

Integrated Safety Update of Abrocitinib in 1014 Young Adult Patients Aged 18 to <40 Years With Moderate-to-Severe Atopic Dermatitis: Data From More Than 2250 Patient-Years With up to 4.5 Years of Exposure

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Background and Objectives

Background

- AD is a chronic inflammatory skin condition with a relapsing-remitting disease course that requires long-term treatment to maintain symptom control^{1,2}
- Abrocitinib is an oral, once-daily, JAK1-selective inhibitor approved for the treatment of adolescents and adults with moderate-to-severe AD^{3,4}
- The manageable long-term safety profile of abrocitinib in adults and a favorable safety profile in adolescents with moderate-to-severe AD with exposure up to 4.5 years have been previously reported^{5,6}
 - The safety profile in young adults aged 18 to <30 years has not yet been described

Objectives

- To evaluate the long-term safety of abrocitinib in young adult patients aged 18 to <30 years with moderate-to-severe AD
- To contextualize these findings with data from adult patients aged 30 to <40 years and adolescents aged 12 to <18 years

Patients, Study Design, and Exposure

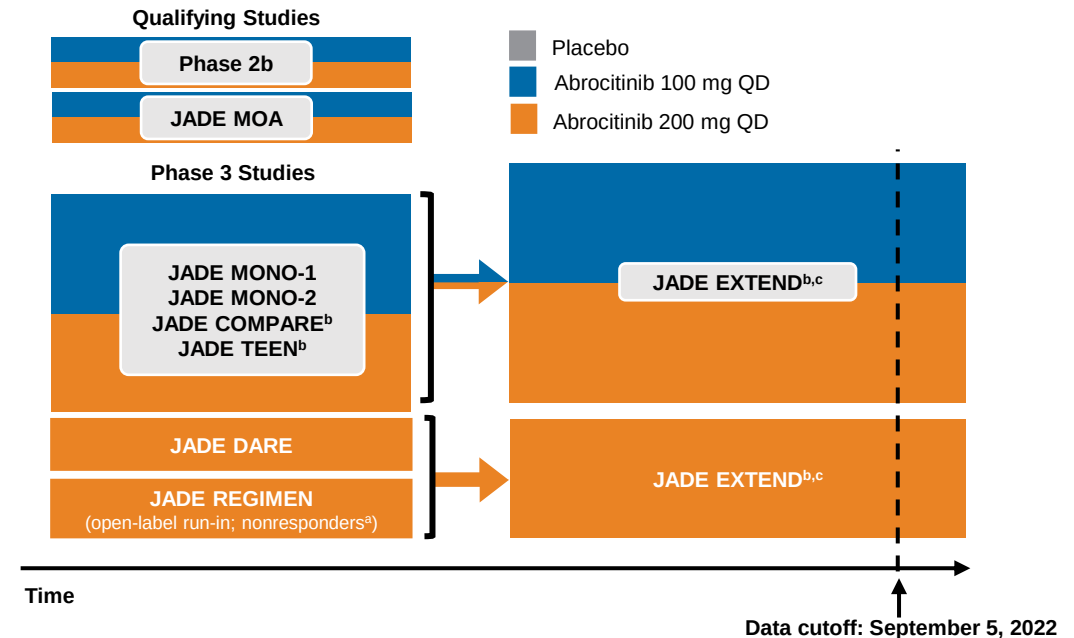
Patients and Study Design

- Data were included from patients with moderate-to-severe AD aged 18 to <30 years (young adults) and adults aged 30 to <40 years treated with abrocitinib (100 mg/200 mg) in a phase 2b trial, phase 2a JADE MOA, phase 3 JADE MONO-1, MONO-2, COMPARE, TEEN and DARE, and in the ongoing extension trial, JADE EXTEND (data cutoff date: September 5, 2022)
 - Patients who were nonresponders^a to abrocitinib 200 mg in the 12-week open-label induction period of JADE REGIMEN were also included
- Safety was assessed via TEAE monitoring
 - IRs (95% CI) per 100 PY for AEs of special interest were assessed in patients stratified by baseline age categories
- Data from young adult patients were compared to data from adult patients and results were contextualized with those previously reported for adolescents aged 12 to <18 years^{1,2}

Exposure

- Data from 1595 patients were analyzed in this study, representing 2569.6 PY of abrocitinib exposure
- The young adult cohort (aged 18 to <30 years) comprised 1014 patients, representing 1607.0 PY of abrocitinib exposure
 - Of these, 297 patients received abrocitinib 100 mg (exposure: 517.5 PY) and 717 patients received abrocitinib 200 mg (exposure: 1089.5 PY)
- The adult cohort (aged 30 to <40 years) comprised 581 patients, representing 962.6 PY of abrocitinib exposure
 - Of these, 210 patients received abrocitinib 100 mg (exposure: 407.6 PY) and 371 patients received abrocitinib 200 mg (exposure: 555.0 PY)
- The adolescent cohort (aged 12 to <18 years) comprised 490 patients, representing 1004.0 PY of abrocitinib exposure^{1,2}
 - Of these, 201 patients received abrocitinib 100 mg (exposure: 404.5 PY) and 289 patients received abrocitinib 200 mg (exposure: 599.5 PY)^{1,2}

Study Design



AD, atopic dermatitis; AE, adverse event; EASI-75, ≥75% improvement from baseline in Eczema Area and Severity Index; IGA 0/1, Investigator's Global Assessment score of 0 (clear) or 1 (almost clear) with ≥2-grade improvement from baseline; IR, incidence rate; PY, patient-years; QD, once daily; TEAE, treatment-emergent adverse event. ^aPatients who did not achieve IGA 0/1 and EASI-75 after 12 weeks of treatment with abrocitinib 200 mg. ^bPatients in JADE COMPARE and JADE TEEN received abrocitinib in combination with topical corticosteroids, and in JADE EXTEND, patients were permitted to use medicated or non-medicated topical treatments throughout the study. ^cIncludes patients who received their first dose of abrocitinib (100 mg or 200 mg) in JADE EXTEND after receiving placebo in a phase 3 placebo-controlled trial or dupilumab in JADE COMPARE or JADE DARE, as well as patients who first received abrocitinib in a qualifying phase 3 trial. ClinicalTrials.gov identifiers: NCT02780167 (phase 2b), NCT03915496 (MOA), NCT03349060 (MONO-1), NCT03575871 (MONO-2), NCT03720470 (COMPARE), NCT03796676 (TEEN), NCT03627767 (REGIMEN), NCT04345367 (DARE), NCT03422822 (EXTEND). 1. Simpson EL et al. Presented at: European Academy of Allergy and Clinical Immunology Congress; May 31-June 3, 2024; Valencia, Spain. 2. Paller AS et al. Presented at: European Academy of Dermatology and Venereology Congress; September 25-28, 2024; Amsterdam, the Netherlands.

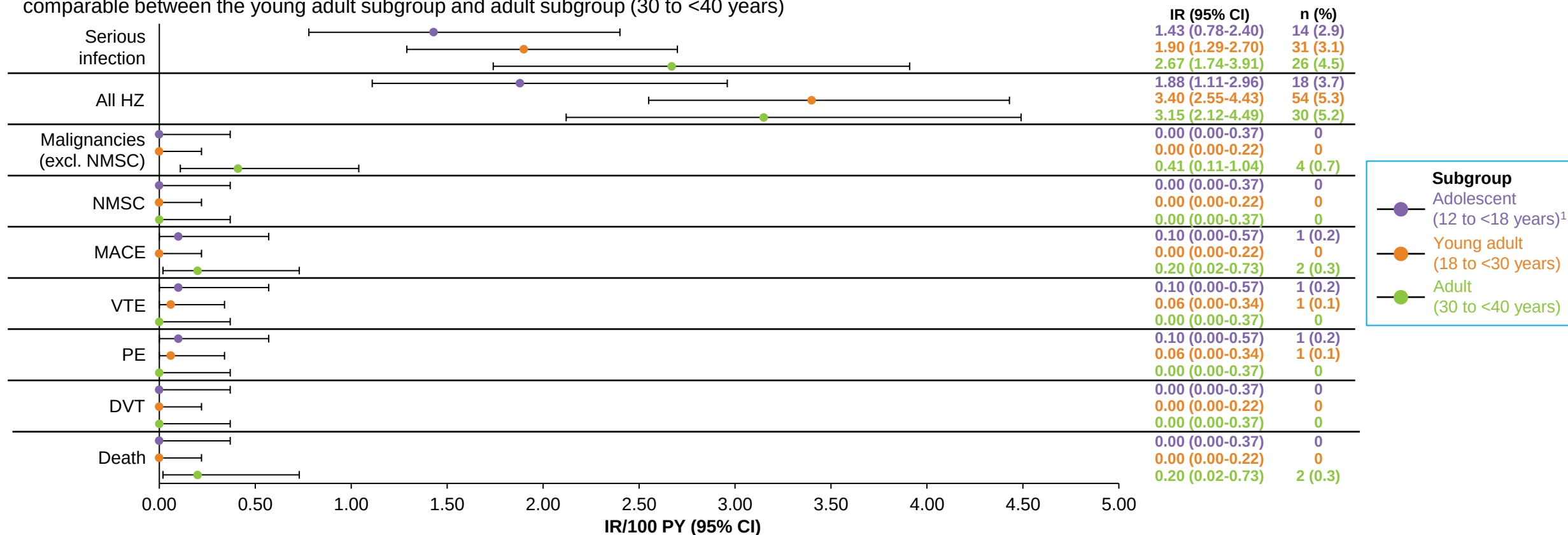
TEAEs Stratified by Age

- The number of TEAEs and discontinuations due to AEs were similar across age groups
- The proportion of patients reporting serious and severe AEs was slightly higher in the adolescent and adult subgroups compared to young adults

n (%)	Adolescent subgroup (12 to <18 years) ^{1,2}			Young adult subgroup (18 to <30 years)			Adult subgroup (30 to <40 years)		
	Abrocitinib 100 mg QD n=201	Abrocitinib 200 mg QD n=289	All abrocitinib n=490	Abrocitinib 100 mg QD n=297	Abrocitinib 200 mg QD n=717	All abrocitinib n=1014	Abrocitinib 100 mg QD n=210	Abrocitinib 200 mg QD n=371	All abrocitinib n=581
AEs	154 (76.6)	244 (84.4)	398 (81.2)	246 (82.8)	613 (85.5)	859 (84.7)	171 (81.4)	315 (84.9)	486 (83.6)
Serious AEs	14 (7.0)	30 (10.4)	44 (9.0)	22 (7.4)	55 (7.7)	77 (7.6)	21 (10.0)	39 (10.5)	60 (10.3)
Severe AEs	20 (10.0)	25 (8.7)	45 (9.2)	23 (7.7)	57 (7.9)	80 (7.9)	21 (10.0)	34 (9.2)	55 (9.5)
Discontinuation due to TEAE	22 (10.9)	38 (13.1)	60 (12.2)	41 (13.8)	91 (12.7)	132 (13.0)	23 (11.0)	53 (14.3)	76 (13.1)

AEs of Special Interest Stratified by Age

- IRs for AEs of special interest were generally comparable between adolescents (12 to <18 years) and young adults (18 to <30 years), except for HZ, where IRs were comparable between the young adult subgroup and adult subgroup (30 to <40 years)



Conclusions

- Abrocitinib was well tolerated in young adults aged 18 to <30 years treated up to 4.5 years, with a safety profile that was generally comparable to adolescents aged 12 to 18 years¹
- No new safety signals were observed in young adults compared with adolescent or adult (aged 30 to <40 years) patients