POST-AUTHORIZATION SAFETY STUDY (PASS) PROGRESS REPORT

Title	A Prospective Active Surveillance Study to Monitor Growth, Development, and Maturation Among Adolescents with Atopic Dermatitis Exposed to Abrocitinib
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Medicinal product	Cibinqo®
Marketing Authorization Holder(s)	Pfizer Europe MA EEIG Boulevard de la Plaine 17 1050 Bruxelles Belgium

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1. MILESTONES

Milestone	Planned date	Actual date
Start of data collection	30 September 2025	30 September 2025
End of data collection	31 January 2036	
Study progress report 1	28 February 2026	
Study progress report 2	28 February 2028	
Interim report 1	30 April 2030	
Interim report 2	30 April 2032	
Interim report 3	30 April 2034	
Final study report	31 July 2036	
Registration in the HMA-EMA Catalogues of RWD Studies	14 April 2025	

2. RATIONALE AND BACKGROUND

Atopic dermatitis (AD) is a common, chronic skin condition characterized by inflammation of the skin and skin barrier defects caused by a combination of genetic and environmental factors (Bieber, 2010). Lesions of AD are characterized by erythema, itching, induration/papulation, and oozing/crusting (Hanifin & Reed, 2007; Bieber, 2010). Manifestations of AD typically appear early in life and often precede other allergic diseases such as asthma or allergic rhinitis. The prevalence of AD has been estimated to be 15-30% in children and 2-10% in adults (Oszukowska, Michalak, Gutfreund, & et al., 2015) presenting a significant burden on healthcare resources and patients' quality of life. The incidence of AD in developed countries has been increasing worldwide (Peters, Kellberger, Vogelberg, & et al., 2010), emphasizing the need for safe and effective therapies.

Treatment for AD can be topical or systemic; approved therapies include corticosteroids and targeted calcineurin, interleukin (IL), janus kinase (JAK), and phosphodiesterase-4 inhibitors. Abrocitinib (PF-04965842), an orally bioavailable small molecule, is a selective

JAK1 inhibitor. The inhibition of JAK1 modulates multiple cytokines involved in the pathophysiology of AD including IL-4, IL-13, IL-31, IL-22, and interferon gamma. Abrocitinib, available as 50, 100, and 200 mg oral film-coated tablets, was approved by the United States (US) Food and Drug Administration (FDA) for the treatment of moderate-to-severe AD in adults on 14 January 2022 and in adolescents 12 years of age and older on 9 February 2023. It was similarly approved by the European Medicines Agency (EMA) in adults on 9 December 2021 and in adolescents 12 years of age and older on 21 March 2024. Indication in the US is limited by the FDA to patients whose disease is not adequately controlled with other systemic drug products, while the EMA indicates it can be used in patients for whom treatment applied directly to the skin cannot be used or is not sufficient.

The available clinical and nonclinical data for abrocitinib do not suggest a risk of impaired physical growth and development, impaired sexual maturation, or an increased incidence of bone fractures in patients 12 years of age and older. However, as clinical data are limited, the potential impact of abrocitinib on these outcomes is considered missing information. Therefore, as part of the abrocitinib pharmacovigilance plan, a long-term follow-up study is being proposed to actively monitor physical growth and development, sexual maturation, and the incidence of bone fractures in adolescents 12-<18 years of age in the post-approval setting.

This noninterventional study is designated as a post-authorization safety study (PASS) and is a Category 3 RMP commitment to the EMA.

3. RESEARCH OBJECTIVES

The purpose of this study is to evaluate, among adolescents (12-<18 years of age) with AD who receive abrocitinib and those unexposed to abrocitinib and receiving advanced systemic treatments for AD, (1) physical growth and development, (2) sexual maturation, and (3) the incidence of bone fractures.

3.1. Primary Objectives

The primary objectives are:

Among adolescent participants with AD who are treated with abrocitinib and, separately, among adolescent participants with AD unexposed to abrocitinib and receiving advanced systemic treatments, to:

- Describe physical growth and development metrics;
- Describe sexual maturation metrics;
- Describe the incidence of bone fractures, stratified by abrocitinib dosage (100 mg and 200 mg QD).

3.2. Exploratory Objectives

The exploratory objectives (sample size permitting) are:

Among 1) adolescent participants with AD who are treated with abrocitinib and 2) adolescent participants with AD unexposed to abrocitinib and receiving advanced systemic treatments, to:

- Compare physical growth and development metrics;
- Compare sexual maturation metrics;
- Compare the incidence of bone fractures.

4. RESEARCH METHODS

This is a prospective observational cohort study of adolescents with moderate-to-severe AD who receive abrocitinib or another advanced systemic therapy approved in adolescents for the treatment of moderate-to-severe AD. This PASS will be conducted as a secondary database study using primary data collected by the PPD™ CorEvitas™ International Adolescent AD Registry. This clinical registry enrols 12–<16 -year-olds with moderate-to-severe AD in the US, Canada, and Europe. Participants are followed until they exit the registry or reach 18 years of age (ie, the participant's 18th birthday), whichever comes first. Registry sites are trained on the eligibility criteria, processes for data collection, and evaluation and documentation of adverse events and Registry protocol-defined safety events of interest. Registry data are collected approximately every 6 months, or at the time of AD treatment change, in the context of routine care. Data are collected through detailed provider and participant questionnaires, and source documents are submitted by participating providers. Adolescents who meet the inclusion criteria are enroled into the registry after having provided assent and parental consent. Participants can withdraw from the registry at any time at their own request, without giving any reason and without consequences for their future treatment.

The study period will include registry data collected from 21 March 2024 until 31 December 2035. Participants who satisfy all the following criteria will be included in analyses for this study:

- Adolescent (12-<16 years of age) enroled in the PPD CorEvitas International Adolescent AD Registry;
- At the time of registry enrollment, or within 6 months prior to registry enrollment:
  - Have newly initiated treatment with abrocitinib; OR
  - Have newly initiated another advanced systemic therapy approved for the treatment of moderate-to-severe AD in adolescents, without previous exposure to abrocitinib;
- Do not have short stature, defined as a height less than the third percentile for their age and sex.

The proposed primary analyses are descriptive and data on all eligible study participants will be analysed. The study will target the enrollment of approximately 500 participants in the US and Canada (250 abrocitinib, 250 comparators) and 200 participants in Europe (100 abrocitinib, 100 comparators), for a total of approximately 700 participants. Around 250 participants in each exposure cohort from the US and Canada will allow the study to estimate the mean height SDS with a 95% confidence interval (CI) half-width of 0.175, assuming a mean of 0 and a standard deviation of 1.41. The study will also be powered to estimate the mean age at Tanner stage progression with a 95% CI half-width ranging from

2.2 to 3.7 months, depending on sex and Tanner stage, and estimate the incidence rate (IR) of bone fractures with a 95% CI total width of 2.11 bone fractures per 100 person-years.

5. STUDY PROGRESS

5.1. Subjects

As of 30 September 2025, the data cut date used for the tables and figures detailed in Section 7 of this report, there have been 3 abrocitinib cohort exposure episodes and 56 comparator cohort exposure episodes among participants residing in North America (NA). Among participants residing in Europe (EUR), there have been 5 abrocitinib cohort exposure episodes and 20 comparator cohort exposure episodes. As of the data cut used for this report, no participants have had a follow-up visit following a qualifying initiation of abrocitinib. Among the participants with at least one follow-up following a qualifying initiation of a comparator medication, the mean duration of follow-up is 0.55 years among NA-residing participants and 0.46 years among EUR-residing participants. Participants are followed until they either withdraw from the registry or reach 18 years of age. To date, one participant residing in EUR has withdrawn consent from the registry, no participants have withdrawn due to reaching 18 years of age. The observed withdrawal rate is within expected limits to date when compared with similar registries (e.g., after two years, 17% of patients had withdrawn from the PROSE Registry) (Simpson, Lockshin, Lee, & et al., 2024).

5.2. Study Conduct

To date, the study has been conducted in full compliance with the approved protocol. No problems or deviations have occurred, and as such, no corrective actions have been required.

5.3. Actions Taken for Safety Reasons

No actions have been taken for safety reasons since study initiation.

5.4. Overall Conclusions

To date, accrual to the abrocitinib cohort remains below projected levels, particularly among participants residing in NA. In contrast, the comparator cohort is currently above projected levels in both regions.

Registry sites have reported several recruitment barriers, including eligibility requirements (e.g., therapy initiation before age 12 when deemed clinically appropriate on currently approved advanced systemic therapies, particularly in NA) and variability in patient populations (e.g., patients aging out of the eligibility window before starting or switching to an eligibly therapy, missed appointments, and reduced patient volume due to seasonal or annual fluctuations typical of the disease state). Recruitment is additionally impacted by several country-specific barriers, including line of therapy for abrocitinib, parental hesitation/consent, and insurance or reimbursement restrictions, which limit the pool of eligible patients.

To mitigate the relatively low accrual of abrocitinib patients in the context of early post-approval implementation and increase enrollment capacity, the PPD CorEvitas International Adolescent AD Registry has been expanded beyond the original target of 50 sites (25 in NA, 25 in EUR) to enable targeted site recruitment based on prescribing patterns and abrocitinib uptake, informed by real world prescribing data. Further expansion of the site network is

underway and planned through 2026, with a target of adding 25 additional sites with an emphasis in NA. Additionally, the Registry sponsor is implementing several other mitigation strategies to support overall enrollment, such as the optimization of various participant recruitment channels (e.g., market share data, provider referrals, professional organizations, publications, conferences), as well as active engagement with investigators, the deployment of a structured survey to better understand and address investigator-identified enrollment challenges, and tailored outreach to further support sites and principal investigators. As the accrual period progresses for this study, enrollment and accrual metrics will continue to be closely monitored to ensure progress toward overall study goals.

6. REFERENCES

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7. TABLES AND FIGURES

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Table 1. Participant characteristics, clinical and disease characteristics, and treatment history at index among NA-residing participants

	Abrocitinib N=3	Comparator N=56
Participant demographics		
Age (years)		
mean (SD)	14.03 (1.73)	13.97 (1.24)
median (Q1, Q3)	14.33 (13.25, 14.96)	13.92 (12.75, 14.96)
minimum, maximum	12.17, 15.58	12.00, 15.92
Missing (n)	0	0
Sex, n (%)		
Female	2 (66.67%)	30 (53.57%)
Male	1 (33.33%)	26 (46.43%)
Intersex	0 (0%)	0 (0%)
Missing (n)	0	0
Race (NA only), n (%)		
American Indian or Alaskan Native	0 (0.00%)	0 (0.00%)
Asian	0 (0.00%)	7 (15.22%)
Black/African American	1 (33.33%)	8 (17.39%)
Native Hawaiian or Other Pacific Islander	0 (0.00%)	0 (0.00%)
Other/Multiracial	2 (66.67%)	11 (23.91%)
White	0 (0.00%)	20 (43.48%)
Missing (n)	0	10
Ethnicity (NA only), n (%)		
Hispanic/Latino	1 (33.33%)	13 (27.66%)
Non-Hispanic/Non-Latino	2 (66.67%)	34 (72.34%)
Missing (n)	0	9
Smoking status [a], n (%)		
Current or former smoker	0 (0.00%)	0 (0.00%)
Never smoker	3 (100.00%)	56 (100.00%)
Missing (n)	0	0
Alcohol use in past 3 months, n (%)		
Some use	0 (0.00%)	0 (0.00%)
No use	3 (100.00%)	56 (100.00%)
Missing (n)	0	0
History of comorbidities, n (%)		
Anaphylaxis/Severe hypersensitivity	0 (0.00%)	2 (3.57%)
Cardiovascular [b]	0 (0.00%)	0 (0.00%)
Hepatic/Gastrointestinal disease [c]	0 (0.00%)	0 (0.00%)

Table 1. Participant characteristics, clinical and disease characteristics, and treatment history at index among NA-residing participants

	Abrocitinib N=3	Comparator N=56
Malignancy [d]	0 (0.00%)	0 (0.00%)
Fracture (serious or non-serious)	1 (33.33%)	1 (1.79%)
Ophthalmologic/Ocular [e]	0 (0.00%)	3 (5.36%)
Venous thromboembolism [f]	0 (0.00%)	0 (0.00%)
Serious infection [g]	0 (0.00%)	0 (0.00%)
Other comorbidities [h]	1 (33.33%)	11 (19.64%)
Missing (n)	0	0
Disease characteristics at index		
Years since AD symptom onset		
mean (SD)	14.06 (2.94)	11.39 (4.49)
median (Q1, Q3)	14.81 (12.81, 15.68)	12.57 (9.76, 14.70)
minimum, maximum	10.81, 16.56	0.31, 18.50
Missing (n)	0	0
Years since AD diagnosis		
mean (SD)	9.16 (6.62)	9.21 (5.24)
median (Q1, Q3)	10.81 (6.34, 12.81)	11.23 (4.25, 13.35)
minimum, maximum	1.87, 14.81	0.00, 16.15
Missing (n)	0	0
BSA % involvement (range: 0%–100%)		
mean (SD)	14.25 (18.01)	17.29 (17.18)
median (Q1, Q3)	5.00 (3.88, 20.00)	12.00 (4.75, 24.50)
minimum, maximum	2.75, 35.00	0.00, 70.00
Missing (n)	0	0
BSA % involvement (categorical), n (%)		
Clear (0%)	0 (0.00%)	3 (5.36%)
Mild (>0%–16%)	2 (66.67%)	33 (58.93%)
Moderate (16%–<40%)	1 (33.33%)	13 (23.21%)
Severe (40%–100%)	0 (0.00%)	7 (12.50%)
Missing (n)	0	0
EASI (range: 0–72)		
mean (SD)	5.73 (6.48)	9.91 (9.97)
median (Q1, Q3)	2.40 (2.00, 7.80)	6.95 (1.75, 13.65)
minimum, maximum	1.60, 13.20	0.00, 38.40
Missing (n)	0	0
EASI (categorical), n (%)		
Clear (0)	0 (0.00%)	4 (7.14%)

Table 1. Participant characteristics, clinical and disease characteristics, and treatment history at index among NA-residing participants

	Abrocitinib N=3	Comparator N=56
Mild (>0–<6)	2 (66.67%)	21 (37.50%)
Moderate (6–<23)	1 (33.33%)	25 (44.64%)
Severe (23–72)	0 (0.00%)	6 (10.71%)
Missing (n)	0	0
Severity of nail changes due to AD (range: 0 = clear/none to 100 = severe abnormalities)		
mean (SD)	0.00 (0.00)	1.73 (9.14)
median (Q1, Q3)	0.00 (0.00, 0.00)	0.00 (0.00, 0.00)
minimum, maximum	0.00, 0.00	0.00, 60.00
Missing (n)	0	0
SCORAD (range: 0–103)		
mean (SD)	33.52 (9.86)	33.56 (18.90)
median (Q1, Q3)	33.52 (30.04, 37.01)	36.10 (18.80, 47.05)
minimum, maximum	26.55, 40.50	0.00, 78.70
Missing (n)	1	1
SCORAD (categorical), n (%)		
Clear (<10)	0 (0.00%)	8 (14.55%)
Mild (10–<29)	1 (50.00%)	16 (29.09%)
Moderate (29–<49)	1 (50.00%)	20 (36.36%)
Severe (49–103)	0 (0.00%)	11 (20.00%)
Missing (n)	1	1
vIGA-AD (range: 0–4), n (%)		
Clear (0)	0 (0.00%)	2 (3.57%)
Almost clear (1)	0 (0.00%)	9 (16.07%)
Mild (2)	1 (33.33%)	12 (21.43%)
Moderate (3)	2 (66.67%)	26 (46.43%)
Severe (4)	0 (0.00%)	7 (12.50%)
Missing (n)	0	0
Patient-reported outcomes		
Global assessment of AD severity, n (%)		
Clear	0 (0.00%)	3 (5.45%)
Almost clear	0 (0.00%)	9 (16.36%)
Mild	1 (50.00%)	11 (20.00%)
Moderate	1 (50.00%)	20 (36.36%)
Severe	0 (0.00%)	12 (21.82%)
Missing (n)	1	1

Table 1. Participant characteristics, clinical and disease characteristics, and treatment history at index among NA-residing participants

	Abrocitinib N=3	Comparator N=56
Global Assessment of AD control, n (%)		
Completely controlled	0 (0.00%)	7 (12.73%)
Mostly controlled	0 (0.00%)	13 (23.64%)
Moderately controlled	0 (0.00%)	15 (27.27%)
A little controlled	2 (100.00%)	14 (25.45%)
Not at all controlled	0 (0.00%)	6 (10.91%)
Missing (n)	1	1
POEM (range: 0–28)		
mean (SD)	10.00 (8.49)	10.84 (7.62)
median (Q1, Q3)	10.00 (7.00, 13.00)	9.00 (4.00, 18.00)
minimum, maximum	4.00, 16.00	0.00, 25.00
Missing (n)	1	1
POEM (categorical), n (%)		
Clear or almost clear (0–2)	0 (0.00%)	11 (20.00%)
Mild (3–7)	1 (50.00%)	12 (21.82%)
Moderate (8–16)	1 (50.00%)	16 (29.09%)
Severe (17–24)	0 (0.00%)	15 (27.27%)
Very severe (25–28)	0 (0.00%)	1 (1.82%)
Missing (n)	1	1
CDLQI (range: 0–30)		
mean (SD)	2.67 (2.89)	6.93 (5.37)
median (Q1, Q3)	1.00 (1.00, 3.50)	6.00 (2.00, 11.00)
minimum, maximum	1.00, 6.00	0.00, 21.00
Missing (n)	0	1
CDLQI (categorical), n (%)		
No effect on child's life (0–1)	2 (66.67%)	13 (23.64%)
Small effect (2–6)	1 (33.33%)	17 (30.91%)
Moderate effect (7–12)	0 (0.00%)	19 (34.55%)
Very large effect (13–18)	0 (0.00%)	4 (7.27%)
Extremely large effect (19–30)	0 (0.00%)	2 (3.64%)
Missing (n)	0	1
PHQ-4 (range: 0–12)		
mean (SD)	3.33 (2.89)	1.60 (2.63)
median (Q1, Q3)	5.00 (2.50, 5.00)	0.00 (0.00, 4.00)
minimum, maximum	0.00, 5.00	0.00, 11.00
Missing (n)	0	1

Table 1. Participant characteristics, clinical and disease characteristics, and treatment history at index among NA-residing participants

	Abrocitinib N=3	Comparator N=56
PHQ-4 (categorical), n (%)		
Normal (0–2)	1 (33.33%)	39 (70.91%)
Mild (3–5)	2 (66.67%)	11 (20.00%)
Moderate (6–8)	0 (0.00%)	3 (5.45%)
Severe (9–12)	0 (0.00%)	2 (3.64%)
Missing (n)	0	1
ADCT (range: 0–24)		
mean (SD)	4.33 (1.53)	7.05 (5.62)
median (Q1, Q3)	4.00 (3.50, 5.00)	6.00 (2.00, 11.50)
minimum, maximum	3.00, 6.00	0.00, 24.00
Missing (n)	0	1
ADCT (categorical), n (%)		
Controlled (<7)	3 (100.00%)	29 (52.73%)
Not controlled (≥7)	0 (0.00%)	26 (47.27%)
Missing (n)	0	1
SCORAD Average pruritus in past 3 days (range: 0–10)		
mean (SD)	5.50 (0.71)	4.07 (2.83)
median (Q1, Q3)	5.50 (5.25, 5.75)	4.00 (2.00, 7.00)
minimum, maximum	5.00, 6.00	0.00, 9.00
Missing (n)	1	1
SCORAD Average sleeplessness in past 3 days (range: 0–10)		
mean (SD)	1.50 (2.12)	2.31 (2.49)
median (Q1, Q3)	1.50 (0.75, 2.25)	1.00 (0.00, 4.00)
minimum, maximum	0.00, 3.00	0.00, 9.00
Missing (n)	1	1
Average pruritus in past 7 days (range: 0–10)		
mean (SD)	4.50 (0.71)	4.73 (2.91)
median (Q1, Q3)	4.50 (4.25, 4.75)	5.00 (2.00, 7.00)
minimum, maximum	4.00, 5.00	0.00, 10.00
Missing (n)	1	1
Peak pruritus in last 24 hours (range: 0–10)		
mean (SD)	5.50 (2.12)	4.18 (3.13)
median (Q1, Q3)	5.50 (4.75, 6.25)	5.00 (1.00, 7.00)
minimum, maximum	4.00, 7.00	0.00, 10.00
Missing (n)	1	1

Table 1. Participant characteristics, clinical and disease characteristics, and treatment history at index among NA-residing participants

	Abrocitinib N=3	Comparator N=56
Worst skin pain in past 24 hours (range: 0–10)		
mean (SD)	6.50 (0.71)	3.11 (2.97)
median (Q1, Q3)	6.50 (6.25, 6.75)	3.00 (0.00, 5.00)
minimum, maximum	6.00, 7.00	0.00, 10.00
Missing (n)	1	1
Worst fatigue in past 7 days (range: 0–10)		
mean (SD)	4.33 (3.79)	2.98 (2.82)
median (Q1, Q3)	6.00 (3.00, 6.50)	2.00 (0.00, 5.00)
minimum, maximum	0.00, 7.00	0.00, 10.00
Missing (n)	0	1
Treatment history at index		
Number of prior biologics		
mean (SD)	1.00 (1.00)	0.21 (0.41)
median (Q1, Q3)	1.00 (0.50, 1.50)	0.00 (0.00, 0.00)
minimum, maximum	0.00, 2.00	0.00, 1.00
Missing (n)	0	0
Index drug, n (%)		
abrocitinib (Cibinqo™)	3 (100.00%)	--
50 mg	0 (0.00%)	--
100 mg	3 (100.00%)	--
200 mg	0 (0.00%)	--
baricitinib (Olumiant™)	--	0 (0.00%)
dupilumab (Dupixent™)	--	35 (62.50%)
lebrikizumab (Ebglyss™)	--	6 (10.71%)
nemolizumab (Nemluvio™)	--	2 (3.57%)
tralokinumab (Adbry™, Adtralza™)	--	3 (5.36%)
upadacitinib (Rinvoq™)	--	10 (17.86%)
Missing (n)	0	0

Table 1. Participant characteristics, clinical and disease characteristics, and treatment history at index among NA-residing participants

	Abrocitinib N=3	Comparator N=56

Data as of September 30, 2025

Percentages are calculated among observations with non-missing data.

Abbreviations: AD = atopic dermatitis; ADCT = Atopic Dermatitis Control Tool; ADHD = Attention-deficit/hyperactivity disorder; BSA = body surface area; CDLQI = Children's Dermatology Life Quality Index; EASI = Eczema Area and Severity Index; NA = North America; PHQ-4 = Patient Health Questionnaire; POEM = Patient Oriented Eczema Measure; Q = quartile; SCORAD = SCORing Atopic Dermatitis; SD = standard deviation; vIGA-AD = Validated Investigator Global Assessment for Atopic Dermatitis

a Includes other tobacco or nicotine products, such as e-cigarettes.

b Defined as prior history of one or more of the following: cardiac arrhythmia; congestive heart failure; coronary angioplasty with or without cardiac stent; coronary artery bypass graft; coronary artery disease; myocardial infarction; peripheral arterial disease (stable), peripheral arterial thromboembolic event; peripheral ischemia or gangrene (necrosis); stroke; transient ischemic attack; unstable angina; urgent peripheral arterial revascularization, other arterial thromboembolism event; other cardiac or vascular condition.

c Defined as prior history of one or more of the following: Crohn's disease; ulcerative colitis; eosinophilic esophagitis; fatty liver disease/nonalcoholic fatty liver disease; gastroesophageal reflux disease/acid reflux; hepatic event (increased liver function tests >3x upper limit of normal); hepatotoxicity (including drug-induced liver injury); other hepatic event or gastrointestinal disorder.

d Defined as prior history of one or more of the following: breast cancer; cervical cancer; colon cancer; leukemia; lung cancer; lymphoma; melanoma skin cancer; nonmelanoma skin cancer; prostate cancer; uterine cancer; other malignancy.

e Defined as prior history of one or more of the following: allergic conjunctivitis; blepharitis; cataract; conjunctivitis (drug-induced, infectious [bacterial, viral, or unknown pathogen], nonallergic noninfectious [e.g., atopic conjunctivitis], vernal, or unknown etiology [chronic follicular/papillary]); glaucoma; herpetic eye disease (H. simplex or H. zoster); keratitis; keratoconus; ocular ulcer (e.g., corneal ulcer, ulcerative blepharitis, ulcerative conjunctivitis); retinal detachment; other ocular event.

f Defined as prior history of one or more of the following: deep vein thrombosis; pulmonary embolism; other venous thromboembolism.

g Defined as prior history of one or more of the following infections that are serious or require treatment with IV antibiotics, or active tuberculosis regardless of seriousness: bronchitis; candidiasis (cutaneous, genital/vulvovaginal, or oropharyngeal); cellulitis or erysipelas; cold sores (Herpes labialis); COVID-19 (confirmed or suspected); diverticulitis; eczema herpeticum; furuncles (boils); gastroenteritis; herpes zoster (ear involvement, eye involvement, other location, or shingles); HIV/AIDS; meningitis/encephalitis; molluscum contagiosum; osteomyelitis; otitis (ear infection); pneumonia; progressive multifocal leukoencephalopathy; sepsis; sinusitis; superficial skin infection (e.g., impetigo, pustules); active tuberculosis; upper respiratory infection; urinary tract infection; viral hepatitis; warts (cutaneous); other infection or skin infection.

h Defined as prior history of one or more of the following: anxiety; asthma (allergic); attention-deficit/hyperactivity disorder; autism spectrum disorder; chronic obstructive pulmonary disease; depression; diabetes mellitus (type 1 or 2); eosinophilia; fibromyalgia; hyperlipidemia; hypertension; insomnia; interstitial lung disease/pulmonary fibrosis; other medical condition; other metabolic condition; other musculoskeletal condition; other neurological disorder; other psychiatric disorder; other respiratory condition

Table 2. Participant characteristics, clinical and disease characteristics, and treatment history at index among EUR-residing participants

	Abrocitinib N=5	Comparator N=20
Participant demographics		
Age (years)		
mean (SD)	13.97 (1.11)	14.38 (1.28)
median (Q1, Q3)	14.00 (13.08, 14.00)	14.12 (13.65, 15.60)
minimum, maximum	13.00, 15.75	12.00, 15.92
Missing (n)	0	0
Sex, n (%)		
Female	0 (0%)	10 (50.00%)
Male	5 (100.00%)	10 (50.00%)
Intersex	0 (0%)	0 (0%)
Missing (n)	0	0
Smoking status [a], n (%)		
Current or former smoker	0 (0.00%)	0 (0.00%)
Never smoker	5 (100.00%)	20 (100.00%)
Missing (n)	0	0
Alcohol use in past 3 months, n (%)		
Some use	0 (0.00%)	3 (15.00%)
No use	5 (100.00%)	17 (85.00%)
Missing (n)	0	0
History of comorbidities, n (%)		
Anaphylaxis/severe hypersensitivity	1 (20.00%)	0 (0.00%)
Cardiovascular [b]	0 (0.00%)	1 (5.00%)
Hepatic/gastrointestinal disease [c]	1 (20.00%)	2 (10.00%)
Malignancy [d]	0 (0.00%)	0 (0.00%)
Fracture (serious or non-serious)	0 (0.00%)	0 (0.00%)
Ophthalmologic/ocular [e]	0 (0.00%)	0 (0.00%)
Venous thromboembolism [f]	0 (0.00%)	0 (0.00%)
Serious infection [g]	0 (0.00%)	5 (25.00%)
Other comorbidities [h]	1 (20.00%)	6 (30.00%)
Missing (n)	0	0
Disease characteristics at index		
Years since AD symptom onset		
mean (SD)	5.56 (4.88)	9.89 (4.31)
median (Q1, Q3)	4.98 (3.01, 5.35)	11.69 (5.63, 12.65)
minimum, maximum	0.80, 13.67	2.03, 15.81

Table 2. Participant characteristics, clinical and disease characteristics, and treatment history at index among EUR-residing participants

	Abrocitinib N=5	Comparator N=20
Missing (n)	0	1
Years since AD diagnosis		
mean (SD)	4.41 (5.51)	8.14 (5.02)
median (Q1, Q3)	2.58 (0.54, 4.98)	10.65 (2.69, 12.04)
minimum, maximum	0.30, 13.67	1.46, 15.74
Missing (n)	0	1
BSA % involvement (range: 0%–100%)		
mean (SD)	14.50 (1.00)	31.52 (18.82)
median (Q1, Q3)	15.00 (14.50, 15.00)	27.00 (20.50, 39.00)
minimum, maximum	13.00, 15.00	5.00, 81.00
Missing (n)	1	5
BSA % involvement (categorical), n (%)		
Clear (0%)	0 (0.00%)	0 (0.00%)
Mild (>0%–16%)	4 (100.00%)	2 (13.33%)
Moderate (16%–<40%)	0 (0.00%)	9 (60.00%)
Severe (40%–100%)	0 (0.00%)	4 (26.67%)
Missing (n)	1	5
EASI (range: 0–72)		
mean (SD)	5.35 (4.53)	16.47 (12.93)
median (Q1, Q3)	5.05 (2.58, 7.82)	14.60 (8.05, 20.10)
minimum, maximum	0.40, 10.90	2.80, 53.00
Missing (n)	1	5
EASI (categorical), n (%)		
Clear (0)	0 (0.00%)	0 (0.00%)
Mild (>0–<6)	2 (50.00%)	3 (20.00%)
Moderate (6–<23)	2 (50.00%)	9 (60.00%)
Severe (23–72)	0 (0.00%)	3 (20.00%)
Missing (n)	1	5
Severity of nail changes due to AD (range: 0 = clear/none to 100 = severe abnormalities)		
mean (SD)	4.00 (8.94)	4.70 (12.11)
median (Q1, Q3)	0.00 (0.00, 0.00)	0.00 (0.00, 0.00)
minimum, maximum	0.00, 20.00	0.00, 50.00
Missing (n)	0	0
SCORAD (range: 0–103)		
mean (SD)	31.02 (19.85)	41.68 (15.76)

Table 2. Participant characteristics, clinical and disease characteristics, and treatment history at index among EUR-residing participants

	Abrocitinib N=5	Comparator N=20
median (Q1, Q3)	29.75 (15.38, 45.40)	42.40 (37.60, 48.20)
minimum, maximum	12.00, 52.60	13.00, 69.70
Missing (n)	1	7
SCORAD (categorical), n (%)		
Clear (<10)	0 (0.00%)	0 (0.00%)
Mild (10–<29)	2 (50.00%)	3 (23.08%)
Moderate (29–<49)	1 (25.00%)	7 (53.85%)
Severe (49–103)	1 (25.00%)	3 (23.08%)
Missing (n)	1	7
vIGA-AD (range: 0–4), n (%)		
Clear (0)	0 (0.00%)	0 (0.00%)
Almost clear (1)	1 (20.00%)	2 (10.00%)
Mild (2)	1 (20.00%)	6 (30.00%)
Moderate (3)	3 (60.00%)	10 (50.00%)
Severe (4)	0 (0.00%)	2 (10.00%)
Missing (n)	0	0
Patient-reported outcomes		
Global assessment of AD severity, n (%)		
Clear	0 (0.00%)	0 (0.00%)
Almost clear	0 (0.00%)	3 (16.67%)
Mild	2 (40.00%)	2 (11.11%)
Moderate	2 (40.00%)	9 (50.00%)
Severe	1 (20.00%)	4 (22.22%)
Missing (n)	0	2
Global Assessment of AD control, n (%)		
Completely controlled	0 (0.00%)	1 (5.26%)
Mostly controlled	2 (40.00%)	4 (21.05%)
Moderately controlled	1 (20.00%)	9 (47.37%)
A little controlled	1 (20.00%)	3 (15.79%)
Not at all controlled	1 (20.00%)	2 (10.53%)
Missing (n)	0	1
POEM (range: 0–28)		
mean (SD)	12.40 (7.54)	9.47 (5.36)
median (Q1, Q3)	15.00 (5.00, 17.00)	8.00 (4.00, 14.00)
minimum, maximum	4.00, 21.00	2.00, 19.00
Missing (n)	0	3

Table 2. Participant characteristics, clinical and disease characteristics, and treatment history at index among EUR-residing participants

	Abrocitinib N=5	Comparator N=20
POEM (categorical), n (%)		
Clear or almost clear (0–2)	0 (0.00%)	1 (5.88%)
Mild (3–7)	2 (40.00%)	5 (29.41%)
Moderate (8–16)	1 (20.00%)	10 (58.82%)
Severe (17–24)	2 (40.00%)	1 (5.88%)
Very severe (25–28)	0 (0.00%)	0 (0.00%)
Missing (n)	0	3
CDLQI (range: 0–30)		
mean (SD)	6.80 (4.32)	7.79 (4.33)
median (Q1, Q3)	6.00 (5.00, 10.00)	8.00 (5.50, 11.50)
minimum, maximum	1.00, 12.00	0.00, 16.00
Missing (n)	0	1
CDLQI (categorical), n (%)		
No effect on child's life (0–1)	1 (20.00%)	2 (10.53%)
Small effect (2–6)	2 (40.00%)	6 (31.58%)
Moderate effect (7–12)	2 (40.00%)	9 (47.37%)
Very large effect (13–18)	0 (0.00%)	2 (10.53%)
Extremely large effect (19–30)	0 (0.00%)	0 (0.00%)
Missing (n)	0	1
PHQ-4 (range: 0–12)		
mean (SD)	3.00 (4.06)	1.89 (2.33)
median (Q1, Q3)	1.00 (1.00, 3.00)	1.00 (0.00, 2.50)
minimum, maximum	0.00, 10.00	0.00, 8.00
Missing (n)	0	1
PHQ-4 (categorical), n (%)		
Normal (0–2)	3 (60.00%)	14 (73.68%)
Mild (3–5)	1 (20.00%)	3 (15.79%)
Moderate (6–8)	0 (0.00%)	2 (10.53%)
Severe (9–12)	1 (20.00%)	0 (0.00%)
Missing (n)	0	1
ADCT (range: 0–24)		
mean (SD)	8.00 (3.94)	7.74 (4.00)
median (Q1, Q3)	8.00 (7.00, 11.00)	7.00 (4.50, 10.50)
minimum, maximum	2.00, 12.00	2.00, 16.00
Missing (n)	0	1
ADCT (categorical), n (%)		

Table 2. Participant characteristics, clinical and disease characteristics, and treatment history at index among EUR-residing participants

	Abrocitinib N=5	Comparator N=20
Controlled (<7)	1 (20.00%)	6 (31.58%)
Not controlled (≥7)	4 (80.00%)	13 (68.42%)
Missing (n)	0	1
SCORAD Average pruritus in past 3 days (range: 0–10)		
mean (SD)	3.60 (2.88)	4.00 (2.09)
median (Q1, Q3)	3.00 (2.00, 6.00)	3.00 (3.00, 5.00)
minimum, maximum	0.00, 7.00	1.00, 8.00
Missing (n)	0	3
SCORAD Average sleeplessness in past 3 days (range: 0–10)		
mean (SD)	2.80 (3.90)	1.18 (1.63)
median (Q1, Q3)	0.00 (0.00, 6.00)	1.00 (0.00, 2.00)
minimum, maximum	0.00, 8.00	0.00, 5.00
Missing (n)	0	3
Average pruritus in past 7 days (range: 0–10)		
mean (SD)	3.20 (3.11)	4.26 (2.31)
median (Q1, Q3)	2.00 (1.00, 6.00)	4.00 (3.00, 6.00)
minimum, maximum	0.00, 7.00	0.00, 8.00
Missing (n)	0	1
Peak pruritus in last 24 hours (range: 0–10)		
mean (SD)	2.40 (2.88)	3.53 (2.67)
median (Q1, Q3)	1.00 (0.00, 5.00)	4.00 (1.50, 5.00)
minimum, maximum	0.00, 6.00	0.00, 10.00
Missing (n)	0	1
Worst skin pain in past 24 hours (range: 0–10)		
mean (SD)	3.60 (2.88)	2.63 (2.22)
median (Q1, Q3)	5.00 (1.00, 6.00)	2.00 (1.00, 4.00)
minimum, maximum	0.00, 6.00	0.00, 7.00
Missing (n)	0	1
Worst fatigue in past 7 days (range: 0–10)		
mean (SD)	2.00 (1.41)	3.53 (1.65)
median (Q1, Q3)	2.50 (1.50, 3.00)	3.00 (3.00, 5.00)
minimum, maximum	0.00, 3.00	0.00, 6.00
Missing (n)	1	1
Treatment history at index		
Number of prior biologics		

Table 2. Participant characteristics, clinical and disease characteristics, and treatment history at index among EUR-residing participants

	Abrocitinib N=5	Comparator N=20
mean (SD)	0.00 (0.00)	0.05 (0.22)
median (Q1, Q3)	0.00 (0.00, 0.00)	0.00 (0.00, 0.00)
minimum, maximum	0.00, 0.00	0.00, 1.00
Missing (n)	0	0
Index drug, n (%)		
abrocitinib (Cibinqo™)	5 (100.00%)	--
50 mg	0 (0.00%)	--
100 mg	5 (100.00%)	--
200 mg	0 (0.00%)	--
baricitinib (Olumiant™)	--	0 (0.00%)
dupilumab (Dupixent™)	--	7 (35.00%)
lebrikizumab (Ebglyss™)	--	2 (10.00%)
nemolizumab (Nemluvio™)	--	0 (0.00%)
tralokinumab (Adbry™, Adtralza™)	--	1 (5.00%)
upadacitinib (Rinvoq™)	--	10 (50.00%)
Missing (n)	0	0

Table 2. Participant characteristics, clinical and disease characteristics, and treatment history at index among EUR-residing participants

	Abrocitinib N=5	Comparator N=20

Data as of September 30, 2025
Percentages are calculated among observations with non-missing data.

Abbreviations: AD = atopic dermatitis; ADCT = Atopic Dermatitis Control Tool; ADHD = Attention-deficit/hyperactivity disorder; BSA = body surface area; CDLQI = Children's Dermatology Life Quality Index; EASI = Eczema Area and Severity Index; EUR = Europe; PHQ = Patient Health Questionnaire; POEM = Patient Oriented Eczema Measure; Q = quartile; SCORAD = SCORing Atopic Dermatitis; SD = standard deviation; vIGA-AD = Validated Investigator Global Assessment for Atopic Dermatitis

a Includes other tobacco or nicotine products, such as e-cigarettes.

b Defined as prior history of one or more of the following: cardiac arrhythmia; congestive heart failure; coronary angioplasty with or without cardiac stent; coronary artery bypass graft; coronary artery disease; myocardial infarction; peripheral arterial disease (stable), peripheral arterial thromboembolic event; peripheral ischemia or gangrene (necrosis); stroke; transient ischemic attack; unstable angina; urgent peripheral arterial revascularization, other arterial thromboembolism event; other cardiac or vascular condition.

c Defined as prior history of one or more of the following: Crohn's disease; ulcerative colitis; eosinophilic esophagitis; fatty liver disease/nonalcoholic fatty liver disease; gastroesophageal reflux disease/acid reflux; hepatic event (increased liver function tests >3x upper limit of normal); hepatotoxicity (including drug-induced liver injury); other hepatic event or gastrointestinal disorder.

d Defined as prior history of one or more of the following: breast cancer; cervical cancer; colon cancer; leukemia; lung cancer; lymphoma; melanoma skin cancer; nonmelanoma skin cancer; prostate cancer; uterine cancer; other malignancy.

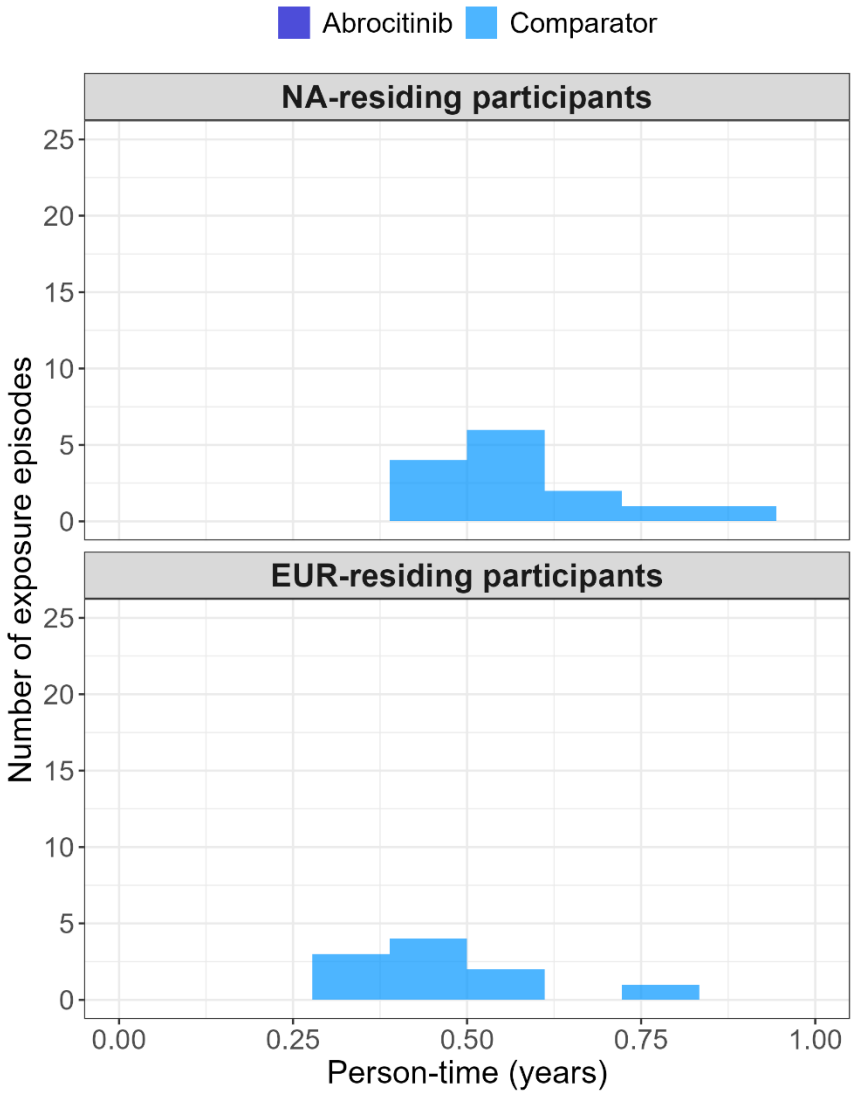
e Defined as prior history of one or more of the following: allergic conjunctivitis; blepharitis; cataract; conjunctivitis (drug-induced, infectious [bacterial, viral, or unknown pathogen], nonallergic noninfectious [e.g., atopic conjunctivitis], vernal, or unknown etiology [chronic follicular/papillary]); glaucoma; herpetic eye disease (H. simplex or H. zoster); keratitis; keratoconus; ocular ulcer (e.g., corneal ulcer, ulcerative blepharitis, ulcerative conjunctivitis); retinal detachment; other ocular event.

f Defined as prior history of one or more of the following: deep vein thrombosis; pulmonary embolism; other venous thromboembolism.

g Defined as prior history of one or more of the following infections that are serious or require treatment with IV antibiotics, or active tuberculosis regardless of seriousness: bronchitis; candidiasis (cutaneous, genital/vulvovaginal, or oropharyngeal); cellulitis or erysipelas; cold sores (Herpes labialis); COVID-19 (confirmed or suspected); diverticulitis; eczema herpeticum; furuncles (boils); gastroenteritis; herpes zoster (ear involvement, eye involvement, other location, or shingles); HIV/AIDS; meningitis/encephalitis; molluscum contagiosum; osteomyelitis; otitis (ear infection); pneumonia; progressive multifocal leukoencephalopathy; sepsis; sinusitis; superficial skin infection (e.g., impetigo, pustules); active tuberculosis; upper respiratory infection; urinary tract infection; viral hepatitis; warts (cutaneous); other infection or skin infection.

h Defined as prior history of one or more of the following: anxiety; asthma (allergic); attention-deficit/hyperactivity disorder; autism spectrum disorder; chronic obstructive pulmonary disease; depression; diabetes mellitus (type 1 or 2); eosinophilia; fibromyalgia; hyperlipidemia; hypertension; insomnia; interstitial lung disease/pulmonary fibrosis; other medical condition; other metabolic condition; other musculoskeletal condition; other neurological disorder; other psychiatric disorder; other respiratory condition

Figure 1. Exposure time among exposure episodes with at least one follow-up visit



Data as of September 30, 2025
Note: As of the data cut for this report, no abrocitinib participants had completed a follow-up visit.

Table 3. Summary of exposure time among exposure episodes with at least one follow-up visit

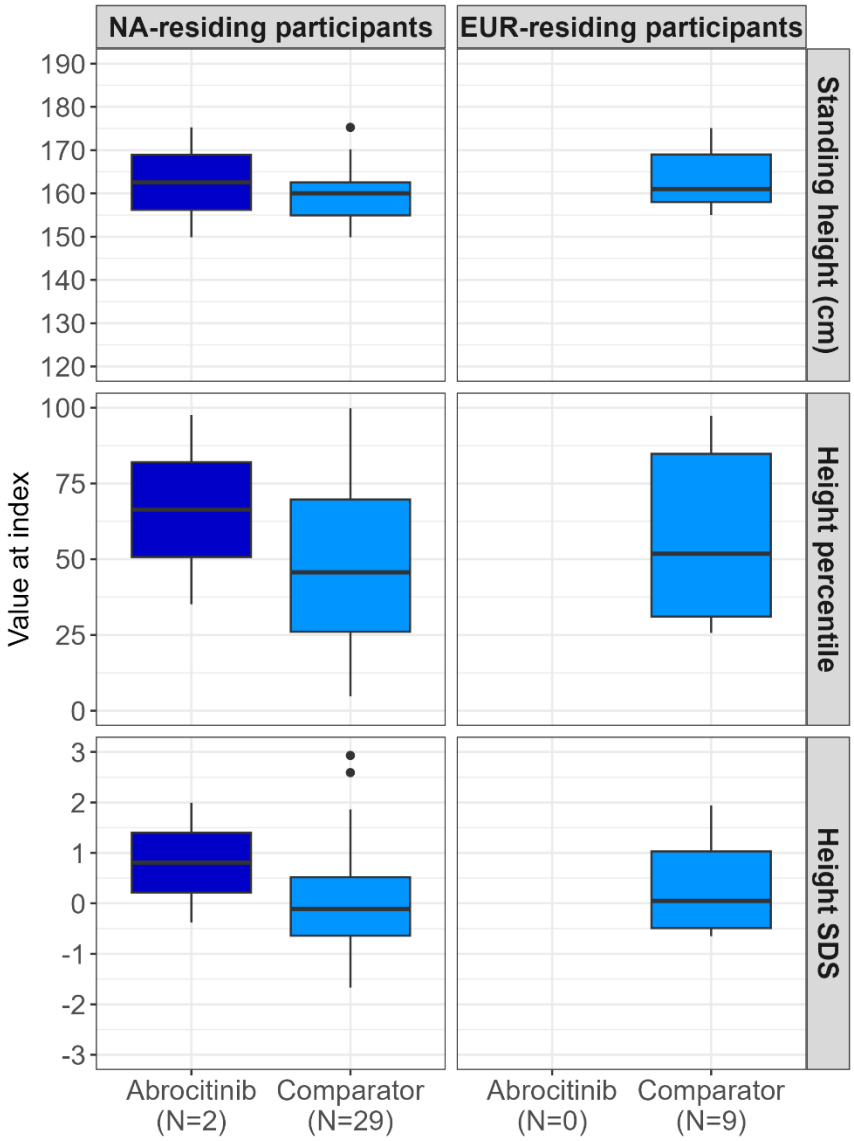
	NA-residing participants		EUR-residing participants	
	Abrocitinib N=0	Comparator N=15	Abrocitinib N=0	Comparator N=10
Person-time[1] (years)				
Total	--	8.24	--	4.59
mean (SD)	--	0.55 (0.19)	--	0.46 (0.13)
median (Q1, Q3)	--	0.50 (0.49, 0.63)	--	0.46 (0.35, 0.53)
minimum, maximum	--	0.04, 0.90	--	0.30, 0.75

Data as of September 30, 2025
Note: As of the data cut for this report, no participants had completed a follow-up visit after the initiation of abrocitinib.

Abbreviations: EUR = Europe; NA = North America; SD = standard deviation; Q = quartile

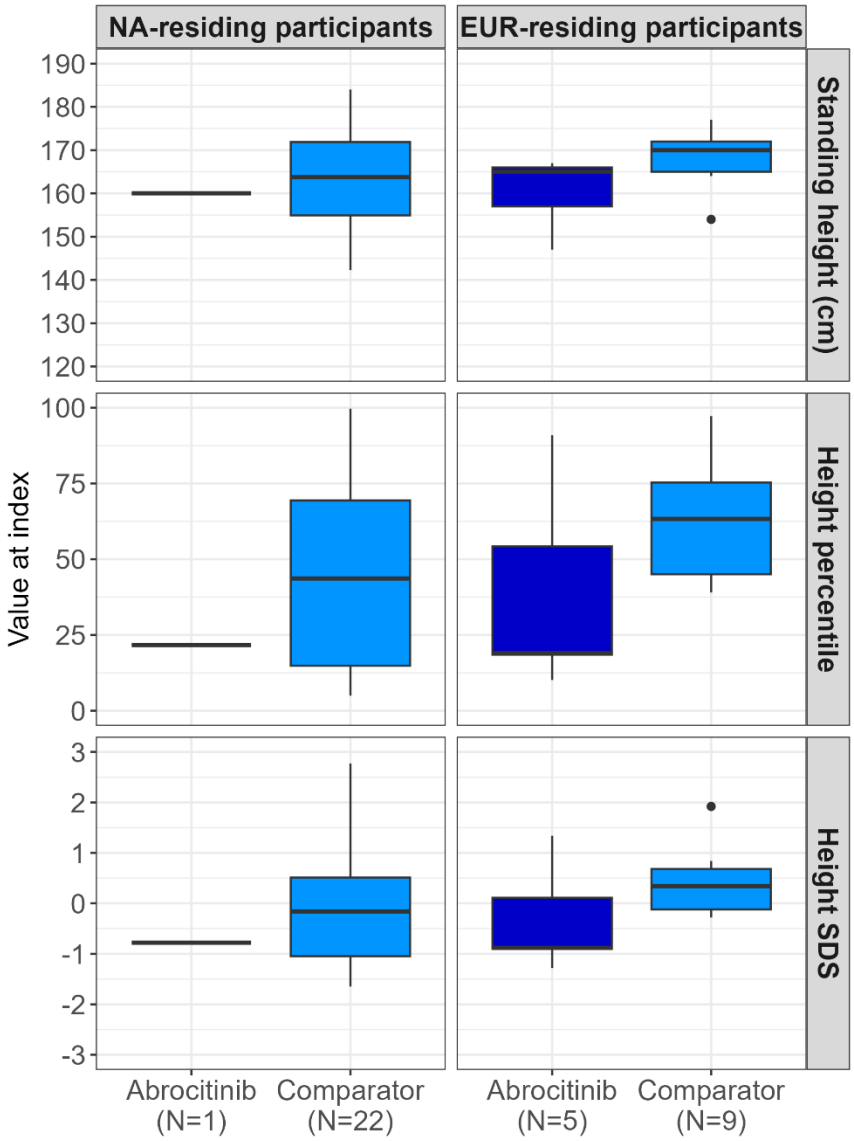
[1] Person-time is calculated as the number of years from the index date to the latest of the most recent medication data entry, Registry visit date, targeted event date (if applicable), or the Registry exit date. Exposure episodes in the comparator cohort are censored at the initiation of abrocitinib; if this occurs, person-time is calculated from the index date to the to the abrocitinib initiation.

Figure 2. Height metrics at index among female participants



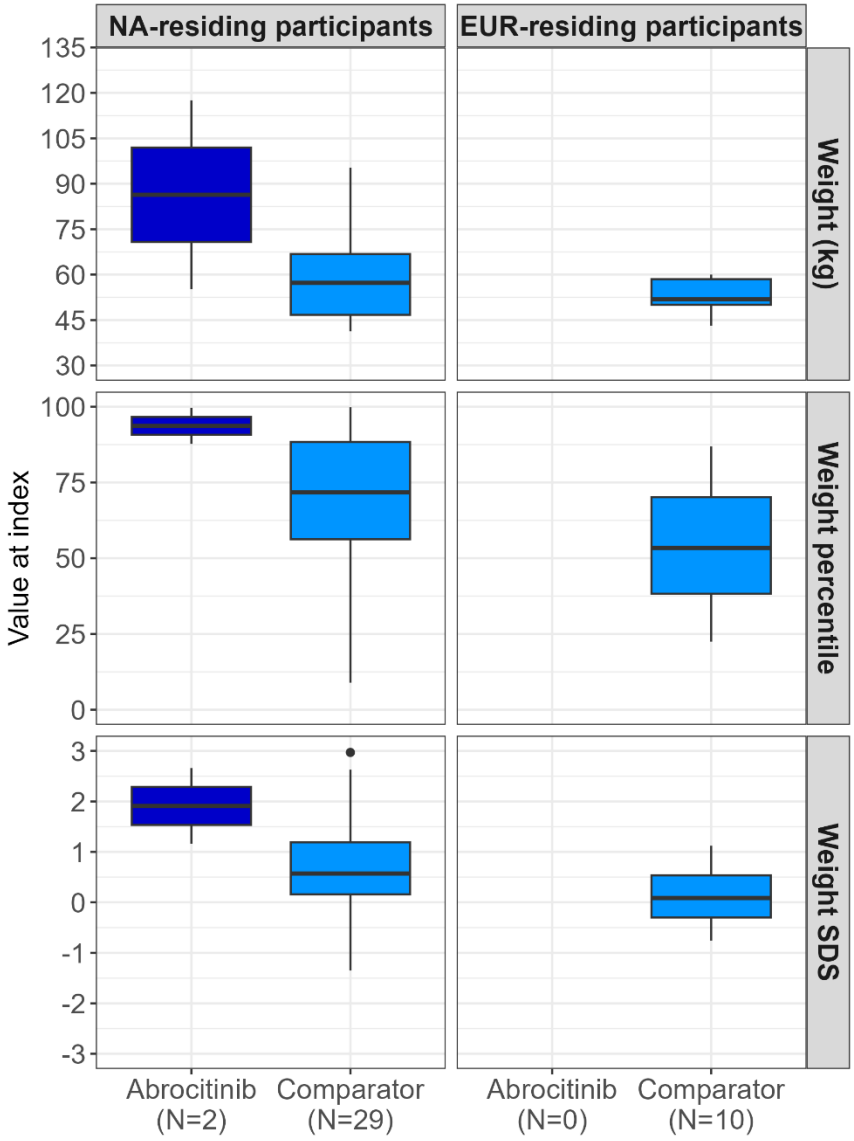
Data as of September 30, 2025
Note: As of the data cut for this report, no EUR-residing female participants had an eligible abrocitinib exposure; Whiskers extend to the further observations within 1.5 times the interquartile range from the first and third quartiles. Values beyond the whiskers are plotted individually as outliers.

Figure 3. Height metrics at index among male participants



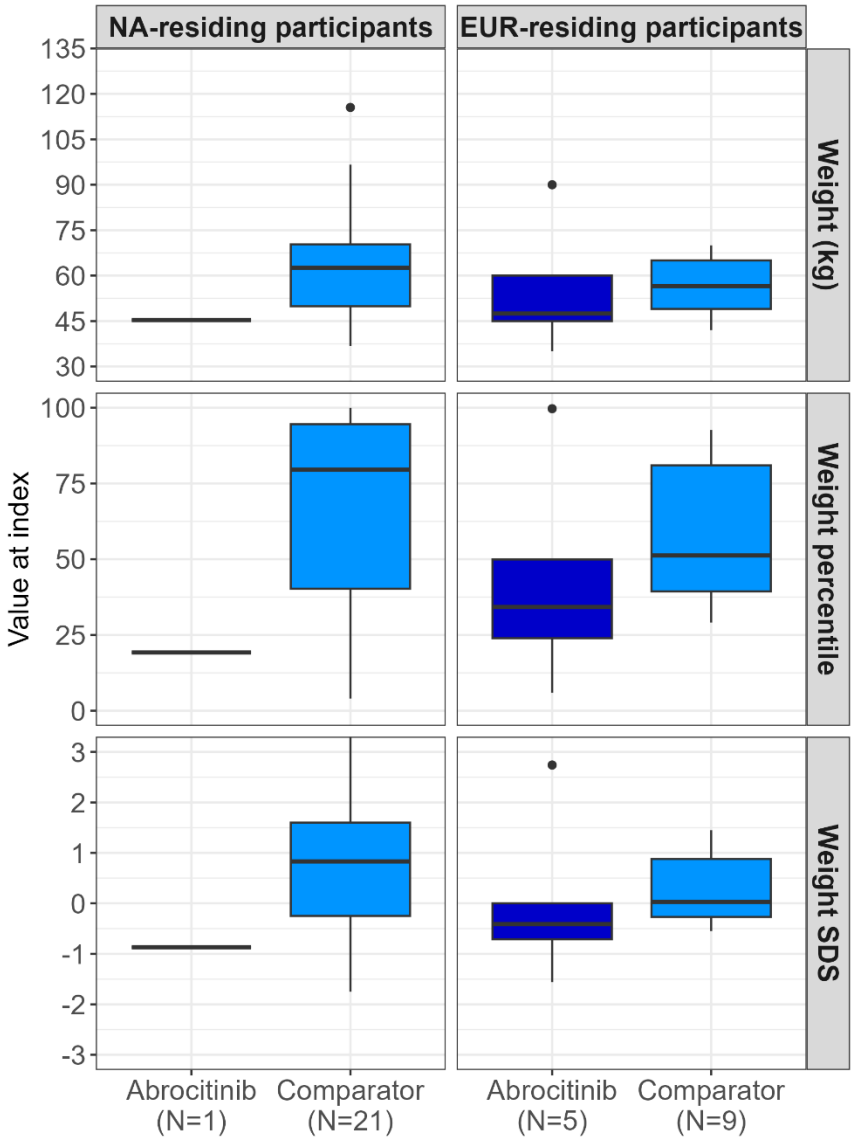
Data as of September 30, 2025
Note: Whiskers extend to the further observations within 1.5 times the interquartile range from the first and third quartiles. Values beyond the whiskers are plotted individually as outliers.

Figure 4. Weight metrics at index among female participants



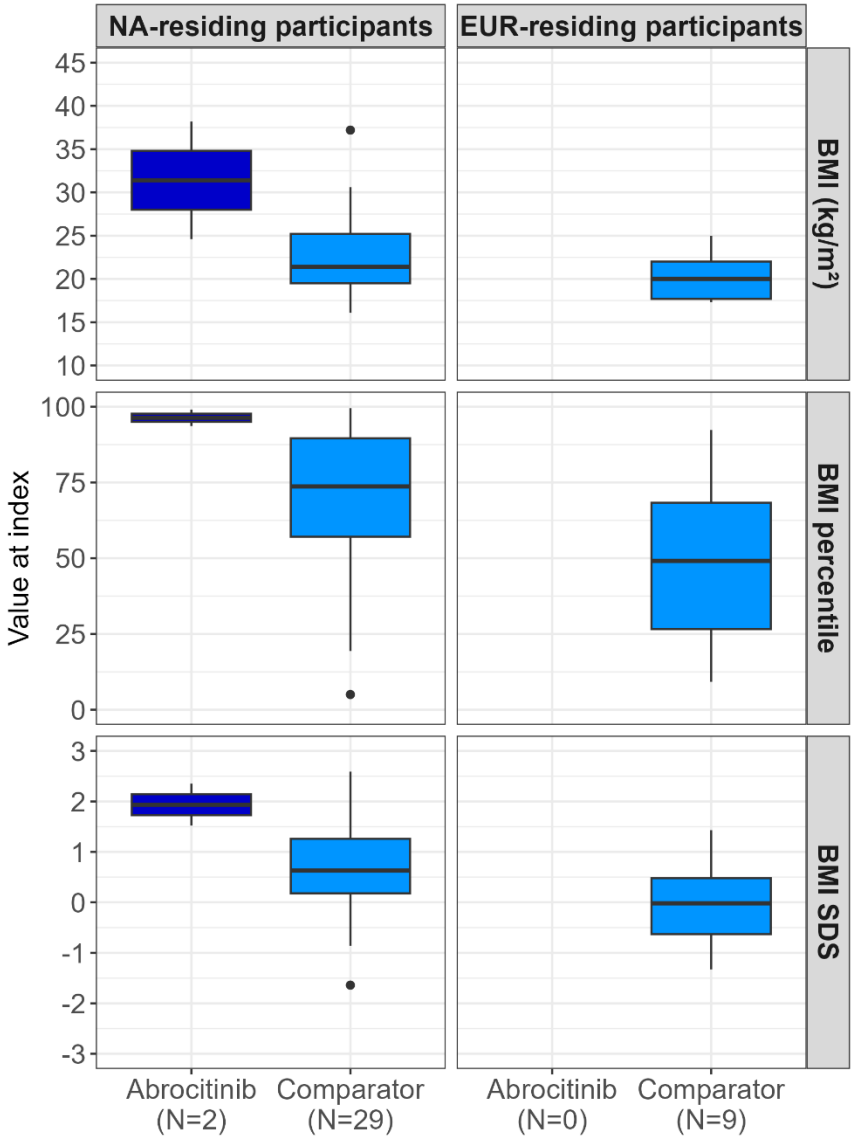
Data as of September 30, 2025
Note: As of the data cut for this report, no EUR-residing female participants had an eligible abrocitinib exposure; Whiskers extend to the further observations within 1.5 times the interquartile range from the first and third quartiles. Values beyond the whiskers are plotted individually as outliers.

Figure 5. Weight metrics at index among male participants



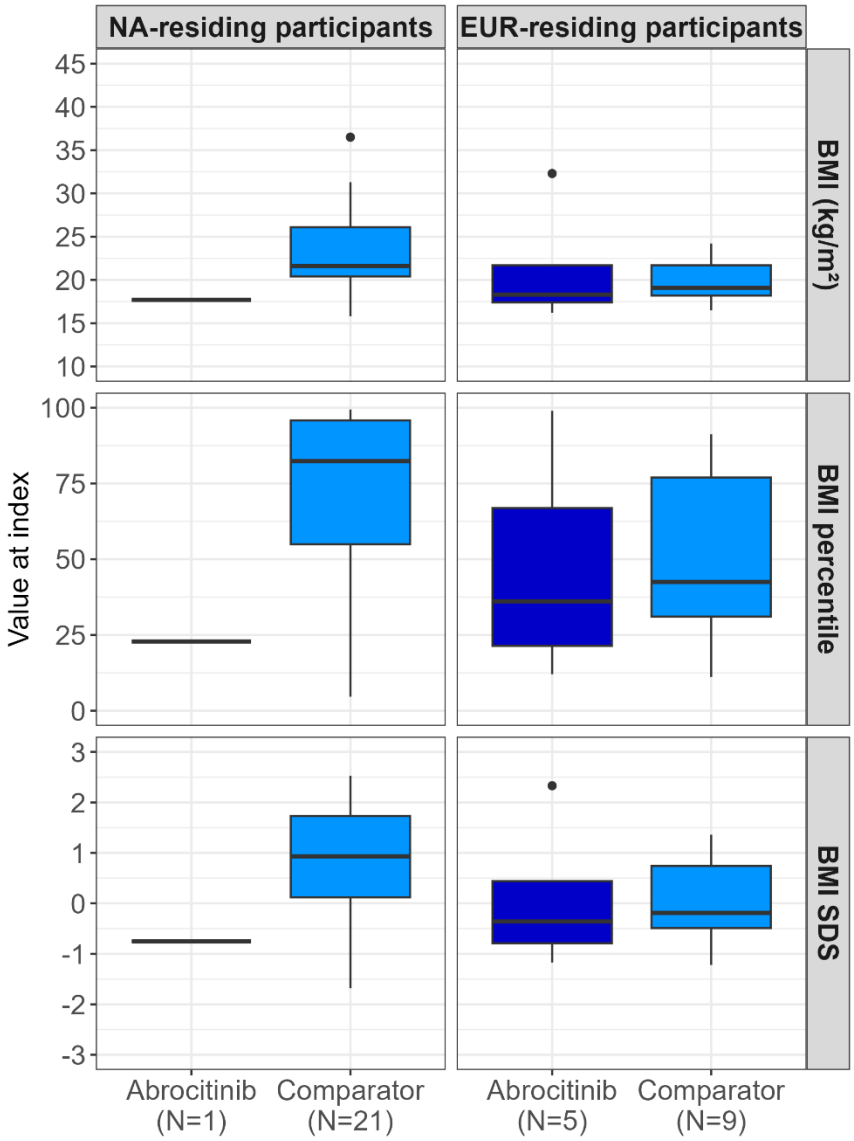
Data as of September 30, 2025
Note: Whiskers extend to the further observations within 1.5 times the interquartile range from the first and third quartiles. Values beyond the whiskers are plotted individually as outliers.

Figure 6. BMI metrics at index among female participants



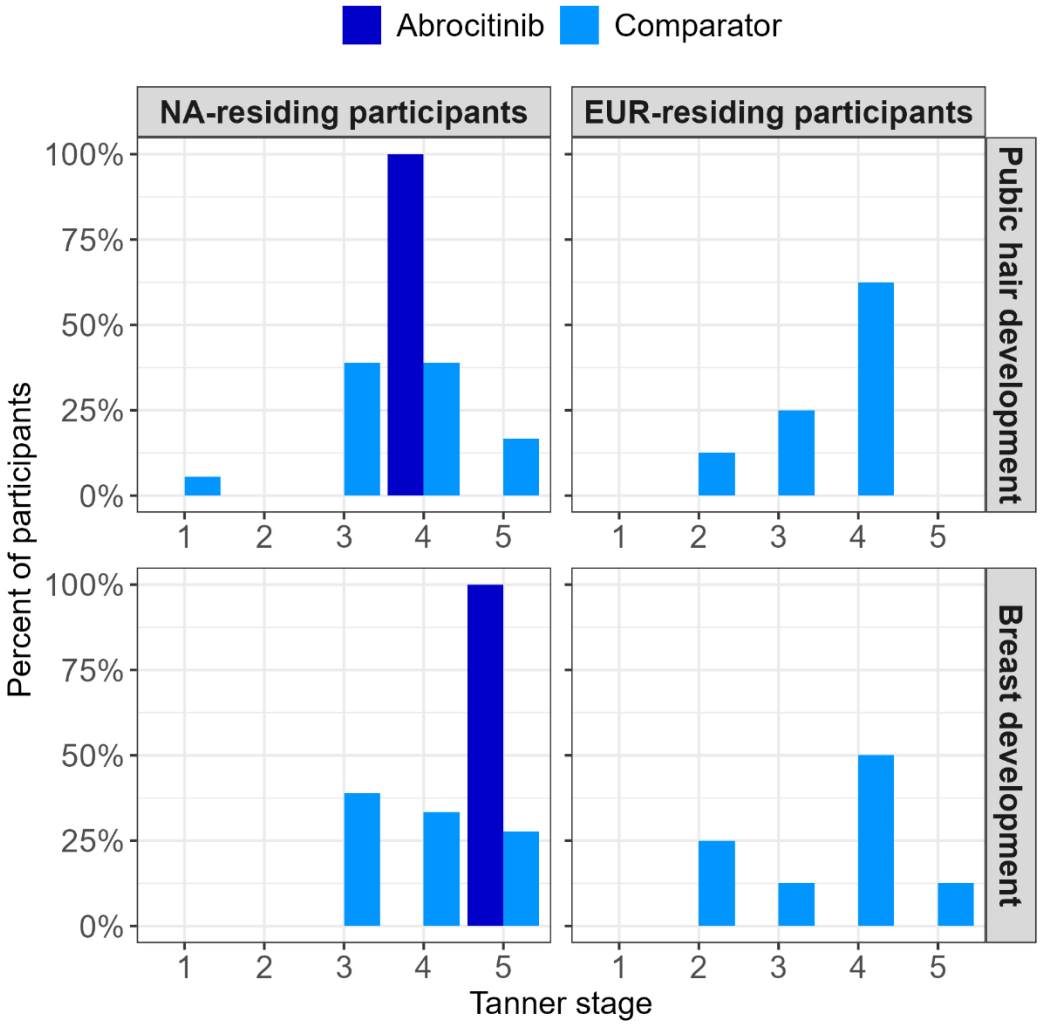
Data as of September 30, 2025
Note: As of the data cut for this report, no EUR-residing female participants had an eligible abrocitinib exposure; Whiskers extend to the further observations within 1.5 times the interquartile range from the first and third quartiles. Values beyond the whiskers are plotted individually as outliers.

Figure 7. BMI metrics at index among male participants



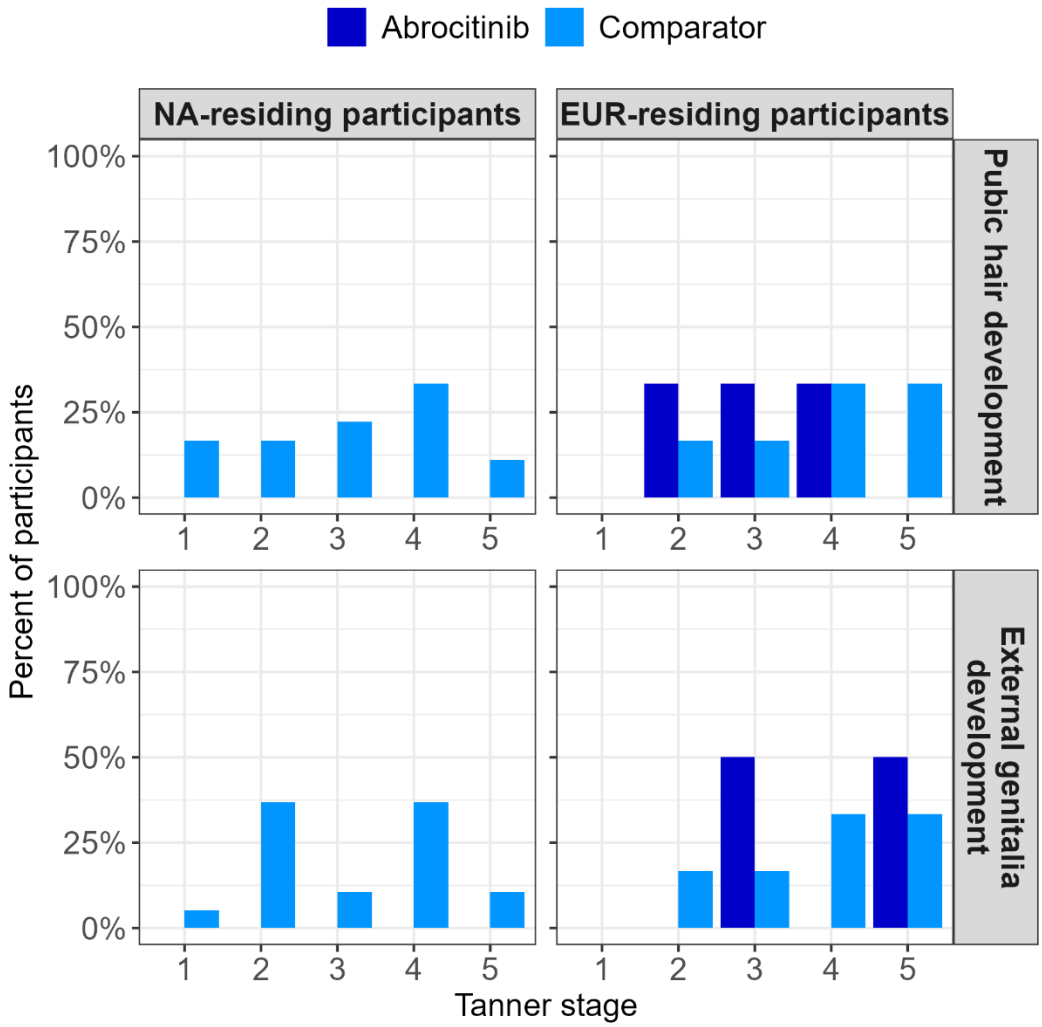
Data as of September 30, 2025
Note: Whiskers extend to the further observations within 1.5 times the interquartile range from the first and third quartiles. Values beyond the whiskers are plotted individually as outliers.

Figure 8. Tanner stage at index among female participants



Data as of September 30, 2025
Note: As of the data cut for this report, no EUR-residing female participants had an eligible abrocitinib exposure.

Figure 9. Tanner stage at index among male participants



Data as of September 30, 2025

Table 4a. Growth and pubertal development measures at index, female participants only

	NA-residing participants		EUR-residing participants	
	Abrocitinib N=2	Comparator N=30	Abrocitinib N=0	Comparator N=10
Growth measures at index				
Standing height (cm)				
mean (SD)	162.56 (17.96)	159.93 (6.30)	--	163.23 (7.19)
median (Q1, Q3)	162.56 (156.21, 168.91)	160.02 (154.94, 162.56)	--	161.00 (158.00, 169.00)
minimum, maximum	149.86, 175.26	149.86, 175.26	--	155.00, 175.10
Missing (n)	0	1	--	1
Height percentile				
mean (SD)	66.38 (44.23)	49.98 (29.68)	--	56.68 (29.30)
median (Q1, Q3)	66.38 (50.75, 82.02)	45.66 (26.08, 69.72)	--	51.82 (31.07, 84.76)
minimum, maximum	35.11, 97.66	4.71, 99.83	--	25.69, 97.36
Missing (n)	0	1	--	1
Height SDS				
mean (SD)	0.80 (1.68)	0.11 (1.12)	--	0.33 (1.02)
median (Q1, Q3)	0.80 (0.21, 1.40)	-0.11 (-0.64, 0.52)	--	0.05 (-0.49, 1.03)
minimum, maximum	-0.38, 1.99	-1.67, 2.93	--	-0.65, 1.94
Missing (n)	0	1	--	1
Weight (kg)				
mean (SD)	86.37 (44.00)	58.86 (13.99)	--	52.90 (5.95)
median (Q1, Q3)	86.37 (70.81, 101.92)	57.30 (46.72, 66.80)	--	51.85 (50.05, 58.50)
minimum, maximum	55.25, 117.48	41.28, 95.25	--	43.10, 60.00
Missing (n)	0	1	--	0
Weight percentile				
mean (SD)	93.69 (8.37)	67.46 (27.14)	--	54.89 (21.89)
median (Q1, Q3)	93.69 (90.73, 96.65)	71.71 (56.24, 88.36)	--	53.36 (38.25, 70.18)
minimum, maximum	87.77, 99.61	8.91, 99.85	--	22.45, 86.86
Missing (n)	0	1	--	0
Weight SDS				
mean (SD)	1.91 (1.06)	0.67 (1.07)	--	0.15 (0.62)
median (Q1, Q3)	1.91	0.57	--	0.08

Table 4a. Growth and pubertal development measures at index, female participants only

	NA-residing participants		EUR-residing participants	
	Abrocitinib N=2	Comparator N=30	Abrocitinib N=0	Comparator N=10
	(1.53, 2.29)	(0.16, 1.19)		(-0.30, 0.53)
minimum, maximum	1.16, 2.66	-1.35, 2.97	--	-0.76, 1.20
Missing (n)	0	1	--	0
BMI (kg/m^2)				
mean (SD)	31.40 (9.62)	22.90 (4.73)		20.01 (2.65)
median (Q1, Q3)	31.40 (28.00, 34.80)	21.40 (19.50, 25.20)	--	20.00 (17.70, 22.00)
minimum, maximum	24.60, 38.20	16.10, 37.20	--	17.30, 25.00
Missing (n)	0	1	--	1
BMI percentile				
mean (SD)	96.35 (3.85)	70.05 (24.79)	--	47.73 (28.73)
median (Q1, Q3)	96.35 (94.99, 97.71)	73.70 (57.11, 89.60)	--	49.11 (26.58, 68.30)
minimum, maximum	93.63, 99.07	5.00, 99.52	--	9.21, 92.34
Missing (n)	0	1	--	1
BMI SDS				
mean (SD)	1.94 (0.59)	0.70 (0.94)	--	-0.07 (0.88)
median (Q1, Q3)	1.94 (1.73, 2.14)	0.63 (0.18, 1.26)	--	-0.02 (-0.63, 0.48)
minimum, maximum	1.52, 2.35	-1.64, 2.59	--	-1.33, 1.43
Missing (n)	0	1	--	1
Participant-reported Tanner staging at index				
Pubic hair development, n (%)				
Stage I	0 (0.00%)	1 (5.56%)	--	0 (0.00%)
Stage II	0 (0.00%)	0 (0.00%)	--	1 (12.50%)
Stage III	0 (0.00%)	7 (38.89%)	--	2 (25.00%)
Stage IV	1 (100.00%)	7 (38.89%)	--	5 (62.50%)
Stage V	0 (0.00%)	3 (16.67%)	--	0 (0.00%)
Missing (n)	1	12	--	2
Breast development, n (%)				
Stage I	0 (0.00%)	0 (0.00%)	--	0 (0.00%)
Stage II	0 (0.00%)	0 (0.00%)	--	2 (25.00%)
Stage III	0 (0.00%)	7 (38.89%)	--	1 (12.50%)
Stage IV	0 (0.00%)	6 (33.33%)	--	4 (50.00%)
Stage V	1 (100.00%)	5 (27.78%)	--	1 (12.50%)
Missing (n)	1	12	--	2

Table 4a. Growth and pubertal development measures at index, female participants only

	NA-residing participants		EUR-residing participants	
	Abrocitinib N=2	Comparator N=30	Abrocitinib N=0	Comparator N=10

Data as of September 30, 2025
Percentages are calculated among observations with non-missing data.

Abbreviations: BMI = body mass index; cm = centimeter; EUR = Europe; kg = kilogram; NA = North America; Q = quartile; SD = standard deviation; SDS = standard deviation score

Table 4b. Growth and pubertal development measures at index, male participants only

	NA-residing participants		EUR-residing participants	
	Abrocitinib N=1	Comparator N=26	Abrocitinib N=5	Comparator N=10
Growth measures at index				
Standing height (cm)				
mean (SD)	160.02 (--)	164.11 (11.07)	160.40 (8.47)	168.44 (6.73)
median (Q1, Q3)	160.02 (160.02, 160.02)	163.78 (154.94, 171.86)	165.00 (157.00, 166.00)	170.00 (165.00, 172.00)
minimum, maximum	160.02, 160.02	142.24, 184.00	147.00, 167.00	154.00, 177.00
Missing (n)	0	4	0	1
Height percentile				
mean (SD)	21.64 (--)	47.16 (33.99)	38.57 (33.85)	63.72 (19.18)
median (Q1, Q3)	21.64 (21.64, 21.64)	43.62 (14.85, 69.42)	19.05 (18.47, 54.26)	63.27 (45.04, 75.29)
minimum, maximum	21.64, 21.64	4.97, 99.72	10.11, 90.94	38.97, 97.24
Missing (n)	0	4	0	1
Height SDS				
mean (SD)	-0.78 (--)	0.07 (1.35)	-0.32 (1.06)	0.44 (0.68)
median (Q1, Q3)	-0.78 (-0.78, -0.78)	-0.16 (-1.05, 0.51)	-0.88 (-0.90, 0.11)	0.34 (-0.12, 0.68)
minimum, maximum	-0.78, -0.78	-1.65, 2.77	-1.28, 1.34	-0.28, 1.92
Missing (n)	0	4	0	1
Weight (kg)				
mean (SD)	45.36 (--)	63.31 (20.42)	55.50 (21.24)	56.97 (10.12)
median (Q1, Q3)	45.36 (45.36, 45.36)	62.60 (49.90, 70.31)	47.50 (44.00, 60.00)	56.50 (49.00, 65.00)
minimum, maximum	45.36, 45.36	36.74, 115.53	35.00, 90.00	42.00, 70.00
Missing (n)	0	5	0	1
Weight percentile				
mean (SD)	19.19 (--)	66.94 (31.75)	42.73 (35.63)	59.78 (24.43)
median (Q1, Q3)	19.19 (19.19, 19.19)	79.54 (40.26, 94.57)	34.24 (23.94, 49.89)	51.23 (39.35, 80.98)
minimum, maximum	19.19, 19.19	3.99, 99.96	5.89, 99.69	29.07, 92.70
Missing (n)	0	5	0	1
Weight SDS				
mean (SD)	-0.87 (--)	0.72 (1.29)	0.01 (1.63)	0.32 (0.72)
median (Q1, Q3)	-0.87	0.83	-0.41	0.03

Table 4b. Growth and pubertal development measures at index, male participants only

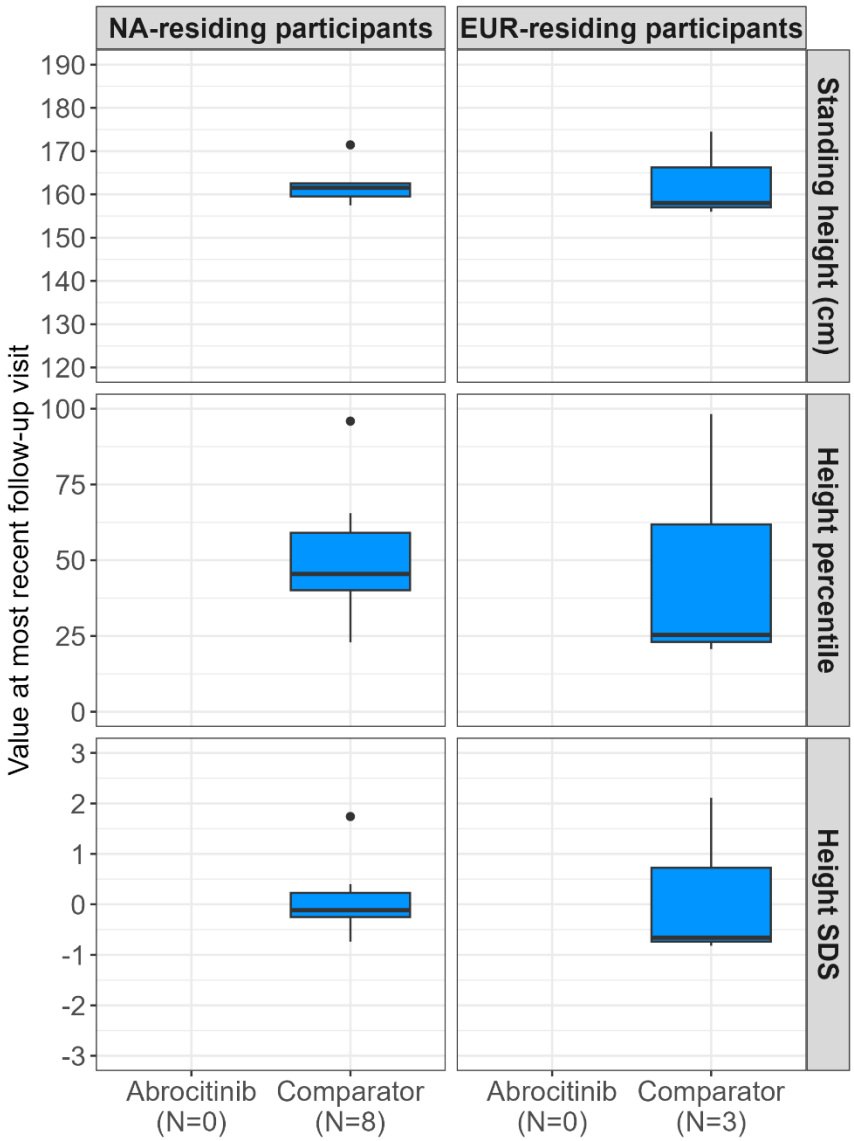
	NA-residing participants		EUR-residing participants	
	Abrocitinib N=1	Comparator N=26	Abrocitinib N=5	Comparator N=10
	(-0.87, -0.87)	(-0.25, 1.60)	(-0.71, -0.00)	(-0.27, 0.88)
minimum, maximum	-0.87, -0.87	-1.75, 3.38	-1.56, 2.74	-0.55, 1.45
Missing (n)	0	5	0	1
BMI (kg/m^2)				
mean (SD)	17.70 (--)	23.11 (5.13)	21.18 (6.54)	19.97 (2.67)
median (Q1, Q3)	17.70 (17.70, 17.70)	21.60 (20.40, 26.10)	18.30 (17.40, 21.70)	19.10 (18.20, 21.70)
minimum, maximum	17.70, 17.70	15.80, 36.50	16.20, 32.30	16.50, 24.20
Missing (n)	0	5	0	1
BMI percentile				
mean (SD)	22.81 (--)	71.92 (28.00)	47.08 (35.70)	51.32 (27.38)
median (Q1, Q3)	22.81 (22.81, 22.81)	82.38 (54.96, 95.84)	36.07 (21.37, 66.88)	42.48 (31.06, 76.96)
minimum, maximum	22.81, 22.81	4.62, 99.44	12.06, 99.01	11.11, 91.29
Missing (n)	0	5	0	1
BMI SDS				
mean (SD)	-0.75 (--)	0.80 (1.06)	0.09 (1.39)	0.06 (0.82)
median (Q1, Q3)	-0.75 (-0.75, -0.75)	0.93 (0.12, 1.73)	-0.36 (-0.79, 0.44)	-0.19 (-0.49, 0.74)
minimum, maximum	-0.75, -0.75	-1.68, 2.53	-1.17, 2.33	-1.22, 1.36
Missing (n)	0	5	0	1
Participant-reported Tanner staging at index				
Pubic hair development, n (%)				
Stage I	0 (0.00%)	3 (16.67%)	0 (0.00%)	0 (0.00%)
Stage II	0 (0.00%)	3 (16.67%)	1 (33.33%)	1 (16.67%)
Stage III	0 (0.00%)	4 (22.22%)	1 (33.33%)	1 (16.67%)
Stage IV	0 (0.00%)	6 (33.33%)	1 (33.33%)	2 (33.33%)
Stage V	0 (0.00%)	2 (11.11%)	0 (0.00%)	2 (33.33%)
Missing (n)	1	8	2	4
External genitalia development, n (%)				
Stage I	0 (0.00%)	1 (5.26%)	0 (0.00%)	0 (0.00%)
Stage II	0 (0.00%)	7 (36.84%)	0 (0.00%)	1 (16.67%)
Stage III	0 (0.00%)	2 (10.53%)	2 (50.00%)	1 (16.67%)
Stage IV	0 (0.00%)	7 (36.84%)	0 (0.00%)	2 (33.33%)
Stage V	0 (0.00%)	2 (10.53%)	2 (50.00%)	2 (33.33%)

Table 4b. Growth and pubertal development measures at index, male participants only

	NA-residing participants		EUR-residing participants	
	Abrocitinib N=1	Comparator N=26	Abrocitinib N=5	Comparator N=10
Missing (n)	1	7	1	4

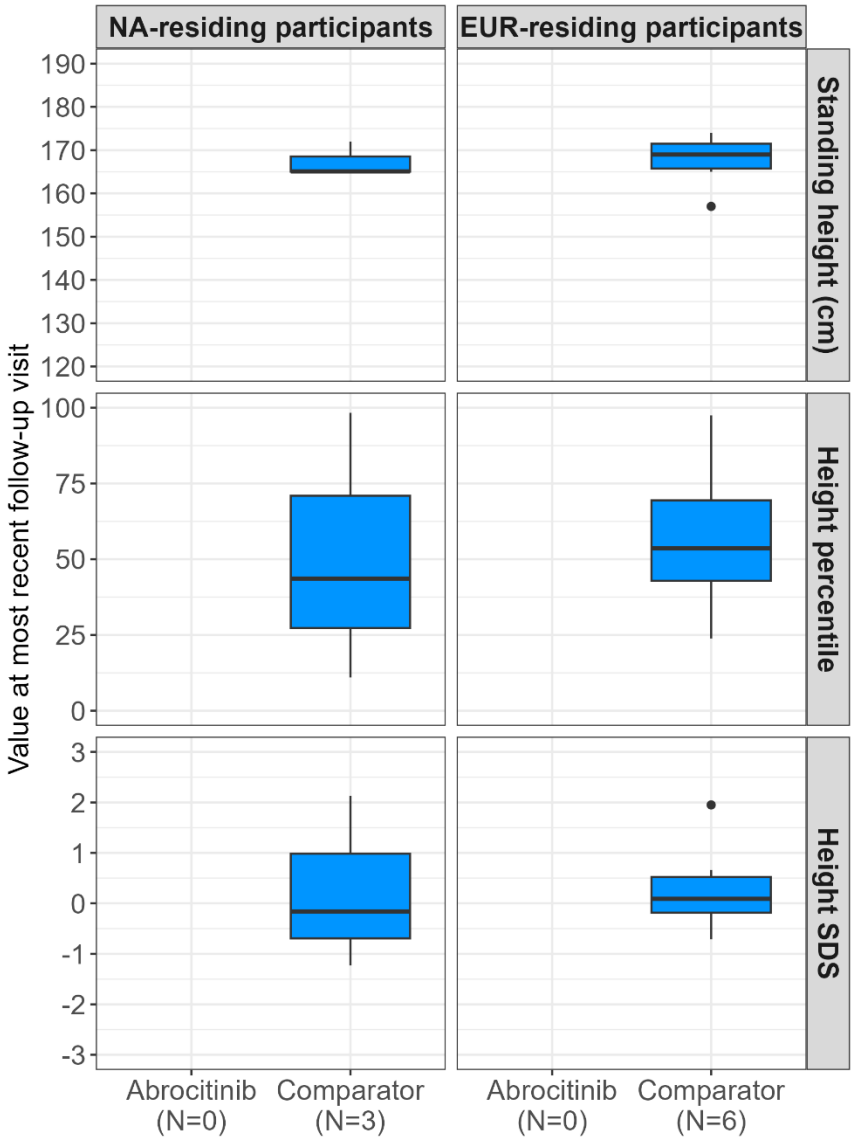
Data as of September 30, 2025
Percentages are calculated among observations with non-missing data.
Abbreviations: BMI = body mass index; cm = centimeter; EUR = Europe; kg = kilogram; NA = North America; Q = quartile; SD = standard deviation; SDS = standard deviation score

Figure 10. Height metrics at most recent follow-up visit for exposure episodes with at least one follow-up visit among female participants



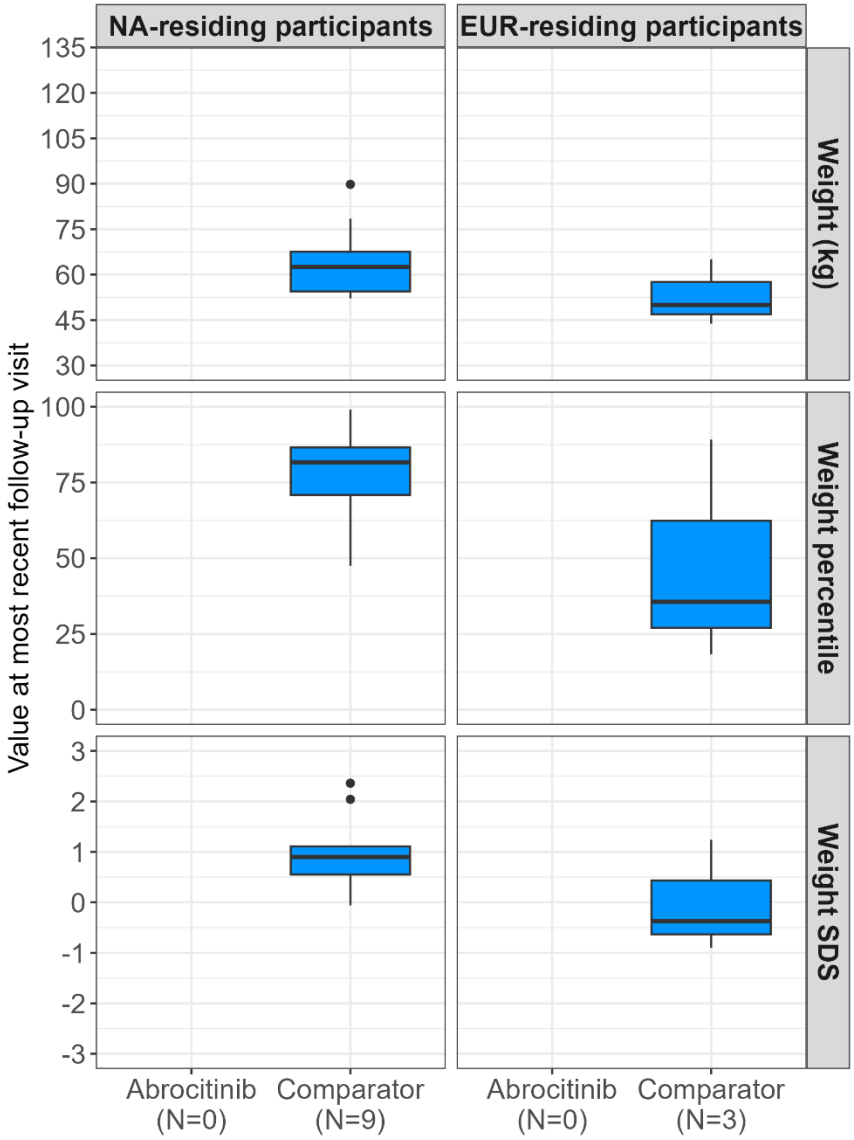
Data as of September 30, 2025
Note: As of the data cut for this report, no participants had completed a follow-up visit after the initiation of abrocitinib; Whiskers extend to the further observations within 1.5 times the interquartile range from the first and third quartiles. Values beyond the whiskers are plotted individually as outliers.

Figure 11. Height metrics at most recent follow-up visit for exposure episodes with at least one follow-up visit among male participants



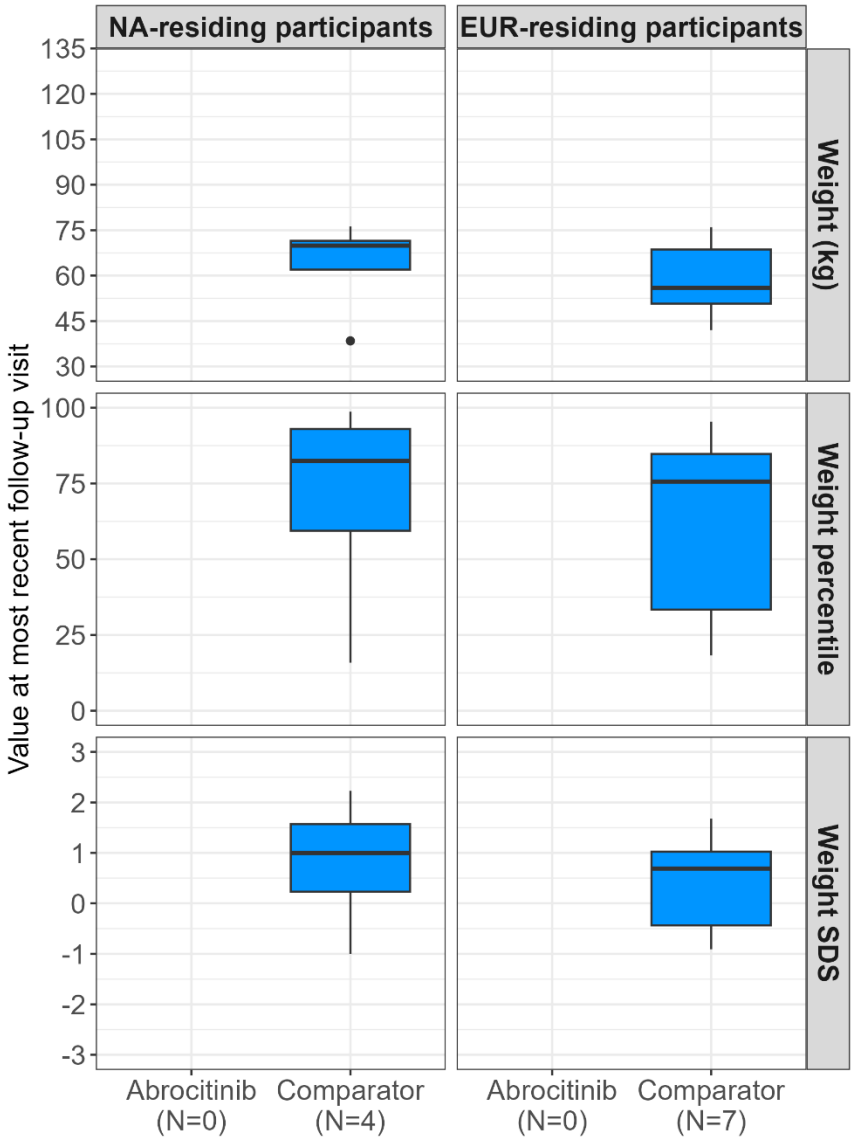
Data as of September 30, 2025
Note: As of the data cut for this report, no participants had completed a follow-up visit after the initiation of abrocitinib; Whiskers extend to the further observations within 1.5 times the interquartile range from the first and third quartiles. Values beyond the whiskers are plotted individually as outliers.

Figure 12. Weight metrics at most recent follow-up visit for exposure episodes with at least one follow-up visit among female participants



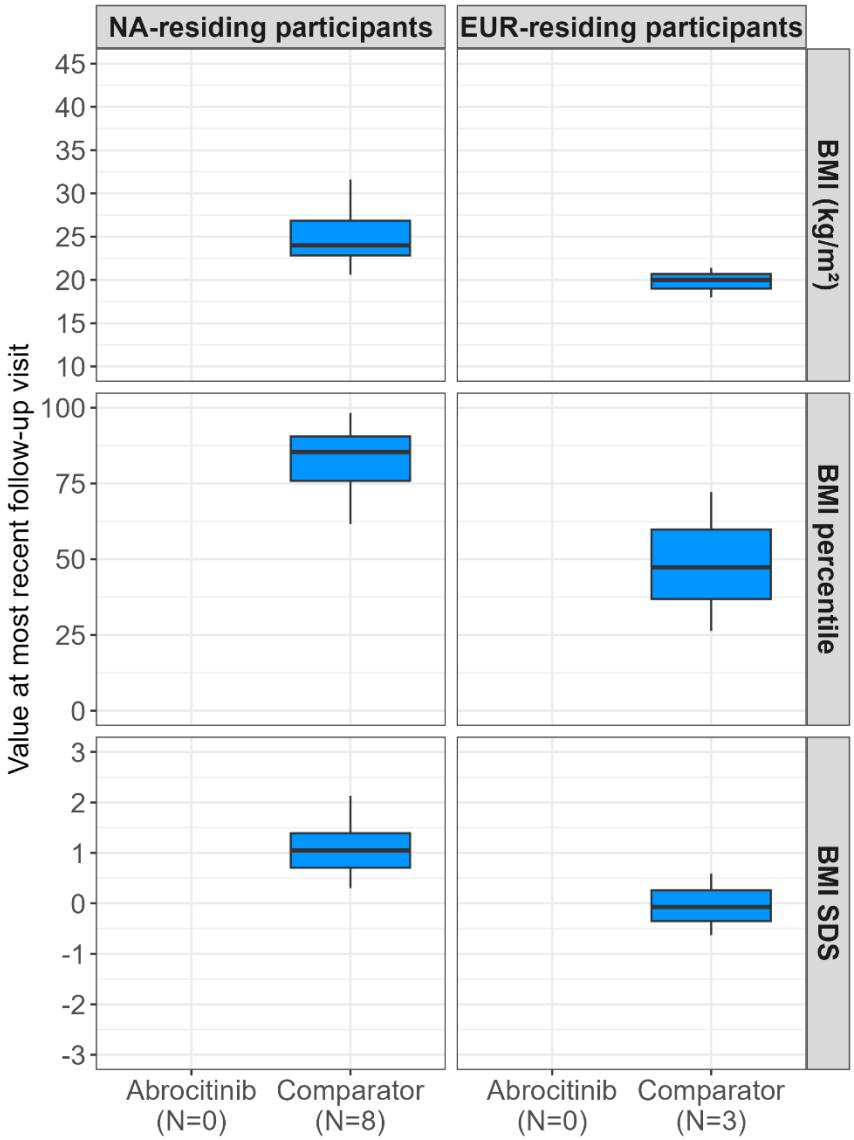
Data as of September 30, 2025
Note: As of the data cut for this report, no participants had completed a follow-up visit after the initiation of abrocitinib; Whiskers extend to the further observations within 1.5 times the interquartile range from the first and third quartiles. Values beyond the whiskers are plotted individually as outliers.

Figure 13. Weight metrics at most recent follow-up visit for exposure episodes with at least one follow-up visit among male participants



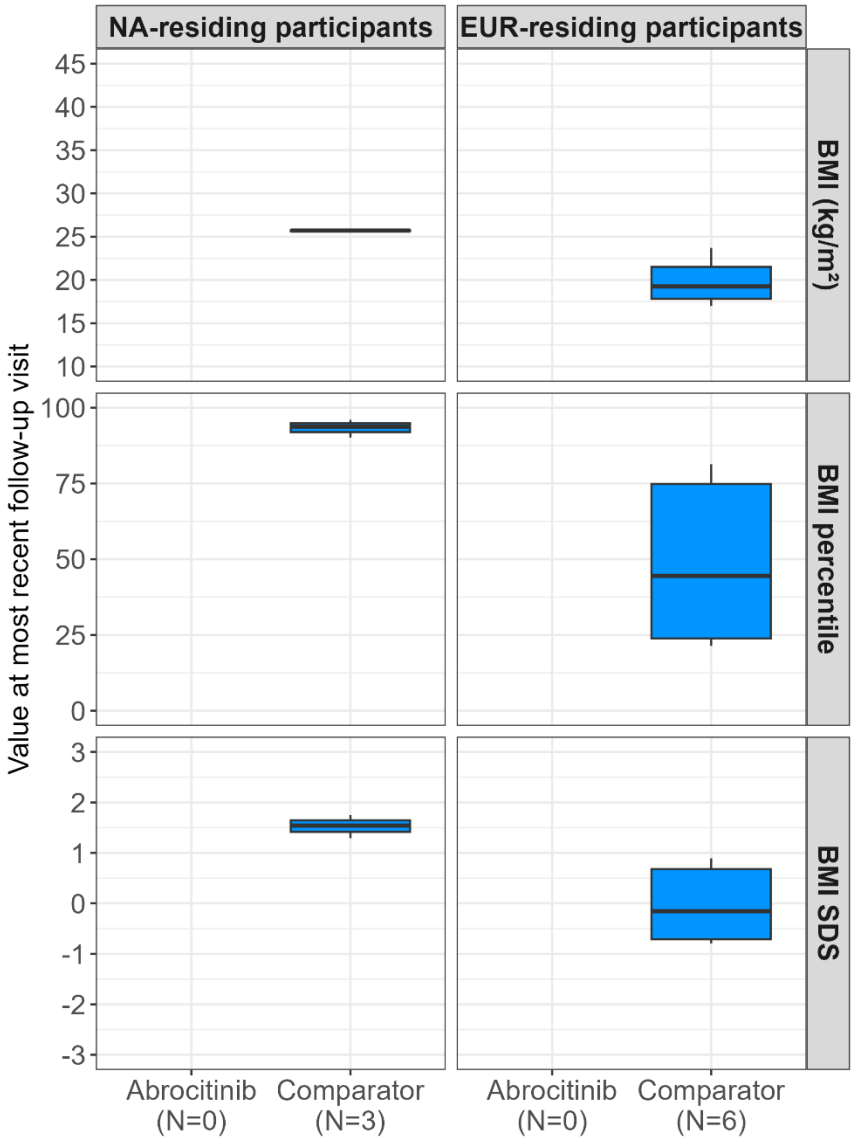
Data as of September 30, 2025
Note: As of the data cut for this report, no participants had completed a follow-up visit after the initiation of abrocitinib; Whiskers extend to the further observations within 1.5 times the interquartile range from the first and third quartiles. Values beyond the whiskers are plotted individually as outliers.

Figure 14. BMI metrics at most recent follow-up visit for exposure episodes with at least one follow-up visit among female participants



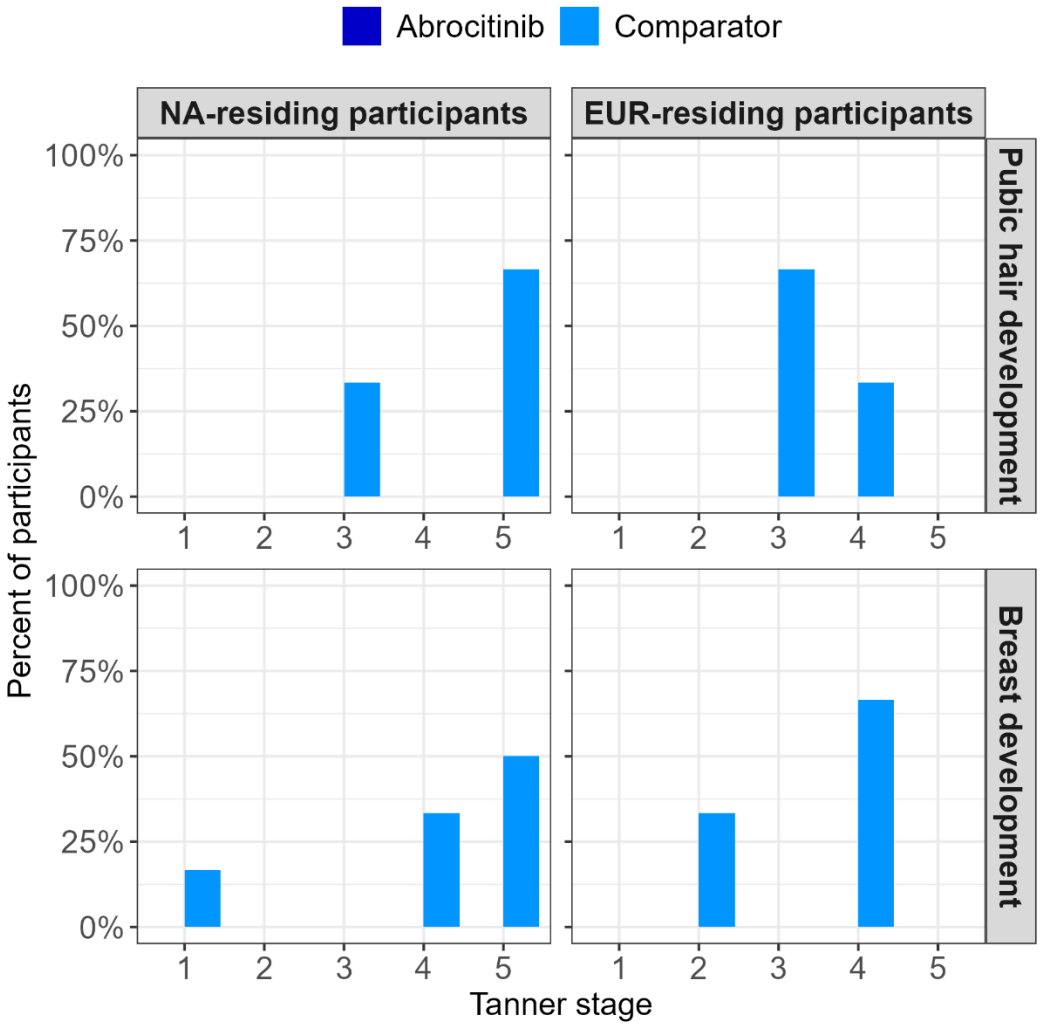
Data as of September 30, 2025
Note: As of the data cut for this report, no participants had completed a follow-up visit after the initiation of abrocitinib; Whiskers extend to the further observations within 1.5 times the interquartile range from the first and third quartiles. Values beyond the whiskers are plotted individually as outliers.

Figure 15. BMI metrics at most recent follow-up visit for exposure episodes with at least one follow-up visit among male participants



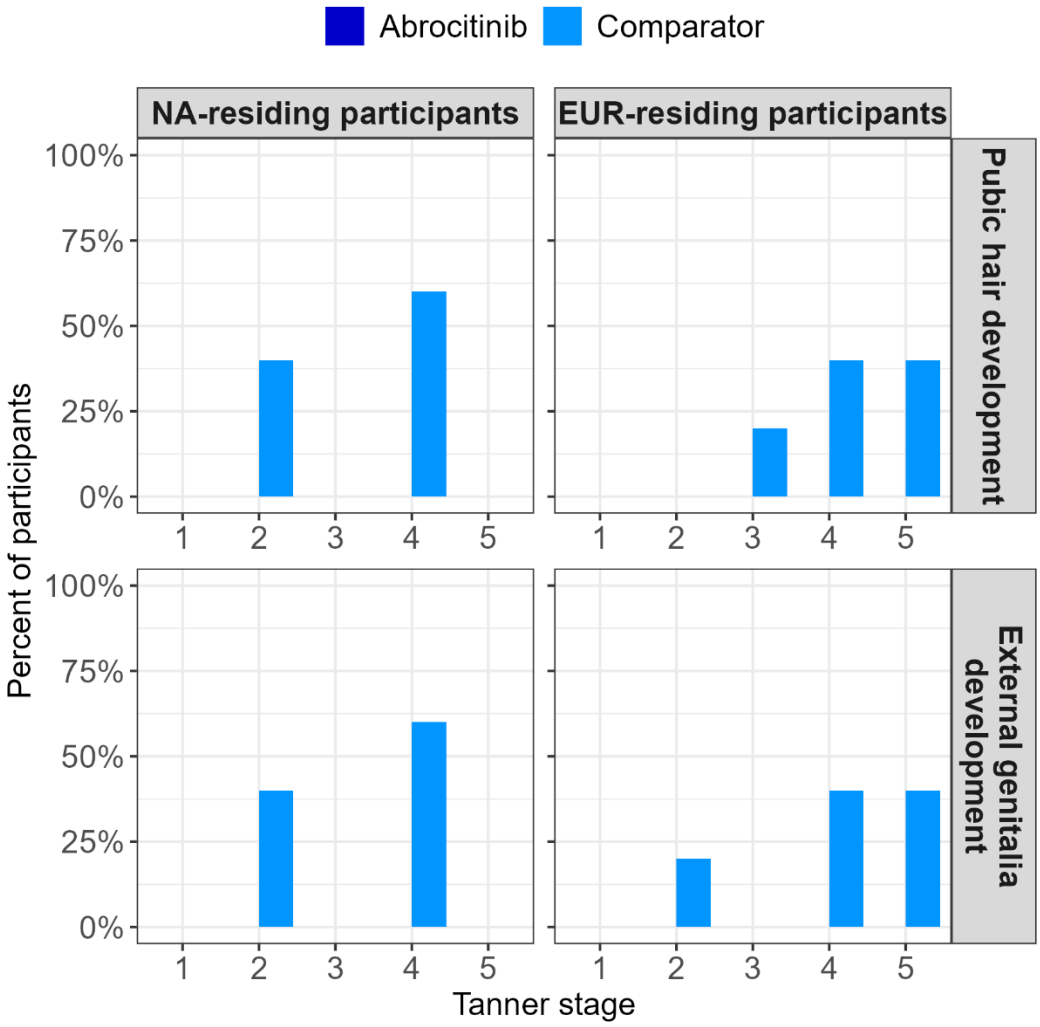
Data as of September 30, 2025
Note: As of the data cut for this report, no participants had completed a follow-up visit after the initiation of abrocitinib; Whiskers extend to the further observations within 1.5 times the interquartile range from the first and third quartiles. Values beyond the whiskers are plotted individually as outliers.

Figure 16. Tanner stage at most recent follow-up visit for exposure episodes with at least one follow-up visit among female participants



Data as of September 30, 2025
Note: As of the data cut for this report, no participants had completed a follow-up visit after the initiation of abrocitinib.

Figure 17. Tanner stage at most recent follow-up visits for exposure episodes with at least one follow-up visit among male participants



Data as of September 30, 2025
Note: As of the data cut for this report, no participants had completed a follow-up visit after the initiation of abrocitinib.

Table 5a. Growth and pubertal development measures at most recent follow-up visit for exposure episodeswith at least one follow-up visit among female participants

	NA-residing participants		EUR-residing participants	
	Abrocitinib N=0	Comparator N=9	Abrocitinib N=0	Comparator N=3
Growth measures				
Standing height (cm)				
mean (SD)	--	161.89 (4.35)	--	162.83 (10.15)
median (Q1, Q3)	--	161.53 (159.52, 162.56)	--	158.00 (157.00, 166.25)
minimum, maximum	--	157.48, 171.45	--	156.00, 174.50
Missing (n)	0	1	0	0
Height percentile				
mean (SD)	--	51.23 (22.21)	--	48.09 (43.50)
median (Q1, Q3)	--	45.47 (40.08, 59.03)	--	25.36 (23.01, 61.80)
minimum, maximum	--	22.91, 95.91	--	20.66, 98.24
Missing (n)	0	1	0	0
Height SDS				
mean (SD)	--	0.10 (0.75)	--	0.21 (1.65)
median (Q1, Q3)	--	-0.12 (-0.25, 0.23)	--	-0.66 (-0.74, 0.72)
minimum, maximum	--	-2.48	--	-0.82– 2.11
Missing (n)	0	1	0	0
Weight (kg)				
mean (SD)	--	64.57 (12.45)	--	52.97 (10.96)
median (Q1, Q3)	--	62.50 (54.43, 67.59)	--	50.00 (46.90, 57.55)
minimum, maximum	--	52.16, 89.81	--	43.80, 65.10
Missing (n)	0	0	0	0
Weight percentile				
mean (SD)	--	76.82 (18.19)	--	47.70 (36.95)
median (Q1, Q3)	--	81.64 (70.90, 86.56)	--	35.62 (26.96, 62.40)
minimum, maximum	--	47.53, 99.09	--	18.30, 89.18
Missing (n)	0	0	0	0
Weight SDS				
mean (SD)	--	0.95 (0.82)	--	-0.01 (1.11)

Table 5a. Growth and pubertal development measures at most recent follow-up visit for exposure episodeswith at least one follow-up visit among female participants

	NA-residing participants		EUR-residing participants	
	Abrocitinib N=0	Comparator N=9	Abrocitinib N=0	Comparator N=3
median (Q1, Q3)	--	0.90 (0.55, 1.11)	--	-0.37 (-0.64, 0.43)
minimum, maximum	--	-0.06, 2.36	--	-0.90, 1.24
Missing (n)	0	0	0	0
BMI (kg/m^2)				
mean (SD)	--	25.16 (3.98)	--	19.80 (1.71)
median (Q1, Q3)	--	24.00 (22.82, 26.85)	--	20.00 (19.00, 20.70)
minimum, maximum	--	20.60, 31.60	--	18.00, 21.40
Missing (n)	0	1	0	0
BMI percentile				
mean (SD)	--	82.80 (13.26)	--	48.62 (22.98)
median (Q1, Q3)	--	85.40 (75.88, 90.55)	--	47.33 (36.82, 59.77)
minimum, maximum	--	61.60, 98.34	--	26.31, 72.22
Missing (n)	0	1	0	0
BMI SDS				
mean (SD)	--	1.12 (0.67)	--	-0.04 (0.61)
median (Q1, Q3)	--	1.05 (0.71, 1.39)	--	-0.07 (-0.35, 0.26)
minimum, maximum	--	0.30, 2.13	--	-0.63, 0.59
Missing (n)	0	1	0	0
Participant-reported Tanner staging				
Pubic hair development, n (%)				
Stage I	--	0 (0.00%)	--	0 (0.00%)
Stage II	--	0 (0.00%)	--	0 (0.00%)
Stage III	--	2 (33.33%)	--	2 (66.67%)
Stage IV	--	0 (0.00%)	--	1 (33.33%)
Stage V	--	4 (66.67%)	--	0 (0.00%)
Missing (n)	0	3	0	0
Breast development, n (%)				
Stage I	--	1 (16.67%)	--	0 (0.00%)
Stage II	--	0 (0.00%)	--	1 (33.33%)
Stage III	--	0 (0.00%)	--	0 (0.00%)
Stage IV	--	2 (33.33%)	--	2 (66.67%)

Table 5a. Growth and pubertal development measures at most recent follow-up visit for exposure episodeswith at least one follow-up visit among female participants

	NA-residing participants		EUR-residing participants	
	Abrocitinib N=0	Comparator N=9	Abrocitinib N=0	Comparator N=3
Stage V	--	3 (50.00%)	--	0 (0.00%)
Missing (n)	0	3	0	0

Data as of September 30, 2025
Percentages are calculated among observations with non-missing data.
Note: As of the data cut for this report, no participants had completed a follow-up visit after the initiation of abrocitinib.
Abbreviations: BMI = body mass index; cm = centimeter; EUR = Europe; kg = kilogram; NA = North America; Q = quartile; SD = standard deviation; SDS = standard deviation score

Table.5b Growth and pubertal development measures at most recent follow-up visit for exposure episodes with at least one follow-up visit among male participants

	NA-residing participants		EUR-residing participants	
	Abrocitinib N=0	Comparator N=6	Abrocitinib N=0	Comparator N=7
Growth measures				
Standing height (cm)				
mean (SD)	--	167.37 (4.01)	--	167.67 (6.09)
median (Q1, Q3)	--	165.10 (165.05, 168.55)	--	169.00 (165.75, 171.50)
minimum, maximum	--	165.00, 172.00	--	157.00, 174.00
Missing (n)	0	3	0	1
Height percentile				
mean (SD)	--	50.96 (44.15)	--	57.08 (25.99)
median (Q1, Q3)	--	43.55 (27.27, 70.94)	--	53.62 (42.84, 69.45)
minimum, maximum	--	10.98, 98.34	--	23.80, 97.46
Missing (n)	0	3	0	1
Height SDS				
mean (SD)	--	0.25 (1.72)	--	0.30 (0.93)
median (Q1, Q3)	--	-0.16 (-0.69, 0.98)	--	0.09 (-0.18, 0.52)
minimum, maximum	--	-1.23, 2.13	--	-0.71, 1.95
Missing (n)	0	3	0	1
Weight (kg)				
mean (SD)	--	63.61 (17.03)	--	58.97 (12.48)
median (Q1, Q3)	--	69.89 (62.00, 71.50)	--	56.00 (50.75, 68.65)
minimum, maximum	--	38.46, 76.20	--	42.00, 76.00
Missing (n)	0	2	0	0
Weight percentile				
mean (SD)	--	69.89 (37.49)	--	60.76 (31.31)
median (Q1, Q3)	--	82.48 (59.37, 93.00)	--	75.59 (33.34, 84.72)
minimum, maximum	--	15.85, 98.72	--	18.24, 95.38
Missing (n)	0	2	0	0
Weight SDS				
mean (SD)	--	0.80 (1.37)	--	0.38 (0.97)

Table.5b Growth and pubertal development measures at most recent follow-up visit for exposure episodes with at least one follow-up visit among male participants

	NA-residing participants		EUR-residing participants	
	Abrocitinib N=0	Comparator N=6	Abrocitinib N=0	Comparator N=7
median (Q1, Q3)	--	1.00 (0.23, 1.57)	--	0.69 (-0.43, 1.02)
minimum, maximum	--	-1.00, 2.23	--	-0.91, 1.68
Missing (n)	0	2	0	0
BMI (kg/m^2)				
mean (SD)	--	25.70 (0.10)	--	19.80 (2.65)
median (Q1, Q3)	--	25.70 (25.65, 25.75)	--	19.25 (17.82, 21.50)
minimum, maximum	--	25.60, 25.80	--	17.00, 23.70
Missing (n)	0	3	0	1
BMI percentile				
mean (SD)	--	93.32 (2.95)	--	48.92 (28.78)
median (Q1, Q3)	--	93.79 (91.98, 94.90)	--	44.50 (23.80, 74.83)
minimum, maximum	--	90.17, 96.01	--	21.37, 81.33
Missing (n)	0	3	0	1
BMI SDS				
mean (SD)	--	1.53 (0.23)	--	-0.02 (0.79)
median (Q1, Q3)	--	1.54 (1.42, 1.64)	--	-0.16 (-0.71, 0.68)
minimum, maximum	--	1.29, 1.75	--	-0.79, 0.89
Missing (n)	0	3	0	1
Participant-reported Tanner staging				
Pubic hair development, n (%)				
Stage I	--	0 (0.00%)	--	0 (0.00%)
Stage II	--	2 (40.00%)	--	0 (0.00%)
Stage III	--	0 (0.00%)	--	1 (20.00%)
Stage IV	--	3 (60.00%)	--	2 (40.00%)
Stage V	--	0 (0.00%)	--	2 (40.00%)
Missing (n)	0	1	0	2
External genitalia development, n (%)				
Stage I	--	0 (0.00%)	--	0 (0.00%)
Stage II	--	2 (40.00%)	--	1 (20.00%)
Stage III	--	0 (0.00%)	--	0 (0.00%)

Table.5b Growth and pubertal development measures at most recent follow-up visit for exposure episodes with at least one follow-up visit among male participants

	NA-residing participants		EUR-residing participants	
	Abrocitinib N=0	Comparator N=6	Abrocitinib N=0	Comparator N=7
Stage IV	--	3 (60.00%)	--	2 (40.00%)
Stage V	--	0 (0.00%)	--	2 (40.00%)
Missing (n)	0	1	0	2

Data as of September 30, 2025
Percentages are calculated among observations with non-missing data.

Note: As of the data cut for this report, no participants had completed a follow-up visit after the initiation of abrocitinib.

Abbreviations: BMI = body mass index; cm = centimeter; EUR = Europe; kg = kilogram; NA = North America; Q = quartile; SD = standard deviation; SDS = standard deviation score

Table 6. Incidence rate of bone fractures among all participants

	NA-residing participants		EUR-residing participants	
	Abrocitinib N=3	Comparator N=56	Abrocitinib N=5	Comparator N=20
Event-level [1]				
N	0	0	0	0
Total PYR [2]	0.00	8.29	0.50	4.59
Incidence rate (95% CI)	--	--	--	--
Participant-level [3]				
N	0	0	0	0
Total PYR [4]	0.00	8.29	0.50	4.59
Incidence rate (95% CI)	--	--	--	--

Data as of September 30, 2025
Abbreviations: CI = confidence interval; EUR = Europe; NA = North America; PYR = person-years

1 Total number of first and subsequent bone fracture events within each exposure episode per 100 person-years.

2 For the event-level IR, person-time is calculated as the number of years from the index date to the latest of the most recent medication data entry, Registry visit date, targeted event date (if applicable), or the Registry exit date. Exposure episodes in the comparator cohort are censored at the initiation of abrocitinib; if this occurs, person-time is calculated from the index date to the to the abrocitinib initiation.

3 Total number of first bone fracture events within each exposure episode per 100 person-years.

4 For the participant-level IR, among exposure episodes with a bone fracture event, person-time is calculated as the number of years from the index date to the first bone fracture event date. For exposure episodes without any bone fracture events, person-time is calculated as the number of years from the index date to the latest of the most recent medication data entry, Registry visit date, targeted event date (if applicable), or the Registry exit date. Exposure episodes in the comparator cohort are censored at the initiation of abrocitinib; if this occurs, person-time is calculated from the index date to the to the abrocitinib initiation

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Table 7. Incident adverse event/reaction event counts and incidence rates among NA-residing participants

Event/Condition	Person-years[1]		Total event count [a]		Incidence rate per 100 person-years [b]	
	Abrocitinib	Comparator	Abrocitinib	Comparator	Abrocitinib	Comparator
Anaphylaxis/hypersensitivity						
Non-serious hypersensitivity reaction	0.00	8.29	--	0	--	0.00
Severe hypersensitivity reaction or anaphylaxis*	0.00	8.29	--	0	--	0.00
Cardiovascular						
Non-serious cardiac arrhythmia	0.00	8.29	--	0	--	0.00
Non-serious congestive heart failure^	0.00	8.29	--	0	--	0.00
Serious congestive heart failure*^	0.00	8.29	--	0	--	0.00
Coronary angioplasty with or without cardiac stent*	0.00	8.29	--	0	--	0.00
Coronary artery bypass graft*	0.00	8.29	--	0	--	0.00
Non-serious coronary artery disease^	0.00	8.29	--	0	--	0.00
Myocardial infarction*	0.00	8.29	--	0	--	0.00
Stable peripheral arterial disease^	0.00	8.29	--	0	--	0.00
Peripheral arterial thromboembolic event*	0.00	8.29	--	0	--	0.00
Peripheral ischemia or gangrene (necrosis)*	0.00	8.29	--	0	--	0.00
Stroke*	0.00	8.29	--	0	--	0.00
Transient ischemic attack*	0.00	8.29	--	0	--	0.00
Unstable angina*	0.00	8.29	--	0	--	0.00
Urgent peripheral arterial revascularization*	0.00	8.29	--	0	--	0.00
Other arterial thromboembolism event*	0.00	8.29	--	0	--	0.00
Other non-serious cardiac condition	0.00	8.29	--	0	--	0.00

Table 7. Incident adverse event/reaction event counts and incidence rates among NA-residing participants

Event/Condition	Person-years[1]		Total event count [a]		Incidence rate per 100 person-years [b]	
	Abrocitinib	Comparator	Abrocitinib	Comparator	Abrocitinib	Comparator
Other serious cardiac condition*	0.00	8.29	--	0	--	0.00
Other non-serious vascular condition	0.00	8.29	--	0	--	0.00
Other serious vascular condition*	0.00	8.29	--	0	--	0.00
Hepatic/Gastrointestinal						
Crohn's disease^	0.00	8.29	--	0	--	0.00
Eosinophilic esophagitis^	0.00	8.29	--	0	--	0.00
Fatty liver disease/Nonalcoholic steatohepatitis^	0.00	8.29	--	0	--	0.00
Gastroesophageal reflux disease/acid reflux^	0.00	8.29	--	0	--	0.00
Hepatic event with liver function tests >3x upper limit of normal	0.00	8.29	--	0	--	0.00
Hepatotoxicity: drug-induced liver injury*	0.00	8.29	--	0	--	0.00
Hepatotoxicity: other hepatotoxicity*	0.00	8.29	--	0	--	0.00
Ulcerative colitis^	0.00	8.29	--	0	--	0.00
Other non-serious gastrointestinal disorder	0.00	8.29	--	0	--	0.00
Other non-serious hepatic event	0.00	8.29	--	0	--	0.00
Other serious hepatic event or event requiring biopsy*	0.00	8.29	--	0	--	0.00
Malignancy						
Breast cancer*	0.00	8.29	--	0	--	0.00
Cervical cancer*, female participants only	0.00	5.26	--	0	--	0.00
Colon cancer*	0.00	8.29	--	0	--	0.00
Leukemia*	0.00	8.29	--	0	--	0.00
Lung cancer*	0.00	8.29	--	0	--	0.00
Lymphoma*	0.00	8.29	--	0	--	0.00

Table 7. Incident adverse event/reaction event counts and incidence rates among NA-residing participants

Event/Condition	Person-years[1]		Total event count [a]		Incidence rate per 100 person-years [b]	
	Abrocitinib	Comparator	Abrocitinib	Comparator	Abrocitinib	Comparator
Melanoma skin cancer*	0.00	8.29	--	0	--	0.00
Non-melanoma skin cancer basal cell*	0.00	8.29	--	0	--	0.00
Non-melanoma skin cancer squamous cell*	0.00	8.29	--	0	--	0.00
Pre-malignancy	0.00	8.29	--	0	--	0.00
Prostate cancer*, male participants only	0.00	3.03	--	0	--	0.00
Uterine cancer*, female participants only	0.00	5.26	--	0	--	0.00
Other malignancy*	0.00	8.29	--	0	--	0.00
Ophthalmologic/Ocular						
Blepharitis*^	0.00	8.29	--	0	--	0.00
Cataract	0.00	8.29	--	0	--	0.00
Conjunctivitis[c] *	0.00	8.29	--	0	--	0.00
Glaucoma^	0.00	8.29	--	0	--	0.00
Herpetic eye disease (H. simplex or H. zoster)*	0.00	8.29	--	0	--	0.00
Keratitis*	0.00	8.29	--	0	--	0.00
Keratoconus^	0.00	8.29	--	0	--	0.00
Ocular ulcer (e.g., corneal ulcer, ulcerative blepharitis, ulcerative conjunctivitis)*	0.00	8.29	--	0	--	0.00
Retinal detachment*	0.00	8.29	--	0	--	0.00
Other ocular event (new onset or worsening)*	0.00	8.29	--	0	--	0.00
Venous thromboembolism						
Deep vein thrombosis*	0.00	8.29	--	0	--	0.00
Pulmonary embolism*	0.00	8.29	--	0	--	0.00
Other venous thromboembolism*	0.00	8.29	--	0	--	0.00
Other event or condition						

Table 7. Incident adverse event/reaction event counts and incidence rates among NA-residing participants

Event/Condition	Person-years[1]		Total event count [a]		Incidence rate per 100 person-years [b]	
	Abrocitinib	Comparator	Abrocitinib	Comparator	Abrocitinib	Comparator
Anxiety	0.00	8.29	--	0	--	0.00
Non-serious asthma^	0.00	7.71	--	0	--	0.00
Serious asthma*	0.00	8.29	--	0	--	0.00
Attention-deficit/hyperactivity disorder^	0.00	8.29	--	0	--	0.00
Autism spectrum disorder^	0.00	8.29	--	0	--	0.00
Non-serious chronic obstructive pulmonary disease^	0.00	8.29	--	0	--	0.00
Serious chronic obstructive pulmonary disease exacerbation*	0.00	8.29	--	0	--	0.00
Depression	0.00	8.29	--	0	--	0.00
Diabetes mellitus (Type I or Type II)^	0.00	8.29	--	0	--	0.00
Eosinophilia	0.00	8.29	--	0	--	0.00
Fibromyalgia^	0.00	8.29	--	0	--	0.00
Hyperlipidemia^	0.00	8.29	--	0	--	0.00
Hypertension^	0.00	8.29	--	0	--	0.00
Insomnia	0.00	8.29	--	0	--	0.00
Interstitial lung disease/pulmonary fibrosis^	0.00	8.29	--	0	--	0.00
Surgery/medical procedure	0.00	8.29	--	0	--	0.00
Other non-serious medical condition	0.00	8.29	--	2	--	24.13
Other serious medical condition*	0.00	8.29	--	0	--	0.00
Other non-serious metabolic condition	0.00	8.29	--	0	--	0.00
Other musculoskeletal condition	0.00	8.29	--	1	--	12.07
Other non-serious neurological disorder	0.00	8.29	--	0	--	0.00
Other non-serious psychiatric disorder	0.00	8.29	--	0	--	0.00

Table 7. Incident adverse event/reaction event counts and incidence rates among NA-residing participants

Event/Condition	Person-years[1]		Total event count [a]		Incidence rate per 100 person-years [b]	
	Abrocitinib	Comparator	Abrocitinib	Comparator	Abrocitinib	Comparator
Other non-serious respiratory condition	0.00	8.29	--	0	--	0.00
Infection						
Progressive multifocal leukoencephalopathy*^	0.00	8.29	--	0	--	0.00
Active tuberculosis*	0.00	8.29	--	0	--	0.00
Serious COVID-19 (confirmed or suspected)*	0.00	8.29	--	0	--	0.00
Other infection (Any infection listed below that is deemed serious [d] is considered a TAE)	0.00	8.29	--	0	--	0.00
Bronchitis	0.00	8.29	--	0	--	0.00
Candidiasis (cutaneous, genital/vulvovaginal, oropharyngeal)	0.00	8.29	--	0	--	0.00
Cellulitis or erysipelas	0.00	8.29	--	0	--	0.00
Cold sores (herpes labialis)	0.00	8.29	--	0	--	0.00
Diverticulitis	0.00	8.29	--	0	--	0.00
Eczema herpeticum	0.00	8.29	--	0	--	0.00
Furuncles (boils)	0.00	8.29	--	0	--	0.00
Gastroenteritis	0.00	8.29	--	0	--	0.00
Herpes zoster (shingles, ear or eye involvement, or other)	0.00	8.29	--	0	--	0.00
Human immunodeficiency virus/AIDS^	0.00	8.29	--	0	--	0.00
Meningitis/Encephalitis	0.00	8.29	--	0	--	0.00
Molluscum contagiosum	0.00	8.29	--	0	--	0.00
Osteomyelitis	0.00	8.29	--	0	--	0.00
Otitis (ear infection)	0.00	8.29	--	0	--	0.00
Pneumonia	0.00	8.29	--	0	--	0.00

Table 7. Incident adverse event/reaction event counts and incidence rates among NA-residing participants

Event/Condition	Person-years[1]		Total event count [a]		Incidence rate per 100 person-years [b]	
	Abrocitinib	Comparator	Abrocitinib	Comparator	Abrocitinib	Comparator
Sepsis	0.00	8.29	--	0	--	0.00
Sinusitis	0.00	8.29	--	0	--	0.00
Superficial skin infection (e.g., impetigo pustules)	0.00	8.29	--	0	--	0.00
Upper respiratory infection	0.00	8.29	--	0	--	0.00
Urinary tract infection	0.00	8.29	--	0	--	0.00
Viral hepatitis	0.00	8.29	--	0	--	0.00
Warts (cutaneous)	0.00	8.29	--	0	--	0.00
Other infection	0.00	8.29	--	0	--	0.00
Other skin infection	0.00	8.29	--	0	--	0.00
Pregnancy [e]						
Pregnancy events occurring on or after registry enrollment, female participants only	0.00	5.26	--	0	--	0.00
Death [f] *						
Known cause of death	0.00	8.29	--	0	--	0.00
Unknown cause of death	0.00	8.29	--	0	--	0.00

Data as of September 30, 2025
Abbreviations: AIDS = acquired immunodeficiency syndrome; COVID = coronavirus disease; NA = North America; TAE = Targeted adverse events

Note: TAEs are denoted by an asterisk; TAEs require the submission of appropriate medical records and completion of a TAEQ to support medical review and event confirmation.^ Excludes participants with a history of the event or condition; event count and incidence rate calculations only include the first event per exposure episode.*

1 Person-time is calculated as the number of years from the index date to the latest of the most recent medication data entry, Registry visit date, targeted event date (if applicable), or the Registry exit date. Exposure episodes in the comparator cohort are censored at the initiation of abrocitinib; if this occurs, person-time is calculated from the index date to the to the abrocitinib initiation. For events/conditions excluding prior history (denoted by ^), person-time is calculated from the index date to the first event date.

a Includes first and subsequent events per exposure episode, unless otherwise noted.

b Number of total events per 100 person-years, unless otherwise noted.

Table 7. Incident adverse event/reaction event counts and incidence rates among NA-residing participants

Event/Condition	Person-years[1]		Total event count [a]		Incidence rate per 100 person-years [b]	
	Abrocitinib	Comparator	Abrocitinib	Comparator	Abrocitinib	Comparator

c Including allergic, drug-induced, infectious (bacterial, viral, or unknown pathogen), non-allergic non-infectious (e.g., atopic conjunctivitis), vernal, and conjunctivitis of unknown etiology.

d A serious infection is one that requires IV antibiotics, requires or prolongs hospitalization, is life threatening, or causes death, disability, permanent damage, a congenital abnormality, or is otherwise serious in the opinion of the site investigator (i.e., may jeopardize the patient and require intervention to prevent one of the other serious outcomes).

e Pregnancy is a targeted event but is not considered an AE.

f Death terms captured via Exit form, in addition to all pre-specified adverse event terms available with ability to select outcome of death and/or assign as a primary cause of death via the Exit form

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Table 8. Incident adverse event/reaction event counts and incidence rates among EUR-residing participants

Event/Condition	Person-years[1]		Total event count [a]		Incidence rate per 100 person-years [b]	
	Abrocitinib	Comparator	Abrocitinib	Comparator	Abrocitinib	Comparator
Anaphylaxis/hypersensitivity						
Non-serious hypersensitivity reaction	0.50	4.59	0	0	0.00	0.00
Severe hypersensitivity reaction or anaphylaxis*	0.50	4.59	0	0	0.00	0.00
Cardiovascular						
Non-serious cardiac arrhythmia	0.50	4.59	0	0	0.00	0.00
Non-serious congestive heart failure^	0.50	4.59	0	0	0.00	0.00
Serious congestive heart failure*^	0.50	4.59	0	0	0.00	0.00
Coronary angioplasty with or without cardiac stent*	0.50	4.59	0	0	0.00	0.00
Coronary artery bypass graft*	0.50	4.59	0	0	0.00	0.00
Non-serious coronary artery disease^	0.50	4.59	0	0	0.00	0.00
Myocardial infarction*	0.50	4.59	0	0	0.00	0.00
Stable peripheral arterial disease^	0.50	4.59	0	0	0.00	0.00
Peripheral arterial thromboembolic event*	0.50	4.59	0	0	0.00	0.00
Peripheral ischemia or gangrene (necrosis)*	0.50	4.59	0	0	0.00	0.00
Stroke*	0.50	4.59	0	0	0.00	0.00
Transient ischemic attack*	0.50	4.59	0	0	0.00	0.00
Unstable angina*	0.50	4.59	0	0	0.00	0.00
Urgent peripheral arterial revascularization*	0.50	4.59	0	0	0.00	0.00
Other arterial thromboembolism event*	0.50	4.59	0	0	0.00	0.00
Other non-serious cardiac condition	0.50	4.59	0	0	0.00	0.00
Other serious cardiac condition*	0.50	4.59	0	0	0.00	0.00
Other non-serious vascular condition	0.50	4.59	0	0	0.00	0.00

Table 8. Incident adverse event/reaction event counts and incidence rates among EUR-residing participants

Event/Condition	Person-years[1]		Total event count [a]		Incidence rate per 100 person-years [b]	
	Abrocitinib	Comparator	Abrocitinib	Comparator	Abrocitinib	Comparator
Other serious vascular condition*	0.50	4.59	0	0	0.00	0.00
Hepatic/Gastrointestinal						
Crohn's disease^	0.50	4.59	0	0	0.00	0.00
Eosinophilic esophagitis^	0.50	4.59	0	0	0.00	0.00
Fatty liver disease/Nonalcoholic steatohepatitis^	0.50	4.59	0	0	0.00	0.00
Gastroesophageal reflux disease/acid reflux^	0.50	4.59	0	0	0.00	0.00
Hepatic event with liver function tests >3x upper limit of normal	0.50	4.59	0	0	0.00	0.00
Hepatotoxicity: drug-induced liver injury*	0.50	4.59	0	0	0.00	0.00
Hepatotoxicity: other hepatotoxicity*	0.50	4.59	0	0	0.00	0.00
Ulcerative colitis^	0.50	4.59	0	0	0.00	0.00
Other non-serious gastrointestinal disorder	0.50	4.59	0	1	0.00	21.78
Other non-serious hepatic event	0.50	4.59	0	0	0.00	0.00
Other serious hepatic event or event requiring biopsy*	0.50	4.59	0	0	0.00	0.00
Malignancy						
Breast cancer*	0.50	4.59	0	0	0.00	0.00
Cervical cancer*, female participants only	0.00	1.36	--	0	--	0.00
Colon cancer*	0.50	4.59	0	0	0.00	0.00
Leukemia*	0.50	4.59	0	0	0.00	0.00
Lung cancer*	0.50	4.59	0	0	0.00	0.00
Lymphoma*	0.50	4.59	0	0	0.00	0.00
Melanoma skin cancer*	0.50	4.59	0	0	0.00	0.00
Non-melanoma skin cancer basal cell*	0.50	4.59	0	0	0.00	0.00

Table 8. Incident adverse event/reaction event counts and incidence rates among EUR-residing participants

Event/Condition	Person-years[1]		Total event count [a]		Incidence rate per 100 person-years [b]	
	Abrocitinib	Comparator	Abrocitinib	Comparator	Abrocitinib	Comparator
Non-melanoma skin cancer squamous cell*	0.50	4.59	0	0	0.00	0.00
Pre-malignancy	0.50	4.59	0	0	0.00	0.00
Prostate cancer*, male participants only	0.50	3.23	0	0	0.00	0.00
Uterine cancer*, female participants only	0.00	1.36	--	0	--	0.00
Other malignancy*	0.50	4.59	0	0	0.00	0.00
Ophthalmologic/Ocular						
Blepharitis*^	0.50	4.59	0	0	0.00	0.00
Cataract	0.50	4.59	0	0	0.00	0.00
Conjunctivitis[c] *	0.50	4.59	0	0	0.00	0.00
Glaucoma^	0.50	4.59	0	0	0.00	0.00
Herpetic eye disease (H. simplex or H. zoster)*	0.50	4.59	0	0	0.00	0.00
Keratitis*	0.50	4.59	0	0	0.00	0.00
Keratoconus^	0.50	4.59	0	0	0.00	0.00
Ocular ulcer (e.g., corneal ulcer, ulcerative blepharitis, ulcerative conjunctivitis)*	0.50	4.59	0	0	0.00	0.00
Retinal detachment*	0.50	4.59	0	0	0.00	0.00
Other ocular event (new onset or worsening)*	0.50	4.59	0	0	0.00	0.00
Venous thromboembolism						
Deep vein thrombosis*	0.50	4.59	0	0	0.00	0.00
Pulmonary embolism*	0.50	4.59	0	0	0.00	0.00
Other venous thromboembolism*	0.50	4.59	0	0	0.00	0.00
Other event or condition						
Anxiety	0.50	4.59	0	0	0.00	0.00
Non-serious asthma^	0.50	4.59	0	0	0.00	0.00

Table 8. Incident adverse event/reaction event counts and incidence rates among EUR-residing participants

Event/Condition	Person-years[1]		Total event count [a]		Incidence rate per 100 person-years [b]	
	Abrocitinib	Comparator	Abrocitinib	Comparator	Abrocitinib	Comparator
Serious asthma*	0.50	4.59	0	0	0.00	0.00
Attention-deficit/hyperactivity disorder^	0.50	4.25	0	0	0.00	0.00
Autism spectrum disorder^	0.50	4.25	0	0	0.00	0.00
Non-serious chronic obstructive pulmonary disease^	0.50	4.59	0	0	0.00	0.00
Serious chronic obstructive pulmonary disease exacerbation*	0.50	4.59	0	0	0.00	0.00
Depression	0.50	4.59	0	0	0.00	0.00
Diabetes mellitus (Type I or Type II)^	0.50	4.59	0	0	0.00	0.00
Eosinophilia	0.50	4.59	0	0	0.00	0.00
Fibromyalgia^	0.50	4.59	0	0	0.00	0.00
Hyperlipidemia^	0.50	4.59	0	0	0.00	0.00
Hypertension^	0.50	4.59	0	0	0.00	0.00
Insomnia	0.50	4.59	0	0	0.00	0.00
Interstitial lung disease/pulmonary fibrosis^	0.50	4.59	0	0	0.00	0.00
Surgery/medical procedure	0.50	4.59	0	0	0.00	0.00
Other non-serious medical condition	0.50	4.59	0	1	0.00	21.78
Other serious medical condition*	0.50	4.59	0	0	0.00	0.00
Other non-serious metabolic condition	0.50	4.59	0	0	0.00	0.00
Other musculoskeletal condition	0.50	4.59	0	1	0.00	21.78
Other non-serious neurological disorder	0.50	4.59	0	0	0.00	0.00
Other non-serious psychiatric disorder	0.50	4.59	0	0	0.00	0.00
Other non-serious respiratory condition	0.50	4.59	0	0	0.00	0.00
Infection						

Table 8. Incident adverse event/reaction event counts and incidence rates among EUR-residing participants

Event/Condition	Person-years[1]		Total event count [a]		Incidence rate per 100 person-years [b]	
	Abrocitinib	Comparator	Abrocitinib	Comparator	Abrocitinib	Comparator
Progressive multifocal leukoencephalopathy*^	0.50	4.59	0	0	0.00	0.00
Active tuberculosis*	0.50	4.59	0	0	0.00	0.00
Serious COVID-19 (confirmed or suspected)*	0.50	4.59	0	0	0.00	0.00
Other infection (Any infection listed below that is deemed serious[d] is considered a TAE)	0.50	4.59	0	0	0.00	0.00
Bronchitis	0.50	4.59	0	0	0.00	0.00
Candidiasis (cutaneous, genital/vulvovaginal, oropharyngeal)	0.50	4.59	0	0	0.00	0.00
Cellulitis or erysipelas	0.50	4.59	0	0	0.00	0.00
Cold sores (herpes labialis)	0.50	4.59	0	0	0.00	0.00
Diverticulitis	0.50	4.59	0	0	0.00	0.00
Eczema herpeticum	0.50	4.59	0	0	0.00	0.00
Furuncles (boils)	0.50	4.59	0	0	0.00	0.00
Gastroenteritis	0.50	4.59	0	0	0.00	0.00
Herpes zoster (shingles, ear or eye involvement, or other)	0.50	4.59	0	0	0.00	0.00
Human immunodeficiency virus/AIDS^	0.50	4.59	0	0	0.00	0.00
Meningitis/Encephalitis	0.50	4.59	0	0	0.00	0.00
Molluscum contagiosum	0.50	4.59	0	0	0.00	0.00
Osteomyelitis	0.50	4.59	0	0	0.00	0.00
Otitis (ear infection)	0.50	4.59	0	0	0.00	0.00
Pneumonia	0.50	4.59	0	0	0.00	0.00
Sepsis	0.50	4.59	0	0	0.00	0.00
Sinusitis	0.50	4.59	0	0	0.00	0.00

Table 8. Incident adverse event/reaction event counts and incidence rates among EUR-residing participants

Event/Condition	Person-years[1]		Total event count [a]		Incidence rate per 100 person-years [b]	
	Abrocitinib	Comparator	Abrocitinib	Comparator	Abrocitinib	Comparator
Superficial skin infection (e.g., impetigo pustules)	0.50	4.59	0	0	0.00	0.00
Upper respiratory infection	0.50	4.59	0	4	0.00	87.11
Urinary tract infection	0.50	4.59	0	0	0.00	0.00
Viral hepatitis	0.50	4.59	0	0	0.00	0.00
Warts (cutaneous)	0.50	4.59	0	0	0.00	0.00
Other infection	0.50	4.59	0	1	0.00	21.78
Other skin infection	0.50	4.59	0	0	0.00	0.00
Pregnancy [e]						
Pregnancy events occurring on or after registry enrollment, female participants only	0.00	1.36	--	0	--	0.00
Death [f] *						
Known cause of death	0.50	4.59	0	0	0.00	0.00
Unknown cause of death	0.50	4.59	0	0	0.00	0.00

Data as of September 30, 2025
Abbreviations: AIDS = acquired immunodeficiency syndrome; COVID = coronavirus disease; EUR = Europe; TAE = Targeted adverse events

Note: TAEs are denoted by an asterisk; TAEs require the submission of appropriate medical records and completion of a TAEQ to support medical review and event confirmation.*

^ Excludes participants with a history of the event or condition; event count and incidence rate calculations only include the first event per exposure episode.

1 Person-time is calculated as the number of years from the index date to the latest of the most recent medication data entry, Registry visit date, targeted event date (if applicable), or the Registry exit date. Exposure episodes in the comparator cohort are censored at the initiation of abrocitinib; if this occurs, person-time is calculated from the index date to the to the abrocitinib initiation. For events/conditions excluding prior history (denoted by ^), person-time is calculated from the index date to the first event date.

a Includes first and subsequent events per exposure episode, unless otherwise noted.

b Number of total events per 100 person-years, unless otherwise noted.

Table 8. Incident adverse event/reaction event counts and incidence rates among EUR-residing participants

Event/Condition	Person-years[1]		Total event count [a]		Incidence rate per 100 person-years [b]	
	Abrocitinib	Comparator	Abrocitinib	Comparator	Abrocitinib	Comparator

c Including allergic, drug-induced, infectious (bacterial, viral, or unknown pathogen), non-allergic non-infectious (e.g., atopic conjunctivitis), vernal, and conjunctivitis of unknown etiology.
d A serious infection is one that requires IV antibiotics, requires or prolongs hospitalization, is life threatening, or causes death, disability, permanent damage, a congenital abnormality, or is otherwise serious in the opinion of the site investigator (i.e., may jeopardize the patient and require intervention to prevent one of the other serious outcomes).
e Pregnancy is a targeted event but is not considered an AE.
f Death terms captured via Exit form, in addition to all pre-specified adverse event terms available with ability to select outcome of death and/or assign as a primary cause of death via the Exit form.

Document Approval Record

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