and then continued to receive placebo once daily for next 20 weeks (maintenance phase). Subjects then entered into extension phase of 24 weeks and receive 50 mg tablet once daily. Subjects were followed up to maximum of 5 weeks after the last dose of study drug.	
Reporting group title	Ritlecitinib (PF-06651600) 200 mg then 50 mg
Reporting group description: Subjects aged 12 years or above with moderate to severe AA with \geq 50 % hair loss of the scalp were randomised to receive Ritlecitinib 4 of 50 mg tablet once daily for 4 weeks (loading phase) and then 50 mg tablet once daily for next 20 weeks (maintenance phase). Subjects then entered into extension phase of 24 weeks and continued to receive 50 mg tablet once daily. Subjects were followed up to maximum of 5 weeks after the last dose of study drug .	
Reporting group title	Ritlecitinib (PF-06651600) 200 mg then 30 mg

Reporting group description:

Subjects aged 12 years or above with moderate to severe AA with $\geq 50\%$ hair loss of the scalp were randomised to receive Ritlecitinib 4 of 50 mg tablet once daily for 4 weeks (loading phase) and then 3 of 10 mg tablet once daily for next 20 weeks (maintenance phase). Subjects then entered into extension phase of 24 weeks and continued to receive 3 of 10 mg tablet once daily. Subjects were followed up to maximum of 5 weeks after the last dose of study drug.

Reporting group title	Ritlecitinib (PF-06651600) 50 mg
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Reporting group description:

Subjects aged 12 years or above with moderate to severe AA with $\geq 50\%$ hair loss of the scalp were randomised to receive Ritlecitinib 50 mg tablet once daily for 4 weeks (loading phase). Subjects then continued to receive 50 mg tablet once daily in maintenance phase of 20 weeks and extension phase of 24 weeks. Subjects were followed up to maximum of 5 weeks after the last dose of study drug.

Reporting group title	Ritlecitinib (PF-06651600) 30 mg
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Reporting group description:

Subjects aged 12 years or above with moderate to severe AA with $\geq 50\%$ hair loss of the scalp were randomised to receive Ritlecitinib 3 of 10 mg tablet once daily for 4 weeks (loading phase). Subjects then continued to receive 3 of 10 mg tablet once daily in maintenance phase of 20 weeks and extension phase of 24 weeks. Subjects were followed up to maximum of 5 weeks after the last dose of study drug.

Reporting group title	Ritlecitinib (PF-06651600) 10 mg
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Reporting group description:

Subjects aged 12 years or above with moderate to severe AA with $\geq 50\%$ hair loss of the scalp were randomised to receive Ritlecitinib 10 mg tablet once daily for 4 weeks (loading phase). Subjects then continued to receive 10 mg tablet once daily in maintenance phase of 20 weeks and extension phase of 24 weeks. Subjects were followed up to maximum of 5 weeks after the last dose of study drug.

Reporting group title	Placebo, Ritlecitinib (PF-06651600) 200 mg then 50 mg
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Reporting group description:

Subjects aged 12 years or above with moderate to severe AA with $\geq 50\%$ hair loss of the scalp were randomised to receive placebo once daily for 4 weeks (loading phase) and then continued placebo once daily for next 20 weeks (maintenance phase). Subjects then entered into extension phase of 24 weeks and received 4 of 50 mg tablet once daily for 4 weeks and then 50 mg tablet once daily for 20 weeks. Subjects were followed up to maximum of 5 weeks after the last dose of study drug.

Reporting group title	Placebo, Ritlecitinib (PF-06651600) 50 mg
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Reporting group description:

Subjects aged 12 years or above with moderate to severe AA with $\geq 50\%$ hair loss of the scalp were randomised to receive placebo once daily for 4 weeks (loading phase) and then continued to receive placebo once daily for next 20 weeks (maintenance phase). Subjects then entered into extension phase of 24 weeks and receive 50 mg tablet once daily. Subjects were followed up to maximum of 5 weeks after the last dose of study drug.

Subject analysis set title	Placebo
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Subject analysis set type	Full analysis
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Subject analysis set description:

Subjects aged 12 years or above with moderate to severe AA with $\geq 50\%$ hair loss of the scalp were randomised to receive placebo once daily for 4 weeks (loading phase) and then continued placebo once daily for next 20 weeks (maintenance phase). Subjects then entered into extension phase of 24 weeks and received either 4 of 50 mg tablet once daily for 4 weeks followed by 50 mg tablet once daily for next 20 weeks or 50 mg tablet once daily for next 24 weeks. Subjects were followed up to maximum of 5 weeks after the last dose of study drug.

Primary: Percentage of Subjects With an Absolute Severity of Alopecia Tool (SALT) Score of Less Than or Equal to 10 at Week 24: Analysis 4

End point title	Percentage of Subjects With an Absolute Severity of Alopecia Tool (SALT) Score of Less Than or Equal to 10 at Week 24: Analysis 4 ^[1]
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End point description:

SALT is a quantitative assessment of AA severity based on the scalp hair loss. The SALT score can vary from 0 (normal) to 100 (severe), with higher scores representing increased severity of disease. In this endpoint, percentage of subjects with SALT score less than or equal to (\leq) 10 at week 24 were reported. Full analysis set (FAS) included all subjects who were randomised, regardless of whether they received study medication. Here, "Number of Subjects Analysed" signifies subjects evaluable for this endpoint. Analysis 4: Data imputed by using a missing at random (MAR) mechanism for subjects with missing data due to COVID-19. Missing data due to reasons not related to COVID-19 were considered as non-responders.

End point type	Primary
End point timeframe:	
Week 24	
Notes:	
[1] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.	
Justification: Statistics were planned only for the arms specified	

End point values	Ritlecitinib (PF-06651600) 200 mg then 50 mg	Ritlecitinib (PF-06651600) 200 mg then 30 mg	Ritlecitinib (PF-06651600) 50 mg	Ritlecitinib (PF-06651600) 30 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	118	119	119	114
Units: Percentage of subjects				
number (not applicable)	21.29	12.87	13.42	10.62

End point values	Ritlecitinib (PF-06651600) 10 mg	Placebo		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	55	125		
Units: Percentage of subjects				
number (not applicable)	1.65	1.54		

Statistical analyses

Statistical analysis title	Ritlecitinib 200mg then 50mg versus Placebo
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Statistical analysis description:

A generalised linear mixed effect model without imputation using observed data up to Week 24 was used as the imputation model. A single complete imputed data set for Week 24 was analysed using the Miettinen and Nurminen method as the analysis model.

Comparison groups	Ritlecitinib (PF-06651600) 200 mg then 50 mg v Placebo
Number of subjects included in analysis	243
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	Miettinen and Nurminen method
Parameter estimate	Estimate of difference
Point estimate	19.75
Confidence interval	
level	95 %
sides	2-sided
lower limit	11.91
upper limit	27.59

Statistical analysis title	Ritlecitinib 200mg then 30mg versus Placebo
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Statistical analysis description:

A generalised linear mixed effect model without imputation using observed data up to Week 24 was used as the imputation model. A single complete imputed data set for Week 24 was analysed using the Miettinen and Nurminen method as the analysis model.

Comparison groups	Ritlecitinib (PF-06651600) 200 mg then 30 mg v Placebo
Number of subjects included in analysis	244
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.000526
Method	Miettinen and Nurminen method
Parameter estimate	Estimate of difference
Point estimate	11.33
Confidence interval	
level	95 %
sides	2-sided
lower limit	4.93
upper limit	17.74

Statistical analysis title

Ritlecitinib 50 mg versus Placebo

Statistical analysis description:

A generalised linear mixed effect model without imputation using observed data up to Week 24 was used as the imputation model. A single complete imputed data set for Week 24 was analysed using the Miettinen and Nurminen method as the analysis model.

Comparison groups	Ritlecitinib (PF-06651600) 50 mg v Placebo
Number of subjects included in analysis	244
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.000311
Method	Miettinen and Nurminen method
Parameter estimate	Estimate of difference
Point estimate	11.88
Confidence interval	
level	95 %
sides	2-sided
lower limit	5.42
upper limit	18.33

Statistical analysis title

Ritlecitinib 30 mg versus Placebo

Statistical analysis description:

A generalised linear mixed effect model without imputation using observed data up to Week 24 was used as the imputation model. A single complete imputed data set for Week 24 was analysed using the Miettinen and Nurminen method as the analysis model.

Comparison groups	Ritlecitinib (PF-06651600) 30 mg v Placebo
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Number of subjects included in analysis	239
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.002922
Method	Miettinen and Nurminen method
Parameter estimate	Estimate of difference
Point estimate	9.09
Confidence interval	
level	95 %
sides	2-sided
lower limit	3.1
upper limit	15.07

Secondary: Percentage of Subjects With an Absolute SALT Score of Less Than or Equal to 20 at Week 24

End point title	Percentage of Subjects With an Absolute SALT Score of Less Than or Equal to 20 at Week 24 ^[2]
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End point description:

SALT is a quantitative assessment of AA severity based on the scalp hair loss. The SALT score can vary from 0 (normal) to 100 (severe), with higher scores representing increased severity of disease. In this endpoint, percentage of subjects with SALT score ≤ 20 at week 24 were reported. subjects with missing SALT scores due to coronavirus disease -19 related reasons were excluded from this analysis, while subjects with missing data due to other reasons were considered as non-responders. FAS included all subjects who were randomised, regardless of whether they received study medication. Here, "Number of Subjects Analysed" signifies subjects evaluable for this endpoint.

End point type	Secondary
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End point timeframe:

Week 24

Notes:

[2] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: Statistics were planned only for the arms specified

End point values	Ritlecitinib (PF-06651600) 200 mg then 50 mg	Ritlecitinib (PF-06651600) 200 mg then 30 mg	Ritlecitinib (PF-06651600) 50 mg	Ritlecitinib (PF-06651600) 30 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	124	121	124	119
Units: Percentage of Subjects				
number (confidence interval 95%)	30.65 (22.53 to 38.76)	22.31 (14.90 to 29.73)	23.39 (15.94 to 30.84)	14.29 (8.00 to 20.57)

End point values	Ritlecitinib (PF-06651600) 10 mg	Placebo		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	59	130		
Units: Percentage of Subjects				
number (confidence interval 95%)	1.69 (0.00 to 4.99)	1.54 (0.00 to 3.65)		

Statistical analyses

Statistical analysis title	Ritlecitinib 200mg then 50mg versus Placebo
Comparison groups	Ritlecitinib (PF-06651600) 200 mg then 50 mg v Placebo
Number of subjects included in analysis	254
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	Miettinen and Nurminen method
Parameter estimate	Estimate of difference
Point estimate	29.11
Confidence interval	
level	95 %
sides	2-sided
lower limit	21.17
upper limit	37.91

Statistical analysis title	Ritlecitinib 200mg then 30mg versus Placebo
Comparison groups	Ritlecitinib (PF-06651600) 200 mg then 30 mg v Placebo
Number of subjects included in analysis	251
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	Miettinen and Nurminen method
Parameter estimate	Estimate of difference
Point estimate	20.78
Confidence interval	
level	95 %
sides	2-sided
lower limit	13.65
upper limit	29.18

Statistical analysis title	Ritlecitinib 50 mg versus Placebo
Comparison groups	Ritlecitinib (PF-06651600) 50 mg v Placebo

Number of subjects included in analysis	254
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	Miettinen and Nurminen method
Parameter estimate	Estimate of difference
Point estimate	21.85
Confidence interval	
level	95 %
sides	2-sided
lower limit	14.65
upper limit	30.23

Statistical analysis title	Ritlecitinib 30 mg versus Placebo
Comparison groups	Ritlecitinib (PF-06651600) 30 mg v Placebo
Number of subjects included in analysis	249
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.000154
Method	Miettinen and Nurminen method
Parameter estimate	Estimate of difference
Point estimate	12.75
Confidence interval	
level	95 %
sides	2-sided
lower limit	6.69
upper limit	20.36

Secondary: Percentage of Subjects With an Absolute SALT Score of Less Than or Equal to 10 at Week 24: Analysis 1

End point title	Percentage of Subjects With an Absolute SALT Score of Less Than or Equal to 10 at Week 24: Analysis 1 ^[3]
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End point description:

SALT is a quantitative assessment of AA severity based on the scalp hair loss. The SALT score can vary from 0 (normal) to 100 (severe), with higher scores representing increased severity of disease. In this endpoint, percentage of subjects with SALT score ≤ 10 at week 24 were reported. FAS included all subjects who were randomised, regardless of whether they received study medication. Here, "Number of Subjects Analysed" signifies subjects evaluable for this endpoint. Analysis 1: Subjects with missing SALT score at Week 24 due to COVID-19 related reasons excluded from analysis at that time point, subjects with missing SALT scores due to other reasons counted as non-responders at that time point.

End point type	Secondary
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End point timeframe:

Week 24

Notes:

[3] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: Statistics were planned only for the arms specified

End point values	Ritlecitinib (PF-06651600) 200 mg then 50 mg	Ritlecitinib (PF-06651600) 200 mg then 30 mg	Ritlecitinib (PF-06651600) 50 mg	Ritlecitinib (PF-06651600) 30 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	124	121	124	119
Units: Percentage of subjects				
number (confidence interval 95%)	21.77 (14.51 to 29.04)	13.22 (7.19 to 19.26)	13.71 (7.66 to 19.76)	10.92 (5.32 to 16.53)

End point values	Ritlecitinib (PF-06651600) 10 mg	Placebo		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	59	130		
Units: Percentage of subjects				
number (confidence interval 95%)	1.69 (0.00 to 4.99)	1.54 (0.00 to 3.65)		

Statistical analyses

Statistical analysis title	Ritlecitinib 200mg then 50mg versus Placebo
Comparison groups	Ritlecitinib (PF-06651600) 200 mg then 50 mg v Placebo
Number of subjects included in analysis	254
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	Miettinen and Nurminen method
Parameter estimate	Estimate of difference
Point estimate	20.24
Confidence interval	
level	95 %
sides	2-sided
lower limit	13.23
upper limit	28.49

Statistical analysis title	Ritlecitinib 200mg then 30mg versus Placebo
Comparison groups	Ritlecitinib (PF-06651600) 200 mg then 30 mg v Placebo
Number of subjects included in analysis	251
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.000337
Method	Miettinen and Nurminen method
Parameter estimate	Estimate of difference
Point estimate	11.68

Confidence interval	
level	95 %
sides	2-sided
lower limit	5.82
upper limit	19.07

Statistical analysis title	Ritlecitinib 50 mg versus Placebo
Comparison groups	Ritlecitinib (PF-06651600) 50 mg v Placebo
Number of subjects included in analysis	254
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.000228
Method	Miettinen and Nurminen method
Parameter estimate	Estimate of difference
Point estimate	12.17
Confidence interval	
level	95 %
sides	2-sided
lower limit	6.27
upper limit	19.53

Statistical analysis title	Ritlecitinib 30 mg versus Placebo
Comparison groups	Ritlecitinib (PF-06651600) 30 mg v Placebo
Number of subjects included in analysis	249
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.001875
Method	Miettinen and Nurminen method
Parameter estimate	Estimate of difference
Point estimate	9.39
Confidence interval	
level	95 %
sides	2-sided
lower limit	3.86
upper limit	16.46

Secondary: Percentage of Subjects With Patient Global Impression of Change (PGI-C) Score of Moderately Improved or Greatly Improved at Week 24

End point title	Percentage of Subjects With Patient Global Impression of Change (PGI-C) Score of Moderately Improved or Greatly Improved at Week 24 ^[4]
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End point description:

PGI-C is a self-administered questionnaire to evaluate the improvement or worsening of subject's AA as compared to the start of the study. PGI-C was assessed on a 7-point Likert scale ranged from 1 (greatly improved) to 7 (greatly worsened). Categories were defined based on the PGI-C scores as follows:

1=greatly improved, 2=moderately improved, 3=slightly improved, 4=not changed, 5=slightly worsened, 6=moderately worsened and 7=greatly worsened. FAS included all subjects who were randomised, regardless of whether they received study medication. Here, "Number of Subjects Analysed" signifies subjects evaluable for this endpoint.

End point type	Secondary
End point timeframe:	
Week 24	

Notes:

[4] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: Statistics were planned only for the arms specified

End point values	Ritlecitinib (PF-06651600) 200 mg then 50 mg	Ritlecitinib (PF-06651600) 200 mg then 30 mg	Ritlecitinib (PF-06651600) 50 mg	Ritlecitinib (PF-06651600) 30 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	120	119	120	116
Units: Percentage of subjects				
number (not applicable)	52.19	45.40	49.17	41.95

End point values	Ritlecitinib (PF-06651600) 10 mg	Placebo		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	55	125		
Units: Percentage of subjects				
number (not applicable)	11.36	9.23		

Statistical analyses

Statistical analysis title	Ritlecitinib 200 mg then 50 mg versus Placebo
Comparison groups	Ritlecitinib (PF-06651600) 200 mg then 50 mg v Placebo
Number of subjects included in analysis	245
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	Miettinen and Nurminen method
Parameter estimate	Estimate of difference
Point estimate	42.96
Confidence interval	
level	95 %
sides	2-sided
lower limit	31.68
upper limit	54.25

Statistical analysis title	Ritlecitinib 200 mg then 30 mg versus Placebo
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Comparison groups	Ritlecitinib (PF-06651600) 200 mg then 30 mg v Placebo
Number of subjects included in analysis	244
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	Miettinen and Nurminen method
Parameter estimate	Estimate of difference
Point estimate	36.18
Confidence interval	
level	95 %
sides	2-sided
lower limit	25.22
upper limit	47.14

Statistical analysis title	Ritlecitinib 50 mg versus Placebo
Comparison groups	Ritlecitinib (PF-06651600) 50 mg v Placebo
Number of subjects included in analysis	245
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	Miettinen and Nurminen method
Parameter estimate	Estimate of difference
Point estimate	39.96
Confidence interval	
level	95 %
sides	2-sided
lower limit	28.85
upper limit	51.06

Statistical analysis title	Ritlecitinib 30 mg versus Placebo
Comparison groups	Ritlecitinib (PF-06651600) 30 mg v Placebo
Number of subjects included in analysis	241
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	Miettinen and Nurminen method
Parameter estimate	Estimate of difference
Point estimate	32.72
Confidence interval	
level	95 %
sides	2-sided
lower limit	21.95
upper limit	43.5

Secondary: Exposure Response of PF-06651600 on Regrowth of Lost Hair Based on Absolute SALT Score of Less Than or Equal to 20 at Week 24: Maximum Effect (Emax) Model

End point title	Exposure Response of PF-06651600 on Regrowth of Lost Hair Based on Absolute SALT Score of Less Than or Equal to 20 at Week 24: Maximum Effect (Emax) Model ^[5]
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End point description:

Exposure response of PF-06651600 on regrowth of scalp hair was characterised using Bayesian three-parameter hyperbolic Emax model for SALT score ≤ 20 at Week 24 with additional term for effect of loading dose. In Emax exposure-response model response function was log odds of percentage of subjects with response based on SALT ≤ 20 at Week 24, which was fit on logistic scale and then back-transformed to percentage. Effect of loading dose is included as fixed factor in model. Variable that represents loading dose has values of 1 for groups 200/50 mg once daily and 200/30 mg once daily and of 0 for remaining groups. SALT is quantitative assessment of AA severity based on scalp hair loss. SALT score can vary from 0 (normal) to 100 (severe), with higher scores representing increased severity of disease. FAS: all subjects who were randomised, regardless of whether they received study medication. Here, "Number of Subjects Analysed" signifies subjects evaluable for this endpoint.

End point type	Secondary
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End point timeframe:

Week 24

Notes:

[5] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period. Justification: Statistics were planned only for the arms specified

End point values	Ritlecitinib (PF-06651600) 200 mg then 50 mg	Ritlecitinib (PF-06651600) 200 mg then 30 mg	Ritlecitinib (PF-06651600) 50 mg	Ritlecitinib (PF-06651600) 30 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	124	121	124	119
Units: Percentage of subjects				
number (not applicable)	32.37	20.57	22.52	13.58

End point values	Ritlecitinib (PF-06651600) 10 mg	Placebo		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	59	130		
Units: Percentage of subjects				
number (not applicable)	4.81	1.63		

Statistical analyses

No statistical analyses for this end point

Secondary: Exposure Response of PF-06651600 on Regrowth of Lost Hair Based on Absolute SALT Score of Less Than or Equal to 10 at Week 24: Maximum Effect (Emax) Model

End point title	Exposure Response of PF-06651600 on Regrowth of Lost Hair Based on Absolute SALT Score of Less Than or Equal to 10 at Week 24: Maximum Effect (Emax) Model ^[6]
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End point description:

Exposure response of PF-06651600 on regrowth of scalp hair was characterised using Bayesian three-parameter hyperbolic Emax model for SALT score ≤ 10 at Week 24 with additional term for effect of loading dose. In Emax exposure-response model response function was log odds of percentage of subjects with response based on SALT ≤ 10 at Week 24, which was fit on logistic scale and then back-transformed to percentage. Effect of loading dose is included as fixed factor in model. Variable that represents loading dose has values of 1 for groups 200/50 mg once daily and 200/30 mg once daily and of 0 for remaining groups. SALT is quantitative assessment of AA severity based on scalp hair loss. SALT score can vary from 0 (normal) to 100 (severe), with higher scores representing increased severity of disease. FAS: all subjects who were randomised, regardless of whether they received study medication. Here, "Number of Subjects Analysed" signifies subjects evaluable for this endpoint.

End point type	Secondary
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End point timeframe:

Week 24

Notes:

[6] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period. Justification: Statistics were planned only for the arms specified

End point values	Ritlecitinib (PF-06651600) 200 mg then 50 mg	Ritlecitinib (PF-06651600) 200 mg then 30 mg	Ritlecitinib (PF-06651600) 50 mg	Ritlecitinib (PF-06651600) 30 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	124	121	124	119
Units: Percentage of subjects				
number (not applicable)	21.29	13.76	14.43	9.02

End point values	Ritlecitinib (PF-06651600) 10 mg	Placebo		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	59	130		
Units: Percentage of subjects				
number (not applicable)	3.88	1.66		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With an Absolute SALT Score of Less Than or Equal to 20 at Week 4, 8, 12, 18, 28, 34, 40, and 48

End point title	Percentage of Subjects With an Absolute SALT Score of Less Than or Equal to 20 at Week 4, 8, 12, 18, 28, 34, 40, and 48
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End point description:

SALT is a quantitative assessment of AA severity based on the scalp hair loss. The SALT score can vary from 0 (normal) to 100 (severe), with higher scores representing increased severity of disease. FAS included all subjects who were randomised, regardless of whether they received study medication. Here, "n" signifies subjects evaluable at specific time point. 99999 signifies that 95% confidence interval (CI) could not be calculated as there were no subjects with SALT score ≤ 20 .

End point type	Secondary
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End point timeframe:

Week 4, 8, 12, 18, 28, 34, 40, and 48

End point values	Ritlecitinib (PF-06651600) 200 mg then 50 mg	Ritlecitinib (PF-06651600) 200 mg then 30 mg	Ritlecitinib (PF-06651600) 50 mg	Ritlecitinib (PF-06651600) 30 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	132	130	130	132
Units: Percentage of subjects				
number (confidence interval 95%)				
Week 4 (n=129, 124, 127, 127, 62, 63, 66)	0.78 (0.00 to 2.29)	0.00 (-99999 to 99999)	0.00 (-99999 to 99999)	0.00 (-99999 to 99999)
Week 8 (n=128, 121, 122, 121, 62, 63, 64)	5.47 (1.53 to 9.41)	4.13 (0.59 to 7.68)	2.46 (0.00 to 5.21)	0.00 (-99999 to 99999)
Week 12 (n= 126, 124, 126, 122, 59, 61, 63)	11.90 (6.25 to 17.56)	8.87 (3.87 to 13.88)	6.35 (2.09 to 10.61)	3.28 (0.12 to 6.44)
Week 18 (n= 121, 121, 122, 117, 60, 60, 62)	19.83 (12.73 to 26.94)	13.22 (7.19 to 19.26)	13.11 (7.12 to 19.10)	9.40 (4.11 to 14.69)
Week 28 (n= 120, 119, 119, 122, 60, 57, 63)	34.17 (25.68 to 42.65)	23.53 (15.91 to 31.15)	26.05 (18.16 to 33.94)	20.49 (13.33 to 27.65)
Week 34 (n= 125, 123, 124, 122, 59, 61, 65)	38.40 (29.87 to 46.93)	27.64 (19.74 to 35.55)	33.87 (25.54 to 42.20)	28.69 (20.66 to 36.71)
Week 40 (n= 128, 123, 122, 120, 59, 65, 65)	39.06 (30.61 to 47.51)	33.33 (25.00 to 41.66)	39.34 (30.68 to 48.01)	30.00 (21.80 to 38.20)
Week 48 (n= 129, 122, 125, 122, 61, 65, 64)	39.53 (31.10 to 47.97)	34.43 (26.00 to 42.86)	43.20 (34.52 to 51.88)	31.15 (22.93 to 39.37)

End point values	Ritlecitinib (PF-06651600) 10 mg	Placebo, Ritlecitinib (PF-06651600) 200 mg then 50 mg	Placebo, Ritlecitinib (PF-06651600) 50 mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	63	65	66	
Units: Percentage of subjects				
number (confidence interval 95%)				
Week 4 (n=129, 124, 127, 127, 62, 63, 66)	0.00 (-99999 to 99999)	0.00 (-99999 to 99999)	0.00 (-99999 to 99999)	
Week 8 (n=128, 121, 122, 121, 62, 63, 64)	0.00 (-99999 to 99999)	0.00 (-99999 to 99999)	0.00 (-99999 to 99999)	
Week 12 (n= 126, 124, 126, 122, 59, 61, 63)	3.39 (0.00 to 8.01)	1.64 (0.00 to 4.83)	1.59 (0.00 to 4.67)	
Week 18 (n= 121, 121, 122, 117, 60, 60, 62)	3.33 (0.00 to 7.88)	1.67 (0.00 to 4.91)	1.61 (0.00 to 4.75)	
Week 28 (n= 120, 119, 119, 122, 60, 57, 63)	5.00 (0.00 to 10.51)	1.75 (0.00 to 5.16)	6.35 (0.33 to 12.37)	
Week 34 (n= 125, 123, 124, 122, 59, 61, 65)	5.08 (0.00 to 10.69)	19.67 (9.70 to 29.65)	9.23 (2.19 to 16.27)	
Week 40 (n= 128, 123, 122, 120, 59, 65, 65)	6.78 (0.36 to 13.19)	23.08 (12.83 to 33.32)	15.38 (6.61 to 24.16)	
Week 48 (n= 129, 122, 125, 122, 61, 65, 64)	9.84 (2.36 to 17.31)	33.85 (22.34 to 45.35)	18.75 (9.19 to 28.31)	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With an Absolute SALT Score of Less Than or Equal to 10 at Week 4, 8, 12, 18, 28, 34, 40, and 48

End point title	Percentage of Subjects With an Absolute SALT Score of Less Than or Equal to 10 at Week 4, 8, 12, 18, 28, 34, 40, and 48
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End point description:

SALT is a quantitative assessment of AA severity based on the scalp hair loss. The SALT score can vary from 0 (normal) to 100 (severe), with higher scores representing increased severity of disease. In this endpoint, percentage of subjects with SALT score ≤ 10 were reported. FAS included all subjects who were randomised, regardless of whether they received study medication. Here, "n" signifies subjects evaluable at specific time point. 99999 signifies that 95% CI could not be calculated as there were no subjects with SALT score ≤ 10 .

End point type	Secondary
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End point timeframe:

Week 4, 8, 12, 18, 28, 34, 40, and 48

End point values	Ritlecitinib (PF-06651600) 200 mg then 50 mg	Ritlecitinib (PF-06651600) 200 mg then 30 mg	Ritlecitinib (PF-06651600) 50 mg	Ritlecitinib (PF-06651600) 30 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	132	130	130	132
Units: Percentage of subjects				
number (confidence interval 95%)				
Week 4 (n=129, 124, 127, 127, 62, 63, 66)	0.78 (0.00 to 2.29)	0.00 (-99999 to 99999)	0.00 (-99999 to 99999)	0.00 (-99999 to 99999)
Week 8 (n=128, 121, 122, 121, 62, 63, 64)	2.34 (0.00 to 4.96)	0.83 (0.00 to 2.44)	0.82 (0.00 to 2.42)	0.00 (-99999 to 99999)
Week 12 (n=126, 124, 126, 122, 59, 61, 63)	6.35 (2.09 to 10.61)	5.65 (1.58 to 9.71)	5.56 (1.56 to 9.56)	0.82 (0.00 to 2.42)
Week 18 (n=121, 121, 122, 117, 60, 60, 62)	12.40 (6.52 to 18.27)	7.44 (2.76 to 12.11)	6.56 (2.16 to 10.95)	5.13 (1.13 to 9.12)
Week 28 (n=120, 119, 119, 122, 60, 57, 63)	29.17 (21.03 to 37.30)	16.81 (10.09 to 23.53)	18.49 (11.51 to 25.46)	16.39 (9.82 to 22.96)
Week 34 (n=125, 123, 124, 122, 59, 61, 65)	30.40 (22.34 to 38.46)	18.70 (11.81 to 25.59)	23.39 (15.94 to 30.84)	22.13 (14.76 to 29.50)
Week 40 (n=128, 123, 122, 120, 59, 65, 65)	31.25 (23.22 to 39.28)	25.20 (17.53 to 32.88)	27.05 (19.17 to 34.93)	25.00 (17.25 to 32.75)
Week 48 (n=129, 122, 125, 122, 61, 65, 64)	33.33 (25.20 to 41.47)	27.87 (19.91 to 35.82)	31.20 (23.08 to 39.32)	25.41 (17.68 to 33.14)

End point values	Ritlecitinib (PF-06651600) 10 mg	Placebo, Ritlecitinib (PF-06651600) 200 mg then 50 mg	Placebo, Ritlecitinib (PF-06651600) 50 mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	63	65	66	
Units: Percentage of subjects				
number (confidence interval 95%)				
Week 4 (n=129, 124, 127, 127, 62, 63, 66)	0.00 (-99999 to 99999)	0.00 (-99999 to 99999)	0.00 (-99999 to 99999)	

Week 8 (n=128, 121, 122, 121, 62, 63, 64)	0.00 (-99999 to 99999)	0.00 (-99999 to 99999)	0.00 (-99999 to 99999)	
Week 12 (n=126, 124, 126, 122, 59, 61, 63)	1.69 (0.00 to 4.99)	0.00 (-99999 to 99999)	1.59 (0.00 to 4.67)	
Week 18 (n=121, 121, 122, 117, 60, 60, 62)	1.67 (0.00 to 4.91)	1.67 (0.00 to 4.91)	1.61 (0.00 to 4.75)	
Week 28 (n=120, 119, 119, 122, 60, 57, 63)	3.33 (0.00 to 7.88)	1.75 (0.00 to 5.16)	3.17 (0.00 to 7.50)	
Week 34 (n=125, 123, 124, 122, 59, 61, 65)	3.39 (0.00 to 8.01)	13.11 (4.64 to 21.59)	4.62 (0.00 to 9.72)	
Week 40 (n=128, 123, 122, 120, 59, 65, 65)	3.39 (0.00 to 8.01)	18.46 (9.03 to 27.89)	9.23 (2.19 to 16.27)	
Week 48 (n=129, 122, 125, 122, 61, 65, 64)	6.56 (0.35 to 12.77)	24.62 (14.14 to 35.09)	14.06 (5.55 to 22.58)	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With at Least 75% Improvement in SALT Score (SALT75) From Baseline at Week 4, 8, 12, 18, 24, 28, 34, 40, and 48

End point title	Percentage of Subjects With at Least 75% Improvement in SALT Score (SALT75) From Baseline at Week 4, 8, 12, 18, 24, 28, 34, 40, and 48
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End point description:

SALT is a quantitative assessment of AA severity based on the scalp hair loss. The SALT score can vary from 0 (normal) to 100 (severe), with higher scores representing increased severity of disease. A SALT 75 response was a 75% or greater reduction from baseline in SALT score. FAS included all subjects who were randomised, regardless of whether they received study medication. Here, "n" signifies subjects evaluable at specific time point. 99999 signifies that CI could not be calculated as there were no subjects with at least 75% improvement in SALT score.

End point type	Secondary
End point timeframe:	
Week 4, 8, 12, 18, 24, 28, 34, 40, and 48	

End point values	Ritlecitinib (PF-06651600) 200 mg then 50 mg	Ritlecitinib (PF-06651600) 200 mg then 30 mg	Ritlecitinib (PF-06651600) 50 mg	Ritlecitinib (PF-06651600) 30 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	132	130	130	132
Units: Percentage of subjects				
number (confidence interval 95%)				
Week 4 (n=129, 124, 127, 127, 62, 63, 66)	0.78 (0.00 to 2.29)	0.00 (-99999 to 99999)	0.00 (-99999 to 99999)	0.00 (-99999 to 99999)
Week 8 (n=128, 121, 122, 121, 62, 63, 64)	4.69 (1.03 to 8.35)	3.31 (0.12 to 6.49)	1.64 (0.00 to 3.89)	0.83 (0.00 to 2.44)
Week 12 (n=126, 124, 126, 122, 59, 61, 63)	11.90 (6.25 to 17.56)	8.06 (3.27 to 12.86)	6.35 (2.09 to 10.61)	2.46 (0.00 to 5.21)
Week 18 (n=121, 121, 122, 117, 60, 60, 62)	20.66 (13.45 to 27.88)	14.88 (8.54 to 21.22)	9.84 (4.55 to 15.12)	11.11 (5.42 to 16.81)
Week 24 (n=124, 121, 124, 119, 59, 65, 65)	31.45 (23.28 to 39.62)	20.66 (13.45 to 27.88)	22.58 (15.22 to 29.94)	13.45 (7.32 to 19.57)

Week 28 (n=120, 119, 119, 122, 60, 57, 63)	34.17 (25.68 to 42.65)	24.37 (16.66 to 32.08)	27.73 (19.69 to 35.77)	21.31 (14.04 to 28.58)
Week 34 (n=125, 123, 124, 122, 59, 61, 65)	38.40 (29.87 to 46.93)	32.52 (24.24 to 40.80)	38.71 (30.14 to 47.28)	28.69 (20.66 to 36.71)
Week 40 (n=128, 123, 122, 120, 59, 65, 65)	39.84 (31.36 to 48.33)	34.96 (26.53 to 43.39)	42.62 (33.85 to 51.40)	30.00 (21.80 to 38.20)
Week 48 (n=129, 122, 125, 122, 61, 65, 64)	39.53 (31.10 to 47.97)	36.07 (27.54 to 44.59)	46.40 (37.66 to 55.14)	31.15 (22.93 to 39.37)

End point values	Ritlecitinib (PF-06651600) 10 mg	Placebo, Ritlecitinib (PF-06651600) 200 mg then 50 mg	Placebo, Ritlecitinib (PF-06651600) 50 mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	63	65	66	
Units: Percentage of subjects				
number (confidence interval 95%)				
Week 4 (n=129, 124, 127, 127, 62, 63, 66)	0.00 (-99999 to 99999)	0.00 (-99999 to 99999)	0.00 (-99999 to 99999)	
Week 8 (n=128, 121, 122, 121, 62, 63, 64)	0.00 (-99999 to 99999)	1.59 (0.00 to 4.67)	0.00 (-99999 to 99999)	
Week 12 (n=126, 124, 126, 122, 59, 61, 63)	1.69 (0.00 to 4.99)	1.64 (0.00 to 4.83)	1.59 (0.00 to 4.67)	
Week 18 (n=121, 121, 122, 117, 60, 60, 62)	1.67 (0.00 to 4.91)	1.67 (0.00 to 4.91)	1.61 (0.00 to 4.75)	
Week 24 (n=124, 121, 124, 119, 59, 65, 65)	1.69 (0.00 to 4.99)	1.54 (0.00 to 4.53)	3.08 (0.00 to 7.28)	
Week 28 (n=120, 119, 119, 122, 60, 57, 63)	5.00 (0.00 to 10.51)	3.51 (0.00 to 8.29)	4.76 (0.00 to 10.02)	
Week 34 (n=125, 123, 124, 122, 59, 61, 65)	5.08 (0.00 to 10.69)	21.31 (11.03 to 31.59)	10.77 (3.23 to 18.31)	
Week 40 (n=128, 123, 122, 120, 59, 65, 65)	5.08 (0.00 to 10.69)	23.08 (12.83 to 33.32)	15.38 (6.61 to 24.16)	
Week 48 (n=129, 122, 125, 122, 61, 65, 64)	9.84 (2.36 to 17.31)	32.31 (20.94 to 43.68)	21.88 (11.75 to 32.00)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in SALT Score at Week 4, 8, 12, 18, and 24

End point title	Change From Baseline in SALT Score at Week 4, 8, 12, 18, and 24 ^[7]
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End point description:

SALT is a quantitative assessment of AA severity based on the scalp hair loss. The SALT score can vary from 0 (normal) to 100 (severe), with higher scores representing increased severity of disease. Baseline was defined as pre-dose on Day 1. FAS included all subjects who were randomised, regardless of whether they received study medication. Here, "n" signifies subjects evaluable at specific time point.

End point type	Secondary
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End point timeframe:

Baseline (Day 1), Week 4, 8, 12, 18, and 24

Notes:

[7] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Statistics were planned only for the arms specified

End point values	Ritlecitinib (PF-06651600) 200 mg then 50 mg	Ritlecitinib (PF-06651600) 200 mg then 30 mg	Ritlecitinib (PF-06651600) 50 mg	Ritlecitinib (PF-06651600) 30 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	132	130	130	132
Units: Units on a scale				
least squares mean (confidence interval 95%)				
Change at Week 4 (n= 127, 121, 124, 124, 58, 127)	-2.3 (-3.64 to -1.01)	-2.7 (-4.03 to -1.35)	-1.8 (-3.16 to 0.50)	-1.3 (-2.60 to 0.06)
Change at Week 8 (n= 124, 119, 117, 115, 57, 124)	-12.8 (-15.56 to -10.05)	-12.5 (-15.28 to -9.71)	-6.3 (-9.10 to -3.50)	-5.0 (-7.82 to -2.21)
Change at Week 12 (n= 121, 120, 121, 115, 56, 122)	-22.7 (-26.47 to -18.97)	-20.1 (-23.87 to -16.30)	-12.4 (-16.18 to -8.61)	-10.3 (-14.11 to -6.47)
Change at Week 18 (n= 117, 119, 117, 112, 56, 119)	-31.2 (-35.63 to -26.83)	-25.0 (-29.41 to -20.55)	-22.5 (-26.94 to -18.07)	-17.5 (-22.02 to -13.02)
Change at Week 24 (n= 118, 119, 119, 114, 55, 125)	-36.5 (-41.54 to -31.53)	-29.2 (-34.21 to -24.15)	-33.3 (-38.33 to -28.25)	-23.6 (-28.72 to -18.45)

End point values	Ritlecitinib (PF-06651600) 10 mg	Placebo		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	63	131		
Units: Units on a scale				
least squares mean (confidence interval 95%)				
Change at Week 4 (n= 127, 121, 124, 124, 58, 127)	-1.3 (-3.19 to 0.69)	-0.9 (-2.17 to 0.46)		
Change at Week 8 (n= 124, 119, 117, 115, 57, 124)	-1.7 (-5.74 to 2.34)	-1.2 (-3.99 to 1.50)		
Change at Week 12 (n= 121, 120, 121, 115, 56, 122)	-3.5 (-9.00 to 1.98)	-2.4 (-6.12 to 1.35)		
Change at Week 18 (n= 117, 119, 117, 112, 56, 119)	-2.4 (-8.87 to 3.97)	-3.9 (-8.31 to 0.43)		
Change at Week 24 (n= 118, 119, 119, 114, 55, 125)	-4.2 (-11.50 to 3.13)	-5.1 (-10.03 to -0.13)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in SALT Score at Week 28, 34, 40, and 48

End point title	Change From Baseline in SALT Score at Week 28, 34, 40, and 48
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End point description:

SALT is a quantitative assessment of AA severity based on the scalp hair loss. The SALT score can vary from 0 (normal) to 100 (severe), with higher scores representing increased severity of disease. Baseline

was defined as pre-dose on Day 1. FAS included all subjects who were randomised, regardless of whether they received study medication. Here, "n" signifies subjects evaluable at specific time point.

End point type	Secondary
End point timeframe:	
Baseline (Day 1), Week 28, 34, 40, and 48	

End point values	Ritlecitinib (PF-06651600) 200 mg then 50 mg	Ritlecitinib (PF-06651600) 200 mg then 30 mg	Ritlecitinib (PF-06651600) 50 mg	Ritlecitinib (PF-06651600) 30 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	132	130	130	132
Units: Units on a scale				
arithmetic mean (standard deviation)				
Baseline (n=132,130,130,132,63,65,66)	90.3 (± 15.05)	90.5 (± 14.28)	90.3 (± 14.69)	90.0 (± 15.07)
Change at Week 28 (n=109,113,111,115,55,54,59)	-44.1 (± 36.35)	-33.3 (± 33.85)	-36.1 (± 33.42)	-29.2 (± 32.56)
Change at Week 34 (n=113,118,117,115,54,59,61)	-48.2 (± 36.16)	-35.5 (± 35.50)	-43.6 (± 34.35)	-33.5 (± 35.01)
Change at Week 40 (n=116,118,113,109,54,61, 60)	-49.3 (± 36.11)	-38.5 (± 37.14)	-46.9 (± 35.68)	-35.9 (± 35.90)
Change at Week 48 (n=114,112,16,107,53,60,59)	-49.4 (± 36.09)	-40.5 (± 37.27)	-48.9 (± 36.63)	-40.1 (± 35.87)

End point values	Ritlecitinib (PF-06651600) 10 mg	Placebo, Ritlecitinib (PF-06651600) 200 mg then 50 mg	Placebo, Ritlecitinib (PF-06651600) 50 mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	63	65	66	
Units: Units on a scale				
arithmetic mean (standard deviation)				
Baseline (n=132,130,130,132,63,65,66)	88.3 (± 16.87)	94.4 (± 9.31)	91.5 (± 13.22)	
Change at Week 28 (n=109,113,111,115,55,54,59)	-5.6 (± 23.15)	-11.5 (± 22.75)	-5.0 (± 18.51)	
Change at Week 34 (n=113,118,117,115,54,59,61)	-7.6 (± 23.61)	-27.5 (± 32.78)	-12.6 (± 24.47)	
Change at Week 40 (n=116,118,113,109,54,61, 60)	-11.4 (± 26.01)	-36.5 (± 34.56)	-23.0 (± 30.64)	
Change at Week 48 (n=114,112,16,107,53,60,59)	-13.3 (± 30.13)	-46.3 (± 35.51)	-32.2 (± 32.39)	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With at Least a 2 Grade Improvement From Baseline or a Score of 3 in Eyebrow Assessment (EBA) Score (Among Subjects Without Normal EBA at Baseline) at Week 4, 8, 12, 18, 24, 28, 34, 40, and 48

End point title	Percentage of Subjects With at Least a 2 Grade Improvement
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End point description:

EBA is a numeric rating scale developed to characterize eyebrow hair loss. The numeric rating scale ranges from 0 (none) to 3 (normal), where, 0= no eyebrow, 1=minimal eyebrow, 2=moderate eyebrow and 3= normal eyebrow, where higher scores represent less hair loss of eyebrows. FAS included all subjects who were randomised, regardless of whether they received study medication. Here, "n" signifies subjects evaluable at specific time point. 99999 signifies that 95% CI could not be calculated as there were no subjects with at least a 2-grade improvement or a score of 3 in EBA.

End point type Secondary

End point timeframe:

Week 4, 8, 12, 18, 24, 28, 34, 40, and 48

End point values	Ritlecitinib (PF-06651600) 200 mg then 50 mg	Ritlecitinib (PF-06651600) 200 mg then 30 mg	Ritlecitinib (PF-06651600) 50 mg	Ritlecitinib (PF-06651600) 30 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	132	130	130	132
Units: Percentage of subjects				
number (confidence interval 95%)				
Week 4 (n= 107, 104, 104, 107, 51, 53, 52)	1.87 (0.00 to 4.44)	2.88 (0.00 to 6.10)	0.00 (-99999 to 99999)	0.93 (0.00 to 2.76)
Week 8 (n= 107, 101, 101, 102, 52, 53, 51)	10.28 (4.53 to 16.03)	13.86 (7.12 to 20.60)	2.97 (0.00 to 6.28)	4.90 (0.71 to 9.09)
Week 12 (n= 105, 103, 104, 105, 48, 51, 50)	22.86 (14.83 to 30.89)	17.48 (10.14 to 24.81)	9.62 (3.95 to 15.28)	7.62 (2.54 to 12.69)
Week 18 (n= 101, 101, 101, 101, 49, 50, 49)	29.70 (20.79 to 38.61)	18.81 (11.19 to 26.43)	17.82 (10.36 to 25.29)	12.87 (6.34 to 19.40)
Week 24 (n= 103, 102, 100, 102, 48, 55, 52)	33.98 (24.83 to 43.13)	25.49 (17.03 to 33.95)	29.00 (20.11 to 37.89)	16.67 (9.43 to 23.90)
Week 28 (n= 100, 100, 99, 105, 49, 48, 50)	37.00 (27.54 to 46.46)	29.00 (20.11 to 37.89)	27.27 (18.50 to 36.05)	24.76 (16.51 to 33.02)
Week 34 (n= 104, 104, 101, 105, 48, 51, 52)	41.35 (31.88 to 50.81)	30.77 (21.90 to 39.64)	34.65 (25.37 to 43.93)	31.43 (22.55 to 40.31)
Week 40 (n= 106, 102, 100, 104, 50, 55, 52)	43.40 (33.96 to 52.83)	30.39 (21.47 to 39.32)	39.00 (29.44 to 48.56)	33.65 (24.57 to 42.74)
Week 48 (n= 107, 101, 101, 105, 50, 55, 51)	42.99 (33.61 to 52.37)	32.67 (23.53 to 41.82)	43.56 (33.89 to 53.23)	33.33 (24.32 to 42.35)

End point values	Ritlecitinib (PF-06651600) 10 mg	Placebo, Ritlecitinib (PF-06651600) 200 mg then 50 mg	Placebo, Ritlecitinib (PF-06651600) 50 mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	63	65	66	
Units: Percentage of subjects				
number (confidence interval 95%)				
Week 4 (n= 107, 104, 104, 107, 51, 53, 52)	1.96 (0.00 to 5.77)	0.00 (-99999 to 99999)	3.85 (0.00 to 9.07)	
Week 8 (n= 107, 101, 101, 102, 52, 53, 51)	3.85 (0.00 to 9.07)	3.77 (0.00 to 8.90)	0.00 (-99999 to 99999)	
Week 12 (n= 105, 103, 104, 105, 48, 51, 50)	6.25 (0.00 to 13.10)	0.00 (-99999 to 99999)	4.00 (0.00 to 9.43)	

Week 18 (n= 101, 101, 101, 101, 49, 50, 49)	10.20 (1.73 to 18.68)	0.00 (-99999 to 99999)	8.16 (0.50 to 15.83)	
Week 24 (n= 103, 102, 100, 102, 48, 55, 52)	8.33 (0.51 to 16.15)	3.64 (0.00 to 8.58)	5.77 (0.00 to 12.11)	
Week 28 (n= 100, 100, 99, 105, 49, 48, 50)	12.24 (3.07 to 21.42)	4.17 (0.00 to 9.82)	6.00 (0.00 to 12.58)	
Week 34 (n= 104, 104, 101, 105, 48, 51, 52)	14.58 (4.60 to 24.57)	15.69 (5.71 to 25.67)	13.46 (4.18 to 22.74)	
Week 40 (n= 106, 102, 100, 104, 50, 55, 52)	16.00 (5.84 to 26.16)	20.00 (9.43 to 30.57)	26.92 (14.87 to 38.98)	
Week 48 (n= 107, 101, 101, 105, 50, 55, 51)	16.00 (5.84 to 26.16)	30.91 (18.70 to 43.12)	31.37 (18.64 to 44.11)	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With at Least a 2 Grade Improvement From Baseline or a Score of 3 in Eyelash Assessment (ELA) Score (Among Subjects Without Normal ELA at Baseline) at Week 4, 8, 12, 18, 24, 28, 34, 40, and 48

End point title	Percentage of Subjects With at Least a 2 Grade Improvement From Baseline or a Score of 3 in Eyelash Assessment (ELA) Score (Among Subjects Without Normal ELA at Baseline) at Week 4, 8, 12, 18, 24, 28, 34, 40, and 48
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End point description:

ELA is a numeric rating scale developed to characterize eyelash hair loss. The numeric rating scale ranges from 0 (none) to 3 (normal), where, 0=no eyelash, 1=minimal eyelash, 2=moderate eyelash and 3=normal eyelash, where higher scores represent less hair loss of eyelash. FAS included all subjects who were randomised, regardless of whether they received study medication. Here, "n" signifies subjects evaluable at specific time point. 99999 signifies that 95% CI could not be calculated as there were no subjects with at least a 2-grade improvement or a score of 3 in ELA.

End point type	Secondary
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End point timeframe:

Week 4, 8, 12, 18, 24, 28, 34, 40, and 48

End point values	Ritlecitinib (PF-06651600) 200 mg then 50 mg	Ritlecitinib (PF-06651600) 200 mg then 30 mg	Ritlecitinib (PF-06651600) 50 mg	Ritlecitinib (PF-06651600) 30 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	132	130	130	132
Units: Percentage of subjects				
number (confidence interval 95%)				
Week 4 (n= 99, 93, 93, 97, 44, 49, 46)	3.03 (0.00 to 6.41)	1.08 (0.00 to 3.17)	5.38 (0.79 to 9.96)	1.03 (0.00 to 3.04)
Week 8 (n= 99, 90, 91, 92, 45, 49, 45)	9.09 (3.43 to 14.75)	4.44 (0.19 to 8.70)	8.79 (2.97 to 14.61)	4.35 (0.18 to 8.51)
Week 12 (n= 97, 91, 94, 95, 42, 47, 44)	16.49 (9.11 to 23.88)	10.99 (4.56 to 17.41)	11.70 (5.20 to 18.20)	7.37 (2.11 to 12.62)
Week 18 (n= 94, 90, 90, 91, 43, 46, 43)	25.53 (16.72 to 34.35)	20.00 (11.74 to 28.26)	20.00 (11.74 to 28.26)	12.09 (5.39 to 18.79)
Week 24 (n= 96, 89, 90, 92, 41, 51, 46)	30.21 (21.02 to 39.39)	21.35 (12.84 to 29.86)	28.89 (19.52 to 38.25)	26.09 (17.11 to 35.06)

Week 28 (n= 94, 88, 87, 95, 42, 44, 44)	29.79 (20.54 to 39.03)	25.00 (15.95 to 34.05)	36.78 (26.65 to 46.91)	24.21 (15.60 to 32.82)
Week 34 (n= 97, 91, 90, 95, 41, 48, 46)	34.02 (24.59 to 43.45)	26.37 (17.32 to 35.43)	38.89 (28.82 to 48.96)	26.32 (17.46 to 35.17)
Week 40 (n= 98, 89, 89, 94, 43, 51, 46)	39.80 (30.10 to 49.49)	28.09 (18.75 to 37.43)	38.20 (28.11 to 48.30)	27.66 (18.62 to 36.70)
Week 48 (n= 99, 88, 90, 95, 43, 51, 45)	38.38 (28.80 to 47.96)	29.55 (20.01 to 39.08)	40.00 (29.88 to 50.12)	30.53 (21.27 to 39.79)

End point values	Ritlecitinib (PF-06651600) 10 mg	Placebo, Ritlecitinib (PF-06651600) 200 mg then 50 mg	Placebo, Ritlecitinib (PF-06651600) 50 mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	63	65	66	
Units: Percentage of subjects				
number (confidence interval 95%)				
Week 4 (n= 99, 93, 93, 97, 44, 49, 46)	4.55 (0.00 to 10.70)	2.04 (0.00 to 6.00)	0.00 (-99999 to 99999)	
Week 8 (n= 99, 90, 91, 92, 45, 49, 45)	2.22 (0.00 to 6.53)	2.04 (0.00 to 6.00)	0.00 (-99999 to 99999)	
Week 12 (n= 97, 91, 94, 95, 42, 47, 44)	4.76 (0.00 to 11.20)	0.00 (-99999 to 99999)	0.00 (-99999 to 99999)	
Week 18 (n= 94, 90, 90, 91, 43, 46, 43)	6.98 (0.00 to 14.59)	2.17 (0.00 to 6.39)	0.00 (-99999 to 99999)	
Week 24 (n= 96, 89, 90, 92, 41, 51, 46)	4.88 (0.00 to 11.47)	9.80 (1.64 to 17.97)	0.00 (-99999 to 99999)	
Week 28 (n= 94, 88, 87, 95, 42, 44, 44)	4.76 (0.00 to 11.20)	6.82 (0.00 to 14.27)	4.55 (0.00 to 10.70)	
Week 34 (n= 97, 91, 90, 95, 41, 48, 46)	7.32 (0.00 to 15.29)	16.67 (6.12 to 27.21)	6.52 (0.00 to 13.66)	
Week 40 (n= 98, 89, 89, 94, 43, 51, 46)	18.60 (6.97 to 30.24)	25.49 (13.53 to 37.45)	17.39 (6.44 to 28.34)	
Week 48 (n= 99, 88, 90, 95, 43, 51, 45)	20.93 (8.77 to 33.09)	37.25 (23.99 to 50.52)	35.56 (21.57 to 49.54)	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With Patient Global Impression of Change (PGI-C) Score of Moderately Improved or Greatly Improved at Week 4, 8, 12, 18, 24, 34, 40, and 48

End point title	Percentage of Subjects With Patient Global Impression of Change (PGI-C) Score of Moderately Improved or Greatly Improved at Week 4, 8, 12, 18, 24, 34, 40, and 48
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End point description:

PGI-C is a self-administered questionnaire to evaluate the improvement or worsening of subject's AA as compared to the start of the study. PGI-C was assessed on a 7-point Likert scale ranged from 1 (greatly improved) to 7 (greatly worsened). Categories were defined based on the PGI-C scores as follows: 1=greatly improved, 2=moderately improved, 3=slightly improved, 4=not changed, 5=slightly worsened, 6=moderately worsened and 7=greatly worsened. FAS included all subjects who were randomised, regardless of whether they received study medication. Here, "Number of Subjects Analysed" signifies subjects evaluable for this endpoint.

End point type	Secondary
End point timeframe:	
Week 4, 8, 12, 18, 24, 34, 40, and 48	

End point values	Ritlecitinib (PF-06651600) 200 mg then 50 mg	Ritlecitinib (PF-06651600) 200 mg then 30 mg	Ritlecitinib (PF-06651600) 50 mg	Ritlecitinib (PF-06651600) 30 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	132	130	130	132
Units: Percentage of subjects				
number (not applicable)				
W4:greatly improved(n=129,124,127,127,62,63,65	5.43	4.03	2.36	0
W4:moderatelyimproved(n=129,124,127,127,62,63,65)	3.10	11.29	4.72	7.87
W8:greatly improved(n=128,121,123,121,61,63,64	17.19	14.88	8.13	4.13
W8:moderatelyimproved(n=128,121,123,121,61,63,64)	13.28	21.49	7.32	16.53
W12:greatly improved(n=127,124,125,123,59,60,63	22.83	22.58	13.60	12.20
W12:moderatelyimproved(n=127,124,125,123,59,60,63)	18.11	19.35	14.40	14.63
W18:greatly improved(n=123,121,122,119,61,60,61	27.64	22.31	18.03	19.33
W18:moderatelyimproved(n=123,121,122,119,61,60,61)	23.58	23.97	27.87	15.13
W24:greatly improved(n=126,121,125,121,60,65,65	36.51	26.45	28.80	28.93
W24:moderatelyimproved(n=126,121,125,121,60,65,65)	16.67	20.66	20.80	13.22
W34:greatly improved(n=125,121,123,122,59,59,64	43.20	35.54	37.40	31.97
W34:moderatelyimproved(n=125,121,123,122,59,59,64)	12.00	17.36	15.45	15.57
W40:greatly improved(n=128,124,122,120,59,65,65	43.75	34.68	37.70	30.00
W40:moderatelyimproved(n=128,124,122,120,59,65,65)	15.63	14.52	14.75	19.17
W48:greatly improved(n=129,123,125,122,61,64,64	44.96	33.33	42.40	31.15
W48:moderatelyimproved(n=129,123,125,122,61,64,64)	13.18	18.70	13.60	18.03

End point values	Ritlecitinib (PF-06651600) 10 mg	Placebo, Ritlecitinib (PF-06651600) 200 mg then 50 mg	Placebo, Ritlecitinib (PF-06651600) 50 mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	63	65	66	
Units: Percentage of subjects				
number (not applicable)				

W4:greatly improved(n=129,124,127,127,62,63,65)	0	0	0	
W4:moderatelyimproved(n=129,124,127,127,62,63,65)	1.61	1.59	1.54	
W8:greatly improved(n=128,121,123,121,61,63,64)	1.64	1.59	1.56	
W8:moderatelyimproved(n=128,121,123,121,61,63,64)	4.92	3.17	4.69	
W12:greatly improved(n=127,124,125,123,59,60,63)	3.39	0	3.17	
W12:moderatelyimproved(n=127,124,125,123,59,60,63)	3.39	10.00	7.94	
W18:greatly improved(n=123,121,122,119,61,60,61)	1.64	1.67	3.28	
W18:moderatelyimproved(n=123,121,122,119,61,60,61)	6.56	10.00	4.92	
W24:greatly improved(n=126,121,125,121,60,65,65)	1.67	1.54	4.62	
W24:moderatelyimproved(n=126,121,125,121,60,65,65)	10.00	9.23	3.08	
W34:greatly improved(n=125,121,123,122,59,59,64)	5.08	18.64	7.81	
W34:moderatelyimproved(n=125,121,123,122,59,59,64)	6.78	22.03	20.31	
W40:greatly improved(n=128,124,122,120,59,65,65)	6.78	30.77	13.85	
W40:moderatelyimproved(n=128,124,122,120,59,65,65)	11.86	24.62	15.38	
W48:greatly improved(n=129,123,125,122,61,64,64)	6.56	42.19	26.56	
W48:moderatelyimproved(n=129,123,125,122,61,64,64)	9.84	17.19	17.19	

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Alopecia Areata Patient Priority Outcomes (AAPPO) Domain Scores at Week 4, 8, 12, 18, and 24: Emotional Symptoms (ES) and Activity Limitations (AL)

End point title	Change From Baseline in Alopecia Areata Patient Priority Outcomes (AAPPO) Domain Scores at Week 4, 8, 12, 18, and 24: Emotional Symptoms (ES) and Activity Limitations (AL) ^[8]
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End point description:

AAPPO scale:11-item self-administered questionnaire that measured hair loss, emotional symptoms, and activity limitations over past week. Items 1-4 assessed current hair loss, eyebrow loss, eyelash loss and body hair loss and analysed separately on scale 0-4(0=no hair loss and 4=complete hair loss). Items 5-8 assessed emotional symptoms. Response were scored from 0=never to 4=always. Items 9-11 assessed activity limitations. Response were scored from 0=not at all to 4=completely. Change from baseline in AAPPO emotional symptoms sub score was calculated as mean of items 5-8(0=never to 4=always),higher scores:more emotional symptoms; Change from baseline in AAPPO activity limitations sub score was calculated as mean of items 9-11(0=not at all to 4=completely),higher scores:more activity limitations. Baseline was defined as pre-dose on Day 1. FAS:subjects randomised, regardless of whether received study medication. Here, "n" signifies subjects evaluable at specific time point.

End point type	Secondary
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End point timeframe:

Baseline (Day 1), Week 4, 8, 12, 18, and 24

Notes:

[8] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Statistics were planned only for the arms specified

End point values	Ritlecitinib (PF-06651600) 200 mg then 50 mg	Ritlecitinib (PF-06651600) 200 mg then 30 mg	Ritlecitinib (PF-06651600) 50 mg	Ritlecitinib (PF-06651600) 30 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	132	130	130	132
Units: Units on a scale				
least squares mean (confidence interval 95%)				
Change at Week 4: ES (n=127,121,123,122,58,124)	-0.37 (-0.49 to -0.25)	-0.22 (-0.34 to -0.10)	-0.33 (-0.45 to -0.21)	-0.31 (-0.44 to -0.19)
Change at Week 8: ES (n=122,119,117,115,56,123)	-0.50 (-0.62 to -0.38)	-0.46 (-0.58 to -0.34)	-0.50 (-0.62 to -0.37)	-0.36 (-0.48 to -0.23)
Change at Week 12: ES (n=122,120,119,116,56,121)	-0.53 (-0.66 to -0.40)	-0.54 (-0.67 to -0.41)	-0.48 (-0.61 to -0.34)	-0.49 (-0.63 to -0.36)
Change at Week 18: ES (n=118,119,116,114,57,118)	-0.64 (-0.78 to -0.51)	-0.57 (-0.71 to -0.44)	-0.60 (-0.74 to -0.46)	-0.54 (-0.68 to -0.40)
Change at Week 24: ES (n=120,118,119,116,55,125)	-0.61 (-0.75 to -0.46)	-0.61 (-0.76 to -0.47)	-0.69 (-0.83 to -0.54)	-0.58 (-0.72 to -0.43)
Change at Week 4: AL (n=127,121,123,122,58,125)	-0.19 (-0.29 to -0.08)	-0.04 (-0.15 to 0.07)	-0.16 (-0.27 to -0.05)	-0.13 (-0.24 to -0.02)
Change at Week 8: AL (n=122,119,117,115,56,123)	-0.24 (-0.34 to -0.13)	-0.25 (-0.36 to -0.14)	-0.18 (-0.29 to -0.07)	-0.09 (-0.20 to 0.02)
Change at Week 12: AL (n=122,120,119,116,56,121)	-0.27 (-0.38 to -0.17)	-0.22 (-0.32 to -0.11)	-0.21 (-0.32 to -0.11)	-0.24 (-0.35 to -0.13)
Change at Week 18: AL (n=118,119,116,114,57,118)	-0.35 (-0.45 to -0.24)	-0.26 (-0.36 to -0.15)	-0.23 (-0.34 to -0.12)	-0.23 (-0.34 to -0.12)
Change at Week 24: AL (n=120,118,119,115,55,125)	-0.30 (-0.40 to -0.20)	-0.30 (-0.40 to -0.20)	-0.31 (-0.41 to -0.21)	-0.28 (-0.38 to -0.18)

End point values	Ritlecitinib (PF-06651600) 10 mg	Placebo		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	63	131		
Units: Units on a scale				
least squares mean (confidence interval 95%)				
Change at Week 4: ES (n=127,121,123,122,58,124)	-0.29 (-0.47 to -0.11)	-0.28 (-0.40 to -0.16)		
Change at Week 8: ES (n=122,119,117,115,56,123)	-0.45 (-0.62 to -0.27)	-0.39 (-0.51 to -0.27)		
Change at Week 12: ES (n=122,120,119,116,56,121)	-0.50 (-0.69 to -0.31)	-0.36 (-0.49 to -0.23)		
Change at Week 18: ES (n=118,119,116,114,57,118)	-0.44 (-0.63 to -0.24)	-0.43 (-0.56 to -0.29)		
Change at Week 24: ES (n=120,118,119,116,55,125)	-0.49 (-0.70 to -0.28)	-0.47 (-0.61 to -0.33)		
Change at Week 4: AL (n=127,121,123,122,58,125)	-0.20 (-0.36 to -0.04)	-0.18 (-0.29 to -0.07)		
Change at Week 8: AL (n=122,119,117,115,56,123)	-0.21 (-0.37 to -0.05)	-0.20 (-0.31 to -0.09)		

Change at Week 12: AL (n=122,120,119,116,56,121)	-0.27 (-0.42 to -0.11)	-0.21 (-0.32 to -0.11)		
Change at Week 18: AL (n=118,119,116,114,57,118)	-0.28 (-0.44 to -0.13)	-0.26 (-0.36 to -0.15)		
Change at Week 24: AL (n=120,118,119,115,55,125)	-0.31 (-0.45 to -0.16)	-0.29 (-0.39 to -0.19)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Alopecia Areata Patient Priority Outcomes (AAPPO) Domain Scores at Week 34, 40, and 48: Emotional Symptoms (ES) and Activity Limitations (AL)

End point title	Change From Baseline in Alopecia Areata Patient Priority Outcomes (AAPPO) Domain Scores at Week 34, 40, and 48: Emotional Symptoms (ES) and Activity Limitations (AL)
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End point description:

AAPPO scale:11-item self-administered questionnaire that measured hair loss, emotional symptoms, and activity limitations over past week. Items 1-4 assessed current hair loss, eyebrow loss, eyelash loss and body hair loss and analysed separately on scale 0-4(0=no hair loss and 4=complete hair loss). Items 5-8 assessed emotional symptoms. Response were scored from 0=never to 4=always. Items 9-11 assessed activity limitations. Response were scored from 0=not at all to 4=completely. Change from baseline in AAPPO emotional symptoms sub score was calculated as mean of items 5-8(0=never to 4=always),higher scores:more emotional symptoms; Change from baseline in AAPPO activity limitations sub score was calculated as mean of items 9-11(0=not at all to 4=completely),higher scores:more activity limitations. Baseline was defined as pre-dose on Day 1. FAS:subjects randomised, regardless of whether received study medication. Here, "n" signifies subjects evaluable at specific time point.

End point type	Secondary
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End point timeframe:

Baseline (Day 1), Week 34, 40, and 48

End point values	Ritlecitinib (PF-06651600) 200 mg then 50 mg	Ritlecitinib (PF-06651600) 200 mg then 30 mg	Ritlecitinib (PF-06651600) 50 mg	Ritlecitinib (PF-06651600) 30 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	132	130	130	132
Units: Units on a scale				
arithmetic mean (standard deviation)				
Change at Week 34:ES (n=112,116,114,113,53,57,60)	-0.78 (± 0.95)	-0.72 (± 1.00)	-0.72 (± 0.93)	-0.71 (± 1.06)
Change at Week 40:ES (n=115,119,112,110,54,62,60)	-0.84 (± 1.04)	-0.80 (± 1.02)	-0.81 (± 0.98)	-0.83 (± 1.11)
Change at Week 48:ES (n=114,112,115,107,53,60,59)	-0.96 (± 0.99)	-0.84 (± 1.07)	-0.85 (± 1.04)	-0.72 (± 1.15)
Change at Week 34:AL (n=112,116,114,115,53,57,60)	-0.37 (± 0.71)	-0.31 (± 0.78)	-0.26 (± 0.73)	-0.37 (± 0.78)
Change at Week 40:AL (n=115,119,112,110,54,62,60)	-0.44 (± 0.76)	-0.33 (± 0.84)	-0.25 (± 0.68)	-0.42 (± 0.81)
Change at Week 48:AL (n=114,112,115,107,53,60,59)	-0.43 (± 0.79)	-0.39 (± 0.84)	-0.29 (± 0.76)	-0.36 (± 0.85)

End point values	Ritlecitinib (PF-06651600) 10 mg	Placebo, Ritlecitinib (PF-06651600) 200 mg then 50 mg	Placebo, Ritlecitinib (PF-06651600) 50 mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	63	65	66	
Units: Units on a scale				
arithmetic mean (standard deviation)				
Change at Week 34:ES (n=112,116,114,113,53,57,60)	-0.62 (± 0.83)	-0.77 (± 0.92)	-0.64 (± 0.91)	
Change at Week 40:ES (n=115,119,112,110,54,62,60)	-0.62 (± 0.96)	-0.83 (± 1.01)	-0.66 (± 1.00)	
Change at Week 48:ES (n=114,112,115,107,53,60,59)	-0.50 (± 0.89)	-0.98 (± 1.05)	-0.68 (± 1.03)	
Change at Week 34:AL (n=112,116,114,115,53,57,60)	-0.33 (± 0.76)	-0.36 (± 0.59)	-0.42 (± 0.78)	
Change at Week 40:AL (n=115,119,112,110,54,62,60)	-0.23 (± 0.71)	-0.40 (± 0.66)	-0.39 (± 0.84)	
Change at Week 48:AL (n=114,112,115,107,53,60,59)	-0.26 (± 0.90)	-0.44 (± 0.71)	-0.36 (± 0.81)	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With Improvement From Baseline on Alopecia Areata Patient Priority Outcomes (AAPPO) Items 1-4 at Week 4, 8, 12, 18, 24, 34, 40, and 48

End point title	Percentage of Subjects With Improvement From Baseline on Alopecia Areata Patient Priority Outcomes (AAPPO) Items 1-4 at Week 4, 8, 12, 18, 24, 34, 40, and 48
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End point description:

AAPPO scale is a 11-item self-administered questionnaire that measured hair loss, emotional symptoms, and activity limitations over the past week. Items 1-4 were to assess the current hair loss (CHL), eyebrow loss, eyelash loss and body hair loss and were analysed separately on a scale of 0-4, with 0 = 'no hair loss' and 4 = 'complete hair loss', where higher scores indicated more hair loss. FAS included all subjects who were randomised, regardless of whether they received study medication. Here, "n" signifies subjects evaluable at specific time point. W=week

End point type	Secondary
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End point timeframe:

Week 4, 8, 12, 18, 24, 34, 40, and 48

End point values	Ritlecitinib (PF-06651600) 200 mg then 50 mg	Ritlecitinib (PF-06651600) 200 mg then 30 mg	Ritlecitinib (PF-06651600) 50 mg	Ritlecitinib (PF-06651600) 30 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	132	130	130	132
Units: Percentage of subjects				
number (confidence interval 95%)				
W4:CHL on scalp (n=123,123,120,124,59,63,63)	11.38 (5.77 to 16.99)	9.76 (4.51 to 15.00)	4.17 (0.59 to 7.74)	4.84 (1.06 to 8.62)
W8:CHL on scalp (n=122,120,116,118,58,63,62)	11.48 (5.82 to 17.13)	16.67 (10.00 to 23.33)	7.76 (2.89 to 12.63)	8.47 (3.45 to 13.50)
W12: CHL on scalp (n=121,123,118,120,56,60,61)	20.66 (13.45 to 27.88)	19.51 (12.51 to 26.52)	12.71 (6.70 to 18.72)	13.33 (7.25 to 19.42)
W18: CHL on scalp (n=117,120,116,116,58,60,59)	27.35 (19.27 to 35.43)	25.00 (17.25 to 32.75)	13.79 (7.52 to 20.07)	16.38 (9.64 to 23.11)
W24: CHL on scalp (n=120,120,118,118,57,65,63)	35.83 (27.25 to 44.41)	30.00 (21.80 to 38.20)	26.27 (18.33 to 34.21)	24.58 (16.81 to 32.34)
W34: CHL on scalp (n=119,119,116,119,56,59,62)	42.02 (33.15 to 50.89)	34.45 (25.92 to 42.99)	29.31 (21.03 to 37.59)	30.25 (22.00 to 38.51)
W40: CHL on scalp (n=122,123,115,117,56,65,63)	41.80 (33.05 to 50.56)	36.59 (28.07 to 45.10)	35.65 (26.90 to 44.41)	32.48 (23.99 to 40.96)
W48: CHL on scalp (n=123,122,118,119,58,65,62)	42.28 (33.55 to 51.01)	33.61 (25.22 to 41.99)	42.37 (33.46 to 51.29)	32.77 (24.34 to 41.21)
W4: CHL on eyebrows (n=99,98,94,96,46,48,46)	9.09 (3.43 to 14.75)	7.14 (2.04 to 12.24)	7.45 (2.14 to 12.75)	4.17 (0.17 to 8.16)
W8:CHL on eyebrows (n=98,95,92,91,46,48,45)	17.35 (9.85 to 24.84)	21.05 (12.85 to 29.25)	11.96 (5.33 to 18.59)	10.99 (4.56 to 17.41)
W12: CHL on eyebrows (n=97,97,94,94,43,45,44)	27.84 (18.92 to 36.75)	27.84 (18.92 to 36.75)	18.09 (10.30 to 25.87)	15.96 (8.55 to 23.36)
W18: CHL on eyebrows (n=94,95,91,91,45,45,42)	27.66 (18.62 to 36.70)	33.68 (24.18 to 43.19)	27.47 (18.30 to 36.64)	19.78 (11.60 to 27.96)
W24: CHL on eyebrows (n=96,94,92,92,44,50,46)	32.29 (22.94 to 41.65)	32.98 (23.47 to 42.48)	30.43 (21.03 to 39.84)	29.35 (20.04 to 38.65)
W34: CHL on eyebrows (n=96,93,90,94,43,44,45)	42.71 (32.81 to 52.60)	38.71 (28.81 to 48.61)	38.89 (28.82 to 48.96)	31.91 (22.49 to 41.34)
W40: CHL on eyebrows (n=97,95,90,92,45,50,46)	42.27 (32.44 to 52.10)	36.84 (27.14 to 46.54)	38.89 (28.82 to 48.96)	38.04 (28.12 to 47.96)
W48: CHL on eyebrows (n=98,94,91,94,45,50,45)	44.90 (35.05 to 54.75)	34.04 (24.46 to 43.62)	43.96 (33.76 to 54.15)	39.36 (29.49 to 49.24)
W4: CHL on eyelashes (n=87,87,79,86,38,45,38)	11.49 (4.79 to 18.20)	4.60 (0.20 to 9.00)	7.59 (1.75 to 13.44)	9.30 (3.16 to 15.44)
W8: CHL on eyelashes (n=86,85,78,81,38,45,37)	17.44 (9.42 to 25.46)	17.65 (9.54 to 25.75)	12.82 (5.40 to 20.24)	14.81 (7.08 to 22.55)
W12: CHL on eyelashes (n=85,86,79,84,36,41,36)	29.41 (19.73 to 39.10)	26.74 (17.39 to 36.10)	16.46 (8.28 to 24.63)	19.05 (10.65 to 27.44)
W18:CHL on eyelashes (n=83,85,76,81,38,41,34)	31.33 (21.35 to 41.30)	37.65 (27.35 to 47.95)	21.05 (11.89 to 30.22)	22.22 (13.17 to 31.28)
W24: CHL on eyelashes (n=86,83,77,82,36,46,38)	31.40 (21.59 to 41.20)	42.17 (31.54 to 52.79)	31.17 (20.82 to 41.51)	28.05 (18.33 to 37.77)
W34: CHL on eyelashes (n=85,82,75,84,35,42,37)	40.00 (29.59 to 50.41)	36.59 (26.16 to 47.01)	37.33 (26.39 to 48.28)	34.52 (24.36 to 44.69)
W40: CHL on eyelashes (n=86,84,76,82,37,46,38)	43.02 (32.56 to 53.49)	39.29 (28.84 to 49.73)	32.89 (22.33 to 43.46)	36.59 (26.16 to 47.01)
W48: CHL on eyelashes (n=86,83,76,84,37,46,38)	41.86 (31.43 to 52.29)	37.35 (26.94 to 47.76)	38.16 (27.24 to 49.08)	34.52 (24.36 to 44.69)
W4: CHL on body (n=96,97,96,94,47,47,44)	11.46 (5.09 to 17.83)	9.28 (3.50 to 15.05)	10.42 (4.31 to 16.53)	6.38 (1.44 to 11.32)
W8:CHL on body (n=95,94,93,89,46,47,43)	14.74 (7.61 to 21.86)	15.96 (8.55 to 23.36)	13.98 (6.93 to 21.03)	10.11 (3.85 to 16.38)
W12: CHL on body (n=94,94,94,91,45,44,42)	17.02 (9.42 to 24.62)	19.15 (11.19 to 27.10)	14.89 (7.70 to 22.09)	14.29 (7.10 to 21.48)

W18: CHL on body (n=91,92,93,88,47,44,40)	19.78 (11.60 to 27.96)	25.00 (16.15 to 33.85)	15.05 (7.79 to 22.32)	15.91 (8.27 to 23.55)
W24: CHL on body (n=93,93,93,90,45,49,44)	25.81 (16.91 to 34.70)	27.96 (18.84 to 37.08)	20.43 (12.24 to 28.62)	22.22 (13.63 to 30.81)
W34: CHL on body (n=93,92,92,92,44,44,43)	33.33 (23.75 to 42.91)	33.70 (24.04 to 43.35)	31.52 (22.03 to 41.02)	26.09 (17.11 to 35.06)
W40: CHL on body (n=94,94,91,90,46,49,44)	35.11 (25.46 to 44.76)	36.17 (26.46 to 45.88)	30.77 (21.29 to 40.25)	25.56 (16.54 to 34.57)
W48: CHL on body (n=95,93,93,92,46,49,44)	34.74 (25.16 to 44.31)	34.41 (24.75 to 44.06)	36.56 (26.77 to 46.35)	30.43 (21.03 to 39.84)

End point values	Ritlecitinib (PF-06651600) 10 mg	Placebo, Ritlecitinib (PF-06651600) 200 mg then 50 mg	Placebo, Ritlecitinib (PF-06651600) 50 mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	63	65	66	
Units: Percentage of subjects				
number (confidence interval 95%)				
W4:CHL on scalp (n=123,123,120,124,59,63,63)	1.69 (0.00 to 4.99)	6.35 (0.33 to 12.37)	3.17 (0.00 to 7.50)	
W8:CHL on scalp (n=122,120,116,118,58,63,62)	1.72 (0.00 to 5.07)	4.76 (0.00 to 10.02)	8.06 (1.29 to 14.84)	
W12: CHL on scalp (n=121,123,118,120,56,60,61)	3.57 (0.00 to 8.43)	6.67 (0.35 to 12.98)	4.92 (0.00 to 10.34)	
W18: CHL on scalp (n=117,120,116,116,58,60,59)	8.62 (1.40 to 15.84)	8.33 (1.34 to 15.33)	6.78 (0.36 to 13.19)	
W24: CHL on scalp (n=120,120,118,118,57,65,63)	5.26 (0.00 to 11.06)	10.77 (3.23 to 18.31)	6.35 (0.33 to 12.37)	
W34: CHL on scalp (n=119,119,116,119,56,59,62)	7.14 (0.40 to 13.89)	22.03 (11.46 to 32.61)	11.29 (3.41 to 19.17)	
W40: CHL on scalp (n=122,123,115,117,56,65,63)	8.93 (1.46 to 16.40)	29.23 (18.17 to 40.29)	19.05 (9.35 to 28.74)	
W48: CHL on scalp (n=123,122,118,119,58,65,62)	8.62 (1.40 to 15.84)	33.85 (22.34 to 45.35)	20.97 (10.83 to 31.10)	
W4: CHL on eyebrows (n=99,98,94,96,46,48,46)	4.35 (0.00 to 10.24)	6.25 (0.00 to 13.10)	8.70 (0.55 to 16.84)	
W8:CHL on eyebrows (n=98,95,92,91,46,48,45)	6.52 (0.00 to 13.66)	4.17 (0.00 to 9.82)	11.11 (1.93 to 20.29)	
W12: CHL on eyebrows (n=97,97,94,94,43,45,44)	11.63 (2.05 to 21.21)	11.11 (1.93 to 20.29)	6.82 (0.00 to 14.27)	
W18: CHL on eyebrows (n=94,95,91,91,45,45,42)	13.33 (3.40 to 23.27)	11.11 (1.93 to 20.29)	7.14 (0.00 to 14.93)	
W24: CHL on eyebrows (n=96,94,92,92,44,50,46)	6.82 (0.00 to 14.27)	12.00 (2.99 to 21.01)	10.87 (1.87 to 19.86)	
W34: CHL on eyebrows (n=96,93,90,94,43,44,45)	16.28 (5.24 to 27.31)	22.73 (10.34 to 35.11)	13.33 (3.40 to 23.27)	
W40: CHL on eyebrows (n=97,95,90,92,45,50,46)	20.00 (8.31 to 31.69)	32.00 (19.07 to 44.93)	23.91 (11.59 to 36.24)	
W48: CHL on eyebrows (n=98,94,91,94,45,50,45)	15.56 (4.97 to 26.14)	38.00 (24.55 to 51.45)	33.33 (19.56 to 47.11)	
W4: CHL on eyelashes (n=87,87,79,86,38,45,38)	5.26 (0.00 to 12.36)	8.89 (0.57 to 17.20)	5.26 (0.00 to 12.36)	
W8: CHL on eyelashes (n=86,85,78,81,38,45,37)	7.89 (0.00 to 16.47)	6.67 (0.00 to 13.95)	8.11 (0.00 to 16.90)	
W12: CHL on eyelashes (n=85,86,79,84,36,41,36)	8.33 (0.00 to 17.36)	14.63 (3.82 to 25.45)	8.33 (0.00 to 17.36)	

W18: CHL on eyelashes (n=83,85,76,81,38,41,34)	7.89 (0.00 to 16.47)	12.20 (2.18 to 22.21)	2.94 (0.00 to 8.62)
W24: CHL on eyelashes (n=86,83,77,82,36,46,38)	8.33 (0.00 to 17.36)	13.04 (3.31 to 22.78)	2.63 (0.00 to 7.72)
W34: CHL on eyelashes (n=85,82,75,84,35,42,37)	11.43 (0.89 to 21.97)	21.43 (9.02 to 33.84)	13.51 (2.50 to 24.53)
W40: CHL on eyelashes (n=86,84,76,82,37,46,38)	10.81 (0.81 to 20.82)	28.26 (15.25 to 41.27)	13.16 (2.41 to 23.91)
W48: CHL on eyelashes (n=86,83,76,84,37,46,38)	8.11 (0.00 to 16.90)	39.13 (25.03 to 53.23)	28.95 (14.53 to 43.37)
W4: CHL on body (n=96,97,96,94,47,47,44)	2.13 (0.00 to 6.25)	4.26 (0.00 to 10.03)	11.36 (1.99 to 20.74)
W8: CHL on body (n=95,94,93,89,46,47,43)	2.17 (0.00 to 6.39)	6.38 (0.00 to 13.37)	11.63 (2.05 to 21.21)
W12: CHL on body (n=94,94,94,91,45,44,42)	4.44 (0.00 to 10.47)	11.36 (1.99 to 20.74)	7.14 (0.00 to 14.93)
W18: CHL on body (n=91,92,93,88,47,44,40)	10.64 (1.82 to 19.45)	9.09 (0.60 to 17.59)	7.50 (0.00 to 15.66)
W24: CHL on body (n=93,93,93,90,45,49,44)	6.67 (0.00 to 13.95)	16.33 (5.98 to 26.68)	11.36 (1.99 to 20.74)
W34: CHL on body (n=93,92,92,92,44,44,43)	11.36 (1.99 to 20.74)	22.73 (10.34 to 35.11)	9.30 (0.62 to 17.98)
W40: CHL on body (n=94,94,91,90,46,49,44)	8.70 (0.55 to 16.84)	22.45 (10.77 to 34.13)	11.36 (1.99 to 20.74)
W48: CHL on body (n=95,93,93,92,46,49,44)	10.87 (1.87 to 19.86)	34.69 (21.37 to 48.02)	20.45 (8.54 to 32.37)

Statistical analyses

No statistical analyses for this end point

Other pre-specified: Change From Baseline in Depression Subscale Score of Hospital Anxiety and Depression Scale (HADS) at Weeks 4, 8, 12, and 24

End point title	Change From Baseline in Depression Subscale Score of Hospital Anxiety and Depression Scale (HADS) at Weeks 4, 8, 12, and 24 ^[9]
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End point description:

HADS: validated 14-item PRO measure assess states of anxiety and depression over past week. Items rated on 4-point severity scale. HADS produces 2 scales, 1 each for anxiety(HADS-A) and depression(HADS-D), differentiating two states with established normal score cut-offs. Instrument have been validated for use by adolescents ≥ 12 years. Each subscale comprised of 7 items and subject responds how each item applies to him/her over past week prior to baseline visit, on 4point response scale. Separate scores calculated for anxiety and depression with score ranges from 0 (no presence of anxiety/depression) to 3 (severe feeling of anxiety/depression). Total score range was from 0-21 for depression subscale; higher score indicating greater severity of depression symptoms. Baseline was defined as pre-dose on Day 1. FAS included all subjects who were randomised, regardless of whether they received study medication. Here, "n" signifies subjects evaluable at specific time point.

End point type	Other pre-specified
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End point timeframe:

Baseline (Day 1), Week 4, 8, 12, and 24

Notes:

[9] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: Statistics were planned only for the arms specified

End point values	Ritlecitinib (PF-06651600) 200 mg then 50 mg	Ritlecitinib (PF-06651600) 200 mg then 30 mg	Ritlecitinib (PF-06651600) 50 mg	Ritlecitinib (PF-06651600) 30 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	132	130	130	132
Units: Units on a scale				
least squares mean (confidence interval 95%)				
Change at Week 4 (n= 126, 120, 123, 121, 58, 125)	-0.1 (-0.54 to 0.26)	-0.4 (-0.82 to 0.01)	-0.1 (-0.48 to 0.33)	-0.1 (-0.48 to 0.33)
Change at Week 8 (n= 124, 119, 118, 114, 56, 124)	-0.5 (-0.89 to 0.06)	-0.3 (-0.71 to 0.12)	-0.2 (-0.58 to 0.26)	0.2 (-0.25 to 0.59)
Change at Week 12 (n= 121, 119, 119, 114, 56, 120)	-0.6 (-1.04 to 0.21)	-0.4 (-0.81 to 0.03)	0.0 (-0.45 to 0.39)	0.1 (-0.32 to 0.53)
Change at Week 24 (n= 120, 118, 120, 116, 56, 124)	-0.4 (-0.79 to 0.07)	-0.8 (-1.21 to 0.35)	-0.3 (-0.70 to 0.16)	-0.2 (-0.66 to 0.21)

End point values	Ritlecitinib (PF-06651600) 10 mg	Placebo		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	63	131		
Units: Units on a scale				
least squares mean (confidence interval 95%)				
Change at Week 4 (n= 126, 120, 123, 121, 58, 125)	-0.3 (-0.86 to 0.32)	-0.3 (-0.73 to 0.07)		
Change at Week 8 (n= 124, 119, 118, 114, 56, 124)	-0.2 (-0.79 to 0.43)	-0.3 (-0.73 to 0.10)		
Change at Week 12 (n= 121, 119, 119, 114, 56, 120)	-0.5 (-1.07 to 0.15)	-0.1 (-0.53 to 0.30)		
Change at Week 24 (n= 120, 118, 120, 116, 56, 124)	-0.4 (-1.04 to 0.21)	0.0 (-0.46 to 0.39)		

Statistical analyses

No statistical analyses for this end point

Other pre-specified: Change From Baseline in Depression Subscale Score of Hospital Anxiety and Depression Scale (HADS) at Weeks 48

End point title	Change From Baseline in Depression Subscale Score of Hospital Anxiety and Depression Scale (HADS) at Weeks 48
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End point description:

HADS: validated 14-item PRO measure assess states of anxiety and depression over past week. Items rated on 4-point severity scale. HADS produces 2 scales, 1 each for anxiety(HADS-A) and depression(HADS-D), differentiating two states with established normal score cut-offs. Instrument have been validated for use by adolescents ≥ 12 years. Each subscale comprised of 7 items and subject responds how each item applies to him/her over past week prior to baseline visit, on 4-point response scale. Separate scores calculated for anxiety and depression with score ranges from 0 (no presence of anxiety/depression) to 3 (severe feeling of anxiety/depression). Total score range was from 0-21 for depression subscale; higher score indicating greater severity of depression symptoms. Baseline was defined as pre-dose on Day 1. FAS included all subjects who were randomised, regardless of whether they received study medication. Here, "n" signifies subjects evaluable at specific time point.

End point type	Other pre-specified
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End point timeframe:

Baseline (Day 1), Week 48

End point values	Ritlecitinib (PF-06651600) 200 mg then 50 mg	Ritlecitinib (PF-06651600) 200 mg then 30 mg	Ritlecitinib (PF-06651600) 50 mg	Ritlecitinib (PF-06651600) 30 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	132	130	130	132
Units: Units on a scale				
arithmetic mean (standard deviation)				
Baseline (n= 131,130, 130, 131, 63, 65, 66)	2.7 (± 2.60)	3.0 (± 3.16)	2.9 (± 3.00)	2.8 (± 2.99)
Change at Week 48(n=118,118,117,111,55,59,60)	-0.7 (± 2.13)	-0.4 (± 3.15)	-0.3 (± 2.67)	-0.6 (± 2.44)

End point values	Ritlecitinib (PF-06651600) 10 mg	Placebo, Ritlecitinib (PF-06651600) 200 mg then 50 mg	Placebo, Ritlecitinib (PF-06651600) 50 mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	63	65	66	
Units: Units on a scale				
arithmetic mean (standard deviation)				
Baseline (n= 131,130, 130, 131, 63, 65, 66)	2.8 (± 2.80)	3.2 (± 3.36)	3.3 (± 3.54)	
Change at Week 48(n=118,118,117,111,55,59,60)	-0.5 (± 2.53)	-0.9 (± 3.25)	-0.4 (± 3.28)	

Statistical analyses

No statistical analyses for this end point

Other pre-specified: Change From Baseline in Anxiety Subscale Score of Hospital Anxiety and Depression Scale (HADS) at Weeks 4, 8, 12, and 24

End point title	Change From Baseline in Anxiety Subscale Score of Hospital Anxiety and Depression Scale (HADS) at Weeks 4, 8, 12, and 24 ^[10]
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End point description:

HADS: validated 14-item PRO measure assess states of anxiety and depression over past week. Items rated on 4-point severity scale. HADS produces 2 scales, 1 each for anxiety(HADS-A) and depression(HADS-D), differentiating two states with established normal score cut-offs. Instrument have been validated for use by adolescents ≥ 12 years. Each subscale comprised of 7 items and subject responds how each item applies to him/her over past week prior to baseline visit, on 4-point response scale. Separate scores calculated for anxiety and depression with score ranges from 0 (no presence of anxiety/depression) to 3 (severe feeling of anxiety/depression). Total score range was from 0-21 for anxiety subscale; higher score indicating greater severity of anxiety symptoms. Baseline was defined as pre-dose on Day 1. FAS included all subjects who were randomised, regardless of whether they received study medication. Here, "n" signifies subjects evaluable at specific time point.

End point type	Other pre-specified
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End point timeframe:

Baseline (Day 1), Week 4, 8, 12, and 24

Notes:

[10] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: Statistics were planned only for the arms specified

End point values	Ritlecitinib (PF-06651600) 200 mg then 50 mg	Ritlecitinib (PF-06651600) 200 mg then 30 mg	Ritlecitinib (PF-06651600) 50 mg	Ritlecitinib (PF-06651600) 30 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	132	130	130	132
Units: Units on a scale				
least squares mean (confidence interval 95%)				
Change at Week 4 (n= 125, 119, 123, 121, 58, 125)	-0.3 (-0.78 to 0.08)	-0.4 (-0.79 to 0.08)	-0.4 (-0.79 to 0.08)	-0.5 (-0.97 to 0.10)
Change at Week 8 (n= 123, 119, 118, 114, 56, 123)	-0.8 (-1.25 to 0.31)	-0.4 (-0.88 to 0.07)	-0.8 (-1.27 to 0.31)	-0.3 (-0.79 to 0.17)
Change at Week 12 (n= 120, 119, 119, 114, 56, 121)	-0.7 (-1.22 to 0.28)	-0.9 (-1.40 to 0.46)	-0.7 (-1.22 to 0.27)	-0.3 (-0.77 to 0.19)
Change at Week 24 (n= 119, 118, 120, 115, 56, 124)	-0.8 (-1.26 to 0.25)	-0.7 (-1.19 to 0.18)	-0.8 (-1.28 to 0.27)	-0.3 (-0.76 to 0.26)

End point values	Ritlecitinib (PF-06651600) 10 mg	Placebo		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	63	131		
Units: Units on a scale				
least squares mean (confidence interval 95%)				
Change at Week 4 (n= 125, 119, 123, 121, 58, 125)	-0.6 (-1.25 to 0.02)	-0.1 (-0.54 to 0.32)		
Change at Week 8 (n= 123, 119, 118, 114, 56, 123)	-0.9 (-1.59 to 0.20)	-0.5 (-0.96 to 0.03)		
Change at Week 12 (n= 120, 119, 119, 114, 56, 121)	-0.9 (-1.55 to 0.17)	-0.4 (-0.84 to 0.09)		
Change at Week 24 (n= 119, 118, 120, 115, 56, 124)	-1.0 (-1.69 to 0.21)	-0.6 (-1.06 to 0.07)		

Statistical analyses

No statistical analyses for this end point

Other pre-specified: Change From Baseline in Anxiety Subscale Score of Hospital Anxiety and Depression Scale (HADS) at Week 48

End point title	Change From Baseline in Anxiety Subscale Score of Hospital Anxiety and Depression Scale (HADS) at Week 48
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End point description:

HADS: validated 14-item PRO measure assess states of anxiety and depression over past week. Items rated on 4-point severity scale. HADS produces 2 scales, 1 each for anxiety(HADS-A) and depression

(HADS-D), differentiating two states with established normal score cut-offs. Instrument have been validated for use by adolescents ≥ 12 years. Each subscale comprised of 7 items and subject responds how each item applies to him/her over past week prior to baseline visit, on 4-point response scale. Separate scores calculated for anxiety and depression with score ranges from 0 (no presence of anxiety/depression) to 3 (severe feeling of anxiety/depression). Total score range was from 0-21 for anxiety subscale; higher score indicating greater severity of anxiety symptoms. Baseline was defined as pre-dose on Day 1. FAS included all subjects who were randomised, regardless of whether they received study medication. Here, "n" signifies subjects evaluable at specific time point.

End point type	Other pre-specified
End point timeframe:	
Baseline (Day 1), Week 48	

End point values	Ritlecitinib (PF-06651600) 200 mg then 50 mg	Ritlecitinib (PF-06651600) 200 mg then 30 mg	Ritlecitinib (PF-06651600) 50 mg	Ritlecitinib (PF-06651600) 30 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	132	130	130	132
Units: Units on a scale				
arithmetic mean (standard deviation)				
Baseline (n= 130, 130, 130, 131, 63, 65, 66)	4.6 (\pm 3.84)	4.5 (\pm 3.18)	4.9 (\pm 3.31)	4.3 (\pm 3.42)
Change at Week 48(n=117,118,117,111,55,59,60)	-1.0 (\pm 2.92)	-0.8 (\pm 3.10)	-0.8 (\pm 3.09)	-0.5 (\pm 3.40)

End point values	Ritlecitinib (PF-06651600) 10 mg	Placebo, Ritlecitinib (PF-06651600) 200 mg then 50 mg	Placebo, Ritlecitinib (PF-06651600) 50 mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	63	65	66	
Units: Units on a scale				
arithmetic mean (standard deviation)				
Baseline (n= 130, 130, 130, 131, 63, 65, 66)	5.2 (\pm 3.38)	5.3 (\pm 4.20)	5.3 (\pm 3.70)	
Change at Week 48(n=117,118,117,111,55,59,60)	-1.2 (\pm 2.89)	-1.3 (\pm 3.31)	-0.5 (\pm 4.53)	

Statistical analyses

No statistical analyses for this end point

Other pre-specified: Percentage of Subjects With a Baseline Score Indicative of Depression Achieving Normal Depression Subscale Score of HADS at Week 4, 8, 12, 24, and 48

End point title	Percentage of Subjects With a Baseline Score Indicative of Depression Achieving Normal Depression Subscale Score of HADS at Week 4, 8, 12, 24, and 48
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End point description:

HADS: validated 14-item PRO measure assess states of anxiety and depression over past week. Items rated on 4-point severity scale. HADS produces 2 scales, 1 each for anxiety(HADS-A) and depression

(HADS-D), differentiating two states with established normal score cut-offs. Instrument have been validated for use by adolescents ≥ 12 years. Each subscale comprised of 7 items and subject responds how each item applies to him/her over past week prior to baseline visit, on 4point response scale. Separate scores calculated for anxiety and depression with score ranges from 0 (no presence of anxiety/depression) to 3 (severe feeling of anxiety/depression). Total score range was from 0-21 for depression subscale; higher score indicating greater severity of depression symptoms. Baseline was defined as pre-dose on Day 1. FAS included all subjects who were randomised, regardless of whether they received study medication. Here, "n" signifies subjects evaluable at specific time point.

End point type	Other pre-specified
End point timeframe:	
Week 4, 8, 12, 24 and 48	

End point values	Ritlecitinib (PF-06651600) 200 mg then 50 mg	Ritlecitinib (PF-06651600) 200 mg then 30 mg	Ritlecitinib (PF-06651600) 50 mg	Ritlecitinib (PF-06651600) 30 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	132	130	130	132
Units: Percentage of subjects				
number (confidence interval 95%)				
Week 4 (n= 7, 10, 13, 14, 5, 5, 10)	42.86 (6.20 to 79.52)	60.00 (29.64 to 90.36)	53.85 (26.75 to 80.95)	42.86 (16.93 to 68.78)
Week 8 (n= 6, 11, 12, 12, 5, 4, 10)	66.67 (28.95 to 100.00)	45.45 (16.03 to 74.88)	58.33 (30.44 to 86.23)	33.33 (6.66 to 60.01)
Week 12 (n= 6, 11, 12, 13, 5, 5, 8)	50.00 (9.99 to 90.01)	63.64 (35.21 to 92.06)	66.67 (39.99 to 93.34)	30.77 (5.68 to 55.86)
Week 24 (n= 7, 11, 12, 14, 4, 4, 10)	71.43 (37.96 to 100.00)	63.64 (35.21 to 92.06)	41.67 (13.77 to 69.56)	42.86 (16.93 to 68.78)
Week 48 (n= 6, 11, 12, 13, 5, 5, 10)	50.00 (9.99 to 90.01)	63.64 (35.21 to 92.06)	58.33 (30.44 to 86.23)	46.15 (19.05 to 73.25)

End point values	Ritlecitinib (PF-06651600) 10 mg	Placebo, Ritlecitinib (PF-06651600) 200 mg then 50 mg	Placebo, Ritlecitinib (PF-06651600) 50 mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	63	65	66	
Units: Percentage of subjects				
number (confidence interval 95%)				
Week 4 (n= 7, 10, 13, 14, 5, 5, 10)	40.00 (0.00 to 82.94)	60.00 (17.06 to 100.00)	50.00 (19.01 to 80.99)	
Week 8 (n= 6, 11, 12, 12, 5, 4, 10)	20.00 (0.00 to 55.06)	50.00 (1.00 to 99.00)	40.00 (9.64 to 70.36)	
Week 12 (n= 6, 11, 12, 13, 5, 5, 8)	20.00 (0.00 to 55.06)	60.00 (17.06 to 100.00)	62.50 (28.95 to 96.05)	
Week 24 (n= 7, 11, 12, 14, 4, 4, 10)	50.00 (1.00 to 99.00)	50.00 (1.00 to 99.00)	50.00 (19.01 to 80.99)	
Week 48 (n= 6, 11, 12, 13, 5, 5, 10)	80.00 (44.94 to 100.00)	60.00 (17.06 to 100.00)	60.00 (29.64 to 90.36)	

Statistical analyses

Other pre-specified: Percentage of Subjects With a Baseline Score Indicative of Anxiety Achieving Normal Anxiety Subscale Score of HADS at Week 4, 8, 12, 24, and 48

End point title	Percentage of Subjects With a Baseline Score Indicative of Anxiety Achieving Normal Anxiety Subscale Score of HADS at Week 4, 8, 12, 24, and 48
End point description:	
HADS: validated 14-item PRO measure assess states of anxiety and depression over past week. Items rated on 4-point severity scale. HADS produces 2 scales, 1 each for anxiety(HADS-A) and depression(HADS-D), differentiating two states with established normal score cut-offs. Instrument have been validated for use by adolescents ≥ 12 years. Each subscale comprised of 7 items and subject responds how each item applies to him/her over past week prior to baseline visit, on 4-point response scale. Separate scores calculated for anxiety and depression with score ranges from 0 (no presence of anxiety/depression) to 3 (severe feeling of anxiety/depression). Total score range was from 0-21 for anxiety subscale; higher score indicating greater severity of anxiety symptoms. Baseline was defined as pre-dose on Day 1. FAS included all subjects who were randomised, regardless of whether they received study medication. Here, "n" signifies subjects evaluable at specific time point.	
End point type	Other pre-specified
End point timeframe:	
Week 4, 8, 12, 24 and 48	

End point values	Ritlecitinib (PF-06651600) 200 mg then 50 mg	Ritlecitinib (PF-06651600) 200 mg then 30 mg	Ritlecitinib (PF-06651600) 50 mg	Ritlecitinib (PF-06651600) 30 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	132	130	130	132
Units: Percentage of subjects				
number (confidence interval 95%)				
Week 4 (29, 22, 26, 16, 15, 19, 13)	51.72 (33.54 to 69.91)	45.45 (24.65 to 66.26)	34.62 (16.33 to 52.90)	37.50 (13.78 to 61.22)
Week 8 (n= 28, 20, 25, 12, 14, 18,13)	46.43 (27.96 to 64.90)	50.00 (28.09 to 71.91)	68.00 (49.71 to 86.29)	41.67 (13.77 to 69.56)
Week 12 (n= 28, 19, 26, 16, 14, 19, 12)	50.00 (31.48 to 68.52)	57.89 (35.69 to 80.10)	38.46 (19.76 to 57.16)	56.25 (31.94 to 80.56)
Week 24 (n= 27, 20, 26, 15, 14, 18, 13)	51.85 (33.01 to 70.70)	65.00 (44.10 to 85.90)	50.00 (30.78 to 69.22)	46.67 (21.42 to 71.91)
Week 48 (n= 26, 18, 25, 14, 13, 19, 12)	53.85 (34.68 to 73.01)	66.67 (44.89 to 88.44)	60.00 (40.80 to 79.20)	50.00 (23.81 to 76.19)

End point values	Ritlecitinib (PF-06651600) 10 mg	Placebo, Ritlecitinib (PF-06651600) 200 mg then 50 mg	Placebo, Ritlecitinib (PF-06651600) 50 mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	63	65	66	
Units: Percentage of subjects				
number (confidence interval 95%)				
Week 4 (29, 22, 26, 16, 15, 19, 13)	40.00 (15.21 to 64.79)	31.58 (10.68 to 52.48)	30.77 (5.68 to 55.86)	
Week 8 (n= 28, 20, 25, 12, 14, 18,13)	71.43 (47.76 to 95.09)	33.33 (11.56 to 55.11)	46.15 (19.05 to 73.25)	

Week 12 (n= 28, 19, 26, 16, 14, 19, 12)	42.86 (16.93 to 68.78)	47.37 (24.92 to 69.82)	41.67 (13.77 to 69.56)	
Week 24 (n= 27, 20, 26, 15, 14, 18, 13)	57.14 (31.22 to 83.07)	44.44 (21.49 to 67.40)	38.46 (12.02 to 64.91)	
Week 48 (n= 26, 18, 25, 14, 13, 19, 12)	61.54 (35.09 to 87.98)	57.89 (35.69 to 80.10)	58.33 (30.44 to 86.23)	

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Baseline up to 5 weeks after last dose of study drug (maximum up to Week 53)

Adverse event reporting additional description:

Same event may appear as both an adverse event(AE) and serious adverse event(SAE). An event may be categorised as serious in one subject and as non-serious in another subject, or one subject may have experienced both a serious and non-serious event during the study. Safety analysis set: all subjects who received at least 1 dose of study medication.

Assessment type	Non-systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	24.0
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Reporting groups

Reporting group title	Ritlecitinib (PF-06651600) 200 mg then 50 mg
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Reporting group description:

Subjects aged 12 years or above with moderate to severe AA with $\geq 50\%$ hair loss of the scalp were randomised to receive Ritlecitinib 200 mg tablet once daily for 4 weeks (loading phase) and then 50 mg tablet once daily for next 20 weeks (maintenance phase). Subjects then entered into extension phase of 24 weeks and continued to receive 50 mg tablet once daily. Subjects were followed up to maximum of 5 weeks after the last dose of study drug .

Reporting group title	Ritlecitinib (PF-06651600) 50 mg
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Reporting group description:

Subjects aged 12 years or above with moderate to severe AA with $\geq 50\%$ hair loss of the scalp were randomised to receive Ritlecitinib 50 mg tablet once daily for 4 weeks (loading phase). Subjects then continued to receive 50 mg tablet once daily in maintenance phase of 20 weeks and extension phase of 24 weeks. Subjects were followed up to maximum of 5 weeks after the last dose of study drug.

Reporting group title	Ritlecitinib (PF-06651600) 200 mg then 30 mg
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Reporting group description:

Subjects aged 12 years or above with moderate to severe AA with $\geq 50\%$ hair loss of the scalp were randomised to receive Ritlecitinib 200 mg tablet once daily for 4 weeks (loading phase) and then 30 mg tablet once daily for next 20 weeks (maintenance phase). Subjects then entered into extension phase of 24 weeks and continued to receive 30 mg tablet once daily. Subjects were followed up to maximum of 5 weeks after the last dose of study drug.

Reporting group title	Ritlecitinib (PF-06651600) 30 mg
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Reporting group description:

Subjects aged 12 years or above with moderate to severe AA with $\geq 50\%$ hair loss of the scalp were randomised to receive Ritlecitinib 30 mg tablet once daily for 4 weeks (loading phase). Subjects then continued to receive 30 mg tablet once daily in maintenance phase of 20 weeks and extension phase of 24 weeks. Subjects were followed up to maximum of 5 weeks after the last dose of study drug.

Reporting group title	Ritlecitinib (PF-06651600) 10 mg
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Reporting group description:

Subjects aged 12 years or above with moderate to severe AA with $\geq 50\%$ hair loss of the scalp were randomised to receive Ritlecitinib 10 mg tablet once daily for 4 weeks (loading phase). Subjects then continued to receive 10 mg tablet once daily in maintenance phase of 20 weeks and extension phase of 24 weeks. Subjects were followed up to maximum of 5 weeks after the last dose of study drug.

Reporting group title	Placebo, Ritlecitinib (PF-06651600) 200 mg then 50 mg
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Reporting group description:

Subjects aged 12 years or above with moderate to severe AA with $\geq 50\%$ hair loss of the scalp were randomised to receive placebo once daily for 4 weeks (loading phase) and then continued placebo once daily for next 20 weeks (maintenance phase). Subjects then entered into extension phase of 24 weeks and received 200 mg tablet once daily for 4 weeks and then 50 mg tablet once daily for 20 weeks. Subjects were followed up to maximum of 5 weeks after the last dose of study drug.

Reporting group title	Placebo, Ritlecitinib (PF-06651600) 50 mg
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Reporting group description:

Subjects aged 12 years or above with moderate to severe AA with $\geq 50\%$ hair loss of the scalp were

randomised to receive placebo once daily for 4 weeks (loading phase) and then continued to receive placebo once daily for next 20 weeks (maintenance phase). Subjects then entered into extension phase of 24 weeks and receive 50 mg tablet once daily. Subjects were followed up to maximum of 5 weeks after the last dose of study drug.

Serious adverse events	Ritlecitinib (PF-06651600) 200 mg then 50 mg	Ritlecitinib (PF-06651600) 50 mg	Ritlecitinib (PF-06651600) 200 mg then 30 mg
Total subjects affected by serious adverse events			
subjects affected / exposed	4 / 131 (3.05%)	2 / 130 (1.54%)	2 / 129 (1.55%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Breast cancer			
subjects affected / exposed	0 / 131 (0.00%)	1 / 130 (0.77%)	0 / 129 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Invasive lobular breast carcinoma			
subjects affected / exposed	1 / 131 (0.76%)	0 / 130 (0.00%)	0 / 129 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Chemical poisoning			
subjects affected / exposed	0 / 131 (0.00%)	0 / 130 (0.00%)	1 / 129 (0.78%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pregnancy, puerperium and perinatal conditions			
Abortion spontaneous			
subjects affected / exposed	1 / 131 (0.76%)	0 / 130 (0.00%)	0 / 129 (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
Reproductive system and breast disorders			
Heavy menstrual bleeding			
subjects affected / exposed	0 / 131 (0.00%)	0 / 130 (0.00%)	0 / 129 (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			
Pulmonary embolism			
subjects affected / exposed	0 / 131 (0.00%)	1 / 130 (0.77%)	0 / 129 (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			
Eczema			
subjects affected / exposed	0 / 131 (0.00%)	0 / 130 (0.00%)	0 / 129 (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			
Conversion disorder			
subjects affected / exposed	0 / 131 (0.00%)	0 / 130 (0.00%)	0 / 129 (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
Suicidal behaviour			
subjects affected / exposed	0 / 131 (0.00%)	0 / 130 (0.00%)	1 / 129 (0.78%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Appendicitis			
subjects affected / exposed	1 / 131 (0.76%)	0 / 130 (0.00%)	1 / 129 (0.78%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diverticulitis			
subjects affected / exposed	0 / 131 (0.00%)	0 / 130 (0.00%)	0 / 129 (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
Empyema			
subjects affected / exposed	1 / 131 (0.76%)	0 / 130 (0.00%)	0 / 129 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			

subjects affected / exposed	1 / 131 (0.76%)	0 / 130 (0.00%)	0 / 129 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Ritlecitinib (PF-06651600) 30 mg	Ritlecitinib (PF-06651600) 10 mg	Placebo, Ritlecitinib (PF-06651600) 200 mg then 50 mg
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 132 (0.76%)	2 / 62 (3.23%)	0 / 65 (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)			
Breast cancer			
subjects affected / exposed	0 / 132 (0.00%)	0 / 62 (0.00%)	0 / 65 (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 / 132 (0.00%)	0 / 62 (0.00%)	0 / 65 (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			
Chemical poisoning			
subjects affected / exposed	0 / 132 (0.00%)	0 / 62 (0.00%)	0 / 65 (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
Pregnancy, puerperium and perinatal conditions			
Abortion spontaneous			
subjects affected / exposed	0 / 132 (0.00%)	0 / 62 (0.00%)	0 / 65 (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
Reproductive system and breast disorders			
Heavy menstrual bleeding			
subjects affected / exposed	0 / 132 (0.00%)	0 / 62 (0.00%)	0 / 65 (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			
Pulmonary embolism			
subjects affected / exposed	0 / 132 (0.00%)	0 / 62 (0.00%)	0 / 65 (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			
Eczema			
subjects affected / exposed	0 / 132 (0.00%)	1 / 62 (1.61%)	0 / 65 (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
Psychiatric disorders			
Conversion disorder			
subjects affected / exposed	0 / 132 (0.00%)	0 / 62 (0.00%)	0 / 65 (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
Suicidal behaviour			
subjects affected / exposed	0 / 132 (0.00%)	1 / 62 (1.61%)	0 / 65 (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
Infections and infestations			
Appendicitis			
subjects affected / exposed	0 / 132 (0.00%)	0 / 62 (0.00%)	0 / 65 (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
Diverticulitis			
subjects affected / exposed	1 / 132 (0.76%)	0 / 62 (0.00%)	0 / 65 (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
Empyema			
subjects affected / exposed	0 / 132 (0.00%)	0 / 62 (0.00%)	0 / 65 (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 / 132 (0.00%)	0 / 62 (0.00%)	0 / 65 (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	Placebo, Ritlecitinib (PF-06651600) 50 mg		
Total subjects affected by serious adverse events			
subjects affected / exposed	3 / 66 (4.55%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Breast cancer			
subjects affected / exposed	0 / 66 (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 / 66 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Injury, poisoning and procedural complications			
Chemical poisoning			
subjects affected / exposed	0 / 66 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pregnancy, puerperium and perinatal conditions			
Abortion spontaneous			
subjects affected / exposed	1 / 66 (1.52%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Reproductive system and breast disorders			
Heavy menstrual bleeding			
subjects affected / exposed	1 / 66 (1.52%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		

Respiratory, thoracic and mediastinal disorders			
Pulmonary embolism			
subjects affected / exposed	0 / 66 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Skin and subcutaneous tissue disorders			
Eczema			
subjects affected / exposed	0 / 66 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Psychiatric disorders			
Conversion disorder			
subjects affected / exposed	1 / 66 (1.52%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Suicidal behaviour			
subjects affected / exposed	0 / 66 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Infections and infestations			
Appendicitis			
subjects affected / exposed	0 / 66 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Diverticulitis			
subjects affected / exposed	0 / 66 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Empyema			
subjects affected / exposed	0 / 66 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Sepsis			

subjects affected / exposed	0 / 66 (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	Ritlecitinib (PF-06651600) 200 mg then 50 mg	Ritlecitinib (PF-06651600) 50 mg	Ritlecitinib (PF-06651600) 200 mg then 30 mg
Total subjects affected by non-serious adverse events			
subjects affected / exposed	84 / 131 (64.12%)	81 / 130 (62.31%)	76 / 129 (58.91%)
Nervous system disorders			
Dizziness			
subjects affected / exposed	9 / 131 (6.87%)	4 / 130 (3.08%)	8 / 129 (6.20%)
occurrences (all)	10	4	8
Headache			
subjects affected / exposed	17 / 131 (12.98%)	16 / 130 (12.31%)	14 / 129 (10.85%)
occurrences (all)	25	21	18
General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	4 / 131 (3.05%)	6 / 130 (4.62%)	6 / 129 (4.65%)
occurrences (all)	4	8	6
Gastrointestinal disorders			
Abdominal pain upper			
subjects affected / exposed	1 / 131 (0.76%)	5 / 130 (3.85%)	5 / 129 (3.88%)
occurrences (all)	1	6	5
Constipation			
subjects affected / exposed	1 / 131 (0.76%)	1 / 130 (0.77%)	0 / 129 (0.00%)
occurrences (all)	1	1	0
Diarrhoea			
subjects affected / exposed	9 / 131 (6.87%)	12 / 130 (9.23%)	4 / 129 (3.10%)
occurrences (all)	9	13	4
Nausea			
subjects affected / exposed	11 / 131 (8.40%)	3 / 130 (2.31%)	3 / 129 (2.33%)
occurrences (all)	14	5	3
Vomiting			

subjects affected / exposed occurrences (all)	6 / 131 (4.58%) 7	2 / 130 (1.54%) 3	7 / 129 (5.43%) 8
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	6 / 131 (4.58%)	3 / 130 (2.31%)	0 / 129 (0.00%)
occurrences (all)	6	4	0
Nasal congestion			
subjects affected / exposed	1 / 131 (0.76%)	2 / 130 (1.54%)	1 / 129 (0.78%)
occurrences (all)	1	2	1
Oropharyngeal pain			
subjects affected / exposed	4 / 131 (3.05%)	6 / 130 (4.62%)	6 / 129 (4.65%)
occurrences (all)	6	6	6
Skin and subcutaneous tissue disorders			
Acne			
subjects affected / exposed	6 / 131 (4.58%)	12 / 130 (9.23%)	10 / 129 (7.75%)
occurrences (all)	9	13	13
Pruritus			
subjects affected / exposed	4 / 131 (3.05%)	1 / 130 (0.77%)	7 / 129 (5.43%)
occurrences (all)	4	1	16
Rash			
subjects affected / exposed	5 / 131 (3.82%)	7 / 130 (5.38%)	3 / 129 (2.33%)
occurrences (all)	7	7	3
Urticaria			
subjects affected / exposed	9 / 131 (6.87%)	7 / 130 (5.38%)	9 / 129 (6.98%)
occurrences (all)	12	13	11
Psychiatric disorders			
Insomnia			
subjects affected / exposed	3 / 131 (2.29%)	2 / 130 (1.54%)	0 / 129 (0.00%)
occurrences (all)	3	2	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	4 / 131 (3.05%)	2 / 130 (1.54%)	5 / 129 (3.88%)
occurrences (all)	4	2	5
Myalgia			
subjects affected / exposed	6 / 131 (4.58%)	3 / 130 (2.31%)	3 / 129 (2.33%)
occurrences (all)	6	4	3

Infections and infestations			
Folliculitis			
subjects affected / exposed	11 / 131 (8.40%)	8 / 130 (6.15%)	11 / 129 (8.53%)
occurrences (all)	13	8	13
Influenza			
subjects affected / exposed	8 / 131 (6.11%)	3 / 130 (2.31%)	1 / 129 (0.78%)
occurrences (all)	8	3	1
Nasopharyngitis			
subjects affected / exposed	19 / 131 (14.50%)	18 / 130 (13.85%)	21 / 129 (16.28%)
occurrences (all)	22	21	27
Upper respiratory tract infection			
subjects affected / exposed	18 / 131 (13.74%)	11 / 130 (8.46%)	12 / 129 (9.30%)
occurrences (all)	21	14	16
Urinary tract infection			
subjects affected / exposed	11 / 131 (8.40%)	1 / 130 (0.77%)	3 / 129 (2.33%)
occurrences (all)	21	1	5

Non-serious adverse events	Ritlecitinib (PF-06651600) 30 mg	Ritlecitinib (PF-06651600) 10 mg	Placebo, Ritlecitinib (PF-06651600) 200 mg then 50 mg
Total subjects affected by non-serious adverse events			
subjects affected / exposed	77 / 132 (58.33%)	32 / 62 (51.61%)	39 / 65 (60.00%)
Nervous system disorders			
Dizziness			
subjects affected / exposed	8 / 132 (6.06%)	1 / 62 (1.61%)	0 / 65 (0.00%)
occurrences (all)	9	2	0
Headache			
subjects affected / exposed	24 / 132 (18.18%)	12 / 62 (19.35%)	8 / 65 (12.31%)
occurrences (all)	40	17	25
General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	6 / 132 (4.55%)	4 / 62 (6.45%)	3 / 65 (4.62%)
occurrences (all)	7	4	3
Gastrointestinal disorders			
Abdominal pain upper			
subjects affected / exposed	3 / 132 (2.27%)	0 / 62 (0.00%)	4 / 65 (6.15%)
occurrences (all)	3	0	4
Constipation			

subjects affected / exposed occurrences (all)	7 / 132 (5.30%) 7	1 / 62 (1.61%) 1	1 / 65 (1.54%) 1
Diarrhoea subjects affected / exposed occurrences (all)	8 / 132 (6.06%) 8	0 / 62 (0.00%) 0	4 / 65 (6.15%) 5
Nausea subjects affected / exposed occurrences (all)	12 / 132 (9.09%) 15	3 / 62 (4.84%) 6	8 / 65 (12.31%) 10
Vomiting subjects affected / exposed occurrences (all)	5 / 132 (3.79%) 8	1 / 62 (1.61%) 1	2 / 65 (3.08%) 2
Respiratory, thoracic and mediastinal disorders Cough subjects affected / exposed occurrences (all)	3 / 132 (2.27%) 3	0 / 62 (0.00%) 0	4 / 65 (6.15%) 4
Nasal congestion subjects affected / exposed occurrences (all)	3 / 132 (2.27%) 3	4 / 62 (6.45%) 4	1 / 65 (1.54%) 2
Oropharyngeal pain subjects affected / exposed occurrences (all)	1 / 132 (0.76%) 1	0 / 62 (0.00%) 0	2 / 65 (3.08%) 3
Skin and subcutaneous tissue disorders Acne subjects affected / exposed occurrences (all)	12 / 132 (9.09%) 12	3 / 62 (4.84%) 4	5 / 65 (7.69%) 5
Pruritus subjects affected / exposed occurrences (all)	3 / 132 (2.27%) 3	1 / 62 (1.61%) 1	1 / 65 (1.54%) 1
Rash subjects affected / exposed occurrences (all)	1 / 132 (0.76%) 2	0 / 62 (0.00%) 0	1 / 65 (1.54%) 1
Urticaria subjects affected / exposed occurrences (all)	5 / 132 (3.79%) 5	1 / 62 (1.61%) 1	4 / 65 (6.15%) 12
Psychiatric disorders			

Insomnia subjects affected / exposed occurrences (all)	1 / 132 (0.76%) 1	1 / 62 (1.61%) 1	1 / 65 (1.54%) 1
Musculoskeletal and connective tissue disorders			
Arthralgia subjects affected / exposed occurrences (all)	4 / 132 (3.03%) 4	2 / 62 (3.23%) 2	2 / 65 (3.08%) 3
Myalgia subjects affected / exposed occurrences (all)	5 / 132 (3.79%) 7	6 / 62 (9.68%) 8	0 / 65 (0.00%) 0
Infections and infestations			
Folliculitis subjects affected / exposed occurrences (all)	5 / 132 (3.79%) 5	4 / 62 (6.45%) 4	4 / 65 (6.15%) 4
Influenza subjects affected / exposed occurrences (all)	3 / 132 (2.27%) 3	3 / 62 (4.84%) 3	1 / 65 (1.54%) 1
Nasopharyngitis subjects affected / exposed occurrences (all)	21 / 132 (15.91%) 29	7 / 62 (11.29%) 13	7 / 65 (10.77%) 8
Upper respiratory tract infection subjects affected / exposed occurrences (all)	16 / 132 (12.12%) 20	2 / 62 (3.23%) 2	7 / 65 (10.77%) 8
Urinary tract infection subjects affected / exposed occurrences (all)	5 / 132 (3.79%) 6	0 / 62 (0.00%) 0	4 / 65 (6.15%) 4

Non-serious adverse events	Placebo, Ritlecitinib (PF-06651600) 50 mg		
Total subjects affected by non-serious adverse events subjects affected / exposed	39 / 66 (59.09%)		
Nervous system disorders			
Dizziness subjects affected / exposed occurrences (all)	2 / 66 (3.03%) 3		
Headache			

subjects affected / exposed occurrences (all)	8 / 66 (12.12%) 13		
General disorders and administration site conditions Fatigue subjects affected / exposed occurrences (all)	2 / 66 (3.03%) 2		
Gastrointestinal disorders Abdominal pain upper subjects affected / exposed occurrences (all) Constipation subjects affected / exposed occurrences (all) Diarrhoea subjects affected / exposed occurrences (all) Nausea subjects affected / exposed occurrences (all) Vomiting subjects affected / exposed occurrences (all)	0 / 66 (0.00%) 0 0 / 66 (0.00%) 0 1 / 66 (1.52%) 1 1 / 66 (1.52%) 1 3 / 66 (4.55%) 3		
Respiratory, thoracic and mediastinal disorders Cough subjects affected / exposed occurrences (all) Nasal congestion subjects affected / exposed occurrences (all) Oropharyngeal pain subjects affected / exposed occurrences (all)	2 / 66 (3.03%) 2 1 / 66 (1.52%) 1 5 / 66 (7.58%) 9		
Skin and subcutaneous tissue disorders Acne subjects affected / exposed occurrences (all)	8 / 66 (12.12%) 9		

Pruritus			
subjects affected / exposed	1 / 66 (1.52%)		
occurrences (all)	1		
Rash			
subjects affected / exposed	1 / 66 (1.52%)		
occurrences (all)	1		
Urticaria			
subjects affected / exposed	4 / 66 (6.06%)		
occurrences (all)	4		
Psychiatric disorders			
Insomnia			
subjects affected / exposed	4 / 66 (6.06%)		
occurrences (all)	4		
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	6 / 66 (9.09%)		
occurrences (all)	6		
Myalgia			
subjects affected / exposed	1 / 66 (1.52%)		
occurrences (all)	1		
Infections and infestations			
Folliculitis			
subjects affected / exposed	4 / 66 (6.06%)		
occurrences (all)	5		
Influenza			
subjects affected / exposed	0 / 66 (0.00%)		
occurrences (all)	0		
Nasopharyngitis			
subjects affected / exposed	4 / 66 (6.06%)		
occurrences (all)	4		
Upper respiratory tract infection			
subjects affected / exposed	6 / 66 (9.09%)		
occurrences (all)	7		
Urinary tract infection			
subjects affected / exposed	2 / 66 (3.03%)		
occurrences (all)	2		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported