Efficacy and Safety of Abrocitinib Versus Dupilumab in Patients Who Self-Identified as Having Skin of Color: A Post Hoc Analysis of JADE COMPARE

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BACKGROUND

- Atopic dermatitis (AD) is a common, chronic, inflammatory skin disorder characterized by recurrent eczematous skin lesions and pruritus with heterogeneous skin manifestations, symptoms, and severity[1]
- Although AD can occur in patients of all racial backgrounds, clinical presentations of the disease and treatment efficacy vary among racial subgroups[2]
  - Variations in pigmentary changes, erythema, and inflammatory response underscore the need for further contextualization of treatment efficacy and safety in people with skin of color (SoC) with AD
- Moderate-to-severe AD can be refractory to topical therapy, and the use of systemic therapy may be needed to achieve disease control, as recommended by 2024 guidelines[3]
  - Dupilumab, an injectable interleukin (IL) 4 receptor alpha inhibitor that inhibits IL-4 and IL-13 signaling, is approved for patients aged ≥6 months with moderate-to-severe AD[4]
  - Abrocitinib is an oral, once-daily, Janus kinase 1–selective inhibitor approved for the treatment of adults and adolescents with moderate-to-severe AD[5,6]
  - The phase 3 JADE COMPARE (NCT03720470) study assessed the short-term efficacy and safety of abrocitinib and dupilumab in patients with moderate-to-severe AD[7]

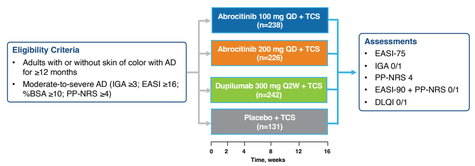
OBJECTIVE

- To assess the short-term efficacy and safety of abrocitinib versus dupilumab in patients with SoC and moderate-to-severe AD in JADE COMPARE

METHODS

- This JADE COMPARE post hoc analysis included data from patients aged ≥18 years who were randomly assigned 2:2:2:1 to receive abrocitinib (200 mg or 100 mg) once daily, dupilumab 300 mg once every 2 weeks, or placebo with concomitant topical therapy for 16 weeks (**Figure 1**)
- Patients who self-reported their race as non-White or did not report their race but identified as Hispanic or Latino were categorized as having SoC
  - Categories of patients with SoC included American Indian or Alaska Native, Asian, Black or African American, multiracial, Native Hawaiian or Other Pacific Islander, and Hispanic or Latino
  - Patients who self-reported their race as White or did not report their race but did not identify as Hispanic or Latino were categorized as White
- Assessments included the following clinical efficacy and patient-reported outcomes:
  - ≥75% improvement from baseline in the Eczema Area and Severity Index (EASI-75)
  - Investigator's Global Assessment score of 0 (clear) or 1 (almost clear) (IGA 0/1)
  - ≥4-point improvement from baseline in the Peak Pruritus Numerical Rating Scale score (PP-NRS 4; used with permission from Regeneron Pharmaceuticals, Inc., and Sanofi)
  - Composite endpoint of ≥90% improvement from baseline in the EASI plus PP-NRS score of 0 or 1 (EASI-90 + PP-NRS 0/1)
  - Dermatology Life Quality Index score of 0 or 1 (DLQI 0/1)
- Missing data were handled using nonresponder imputation
- Safety was assessed via treatment-emergent adverse event (TEAE) monitoring

Figure 1. Study Design



%BSA, percentage of body surface area; AD, atopic dermatitis; DLQI, Dermatology Life Quality Index; EASI, Eczema Area and Severity Index; EASI-75, ≥75% improvement from baseline in Eczema Area and Severity Index; EASI-90, ≥90% improvement from baseline in Eczema Area and Severity Index; IGA, Investigator's Global Assessment; PP-NRS, Peak Pruritus Numerical Rating Scale; PP-NRS 4, ≥4-point improvement from baseline in Peak Pruritus Numerical Rating Scale; Q2W, every 2 weeks; QD, once daily; TCS, topical corticosteroids.

RESULTS

Patient Population

- Of 837 patients in JADE COMPARE, 227 (27.1%) were categorized as having SoC (placebo, n=42; abrocitinib 100 mg, n=56; abrocitinib 200 mg, n=65; dupilumab 300 mg, n=64) and 610 (72.9%) were categorized as White (placebo, n=89; abrocitinib 100 mg, n=182; abrocitinib 200 mg, n=161; dupilumab 300 mg, n=178) (**Table 1**)
- Among patients with SoC, the majority were Asian (78.4%), and 15.4% were Black or African American
- Baseline disease characteristics were generally balanced between treatment groups independent of skin color

Table 1. Baseline Demographics and Disease Characteristics

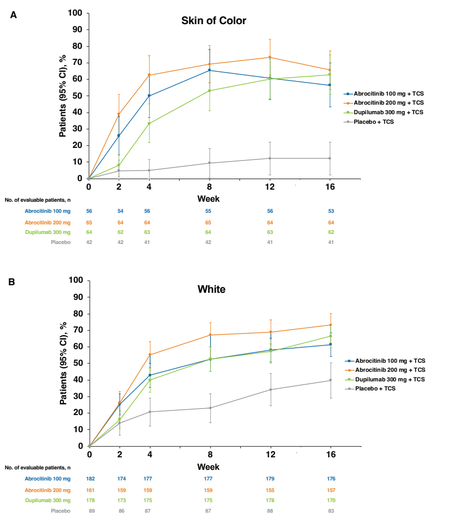
Characteristic	Skin of Color				White			
	Placebo + TCS (n=42)	Abrocitinib 100 mg + TCS (n=56)	Abrocitinib 200 mg + TCS (n=65)	Dupilumab 300 mg + TCS (n=64)	Placebo + TCS (n=89)	Abrocitinib 100 mg + TCS (n=182)	Abrocitinib 200 mg + TCS (n=161)	Dupilumab 300 mg + TCS (n=178)
Age, mean (SD), years	32.9 (10.5)	32.7 (9.8)	35.9 (14.0)	36.0 (13.5)	39.5 (16.6)	38.7 (15.7)	39.9 (14.6)	37.6 (15.0)
Male, n (%)	29 (69.0)	33 (58.9)	36 (55.4)	35 (54.7)	48 (53.9)	87 (47.8)	68 (42.2)	73 (41.0)
Race, n (%)								
American Indian or Alaska Native	2 (4.8)	1 (1.8)	0	2 (3.1)	0	0	0	0
Asian	31 (73.8)	48 (85.7)	53 (81.5)	46 (71.9)	0	0	0	0
Black or African American	6 (14.3)	6 (10.7)	9 (13.8)	14 (21.9)	0	0	0	0
Multiracial	1 (2.4)	1 (1.8)	1 (1.5)	2 (3.1)	0	0	0	0
Native Hawaiian or Other Pacific Islander	1 (2.4)	0	1 (1.5)	0	0	0	0	0
White	0	0	0	0	87 (97.8)	182 (100)	161 (100)	176 (98.9)
Not reported	1 (2.4)	0	1 (1.5)	0	2 (2.2)	0	0	2 (1.1)
Ethnicity, n (%)								
Hispanic or Latino	2 (4.8)	1 (1.8)	2 (3.1)	3 (4.7)	14 (15.7)	34 (18.7)	34 (21.1)	34 (19.1)
Not Hispanic or Latino	38 (90.5)	54 (96.4)	61 (93.8)	61 (95.3)	75 (84.3)	146 (80.2)	126 (78.3)	140 (78.7)
Not reported	2 (4.8)	1 (1.8)	2 (3.1)	0	0	2 (1.1)	1 (0.6)	4 (2.2)
BMI, mean (SD), kg/m²	26.3 (6.6)	25.1 (4.5)	26.5 (6.8)	26.1 (5.7)	25.9 (4.9)	26.6 (5.4)	26.7 (5.6)	26.9 (5.7)
%BSA, mean (SD)	57.6 (23.5)	51.5 (23.4)	56.1 (21.7)	52.3 (19.8)	44.8 (24.6)	47.0 (23.0)	48.7 (23.3)	44.4 (22.5)
EASI at baseline, mean (SD)	34.3 (12.5)	31.9 (14.3)	33.1 (13.0)	31.9 (13.0)	29.4 (12.4)	29.8 (13.3)	31.6 (13.1)	29.9 (11.6)
IGA at baseline, n (%)								
Moderate	22 (52.4)	29 (51.8)	31 (47.7)	34 (53.1)	66 (74.2)	124 (68.1)	107 (66.5)	128 (71.9)
Severe	20 (47.6)	27 (48.2)	34 (52.3)	30 (46.9)	23 (25.8)	58 (31.9)	54 (33.5)	50 (28.1)
PP-NRS, mean (SD)	7.3 (2.0)	7.3 (1.6)	7.8 (1.5)	7.4 (1.7)	7.1 (1.6)	7.1 (1.7)	7.6 (1.5)	7.2 (1.6)
DLQI, mean (SD)	15.7 (7.3)	15.3 (6.6)	15.4 (6.3)	15.5 (7.1)	14.9 (6.8)	15.5 (6.4)	16.7 (6.7)	15.6 (6.6)

%BSA, percentage of body surface area; BMI, body mass index; DLQI, Dermatology Life Quality Index; EASI, Eczema Area and Severity Index; IGA, Investigator's Global Assessment; PP-NRS, Peak Pruritus Numerical Rating Scale; TCS, topical corticosteroids.

Efficacy Assessments

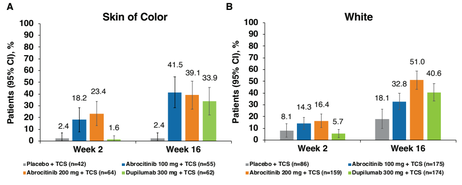
- The proportions of patients achieving efficacy responses were generally higher or comparable with abrocitinib 200 mg versus dupilumab through Week 16 and were comparable between patients with SoC and White patients
- A higher proportion of patients with SoC receiving abrocitinib 200 mg than those receiving dupilumab 300 mg achieved an EASI-75 response (39.1% versus 8.1%) (**Figure 2**), IGA 0/1 (23.4% versus 1.6%) (**Figure 3**), and EASI-90 + PP-NRS 0/1 (3.1% versus 0.0%) (**Figure 4**) by Week 2
  - Similar findings were reported for White patients (EASI-75, 26.4% versus 16.2%; IGA 0/1, 16.4% versus 5.7%; EASI-90 + PP-NRS 0/1, 3.8% versus 1.2%)
- The proportions of patients with SoC receiving abrocitinib 200 mg who achieved an EASI-75 response at Week 16 were similar to those receiving dupilumab 300 mg (65.6% versus 62.9%) (**Figure 2**)
  - Similar findings were reported for White patients (73.2% versus 66.5%)
- At Week 16, the proportions of patients receiving abrocitinib 200 mg who achieved an IGA 0/1 response or EASI-90 + PP-NRS 0/1 were similar to or higher than those receiving dupilumab 300 mg, independent of skin color (**Figures 3** and **4**)

Figure 2. Achievement of EASI-75 Response in (A) Patients With SoC and (B) White Patients



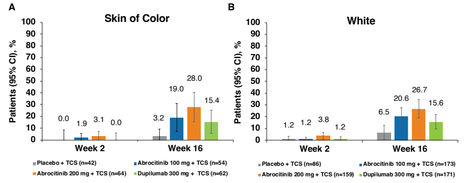
EASI-75, ≥75% improvement from baseline in Eczema Area and Severity Index; SoC, skin of color; TCS, topical corticosteroids.

Figure 3. Achievement of IGA 0/1 Response at Weeks 2 and 16 in (A) Patients With SoC and (B) White Patients



IGA, Investigator's Global Assessment; SoC, skin of color; TCS, topical corticosteroids.

Figure 4. Achievement of EASI-90 + PP-NRS 0/1 at Weeks 2 and 16 in (A) Patients With SoC and (B) White Patients

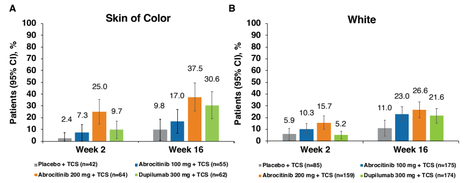


EASI-90, ≥90% improvement from baseline in Eczema Area and Severity Index; PP-NRS, Peak Pruritus Numerical Rating Scale; SoC, skin of color; TCS, topical corticosteroids.

Patient-Reported Outcome Assessments

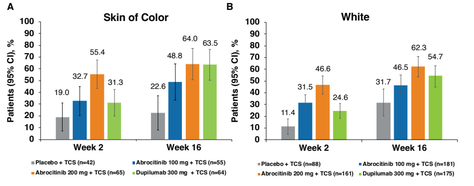
- A higher proportion of patients with SoC receiving abrocitinib 200 mg than those receiving dupilumab 300 mg achieved DLQI 0/1 (25.0% versus 9.7%) (**Figure 5**) and PP-NRS 4 (55.4% versus 31.3%) (**Figure 6**) by Week 2
  - Similar findings were reported for White patients (DLQI 0/1, 15.7% versus 5.2%; PP-NRS 4, 46.6% versus 24.6%)
- At Week 16, the proportions achieving DLQI 0/1 and PP-NRS 4 were similar or greater in patients receiving abrocitinib 200 mg than in those receiving dupilumab 300 mg among patients with SoC (DLQI, 37.5% versus 30.6%; PP-NRS 4, 64.0% versus 63.5%) and White patients (DLQI, 26.6% versus 21.6%; PP-NRS 4, 62.3% versus 54.7%)

Figure 5. Achievement of DLQI 0/1 at Weeks 2 and 16 in (A) Patients With SoC and (B) White Patients



DLQI, Dermatology Life Quality Index; SoC, skin of color; TCS, topical corticosteroids.

Figure 6. Achievement of PP-NRS 4 at Weeks 2 and 16 in (A) Patients With SoC and (B) White Patients



PP-NRS 4, ≥4-point improvement from baseline in Peak Pruritus Numerical Rating Scale; SoC, skin of color; TCS, topical corticosteroids.

Safety

- Adverse events, including herpes zoster, were more frequent with abrocitinib versus dupilumab or placebo in both patient subgroups, although overall frequency of herpes zoster was low (**Table 2**)
- TEAEs in the placebo, abrocitinib 100 mg, abrocitinib 200 mg, and dupilumab 300 mg groups were reported by 57.1%, 57.1%, 66.2%, and 48.4% of patients with SoC and 51.7%, 48.9%, 60.2%, and 50.6% of White patients, respectively (**Table 2**)
  - The percentage of TEAEs leading to discontinuation from the study was low (2%-6% in each group)
- Serious adverse events in the placebo, abrocitinib 100 mg, abrocitinib 200 mg, and dupilumab 300 mg groups were reported by 4.8%, 3.6%, 0%, and 0% of patients with SoC and 3.4%, 2.2%,1.2%, and 1.1% of White patients, respectively

Table 2. Summary of Safety Findings

	SoC n=227				White n=610			
	Placebo (n=42)	Abrocitinib 100 mg (n=56)	Abrocitinib 200 mg (n=65)	Dupilumab 300 mg (n=64)	Placebo (n=89)	Abrocitinib 100 mg (n=182)	Abrocitinib 200 mg (n=161)	Dupilumab 300 mg (n=178)
Safety, n (%)								
TEAEs	24 (57.1)	32 (57.1)	43 (66.2)	31 (48.4)	46 (51.7)	89 (48.9)	97 (60.2)	90 (50.6)
TEAEs leading to discontinuation	0 (0.0)	1 (1.8)	4 (6.2)	2 (3.1)	5 (5.6)	5 (2.7)	6 (3.7)	6 (3.4)
SAEs	2 (4.8)	2 (3.6)	0 (0.0)	0 (0.0)	3 (3.4)	4 (2.2)	2 (1.2)	2 (1.1)
Herpes zoster	0 (0.0)	0 (0.0)	2 (3.1)	0 (0.0)	0 (0.0)	1 (0.5)	2 (1.2)	0 (0.0)

SAE, serious adverse event; SoC, skin of color; TEAE, treatment-emergent adverse event.

CONCLUSIONS

- Greater proportions of patients with SoC and White patients achieved efficacy responses, including the high-threshold composite endpoint of EASI-90 + PP-NRS 0/1, with abrocitinib versus dupilumab as early as Week 2 of treatment
- Achievement of efficacy and patient-reported outcomes at Week 16 was generally higher in patients receiving abrocitinib versus dupilumab, independent of skin color
- The safety profiles of abrocitinib and dupilumab were consistent with previous analyses in the overall population from JADE COMPARE[8,9]

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