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Efficacy and Safety of Abrocitinib Versus Dupilumab in Patients with Skin of Colour: A Post Hoc Analysis

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BACKGROUND

- Atopic dermatitis (AD) is a common, chronic, inflammatory skin disorder characterised 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 contextualisation of treatment efficacy and safety in people with skin of colour (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 recent guidelines[3]
  - Dupilumab, an injectable interleukin (IL) 4 receptor alpha inhibitor that inhibits IL-4 and IL-13 signalling, is approved for patients aged ≥6 months with moderate-to-severe AD[4]
  - Abrocitinib is an oral, once-daily, selective Janus kinase 1 inhibitor approved for the treatment of adults and adolescents with moderate-to-severe AD[5-7]
- In the JADE phase 3 clinical trials, abrocitinib 200 or 100 mg was efficacious and well tolerated as monotherapy or in combination with medicated topical therapies[6-13]
- A post hoc analysis of pooled data from a phase 2b trial (NCT02780167) and two phase 3 trials, JADE MONO-1 (NCT03349060) and JADE MONO-2 (NCT03575871), showed that abrocitinib monotherapy was more efficacious in Asian, Black, and Hispanic/Latino patients across a range of phototypes based on Fitzpatrick skin type compared with placebo[14]
  - Dose response was most prominent in White patients
  - The abrocitinib safety profile and treatment-emergent adverse events (TEAEs) were consistent with those characterised in previous publications[15]

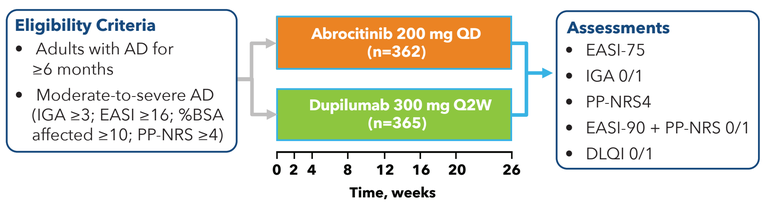
OBJECTIVE

- To assess the short-term efficacy and safety of abrocitinib versus dupilumab in patients with SoC and moderate-to-severe AD in the head-to-head phase 3 study JADE DARE (NCT04345367)

METHODS

- This post hoc analysis included data from patients aged ≥18 years with moderate-to-severe AD who received abrocitinib 200 mg once daily or dupilumab 300 mg every 2 weeks with concomitant background topical therapy for 26 weeks in JADE DARE (**Figure 1**)
- Patients who self-reported their race as non-White or did not report their race but identified as Hispanic or Latino were categorised as having SoC
  - Categories of patients with SoC included Asian, American Indian or Alaska Native, multiracial, Black or African American, 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 categorised 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-NRS4; 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 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-NRS4, ≥4-point improvement from baseline in Peak Pruritus Numerical Rating Scale; Q2W, every 2 weeks; QD, once daily.

RESULTS

Patient Population

- Of 727 patients in JADE DARE, 205 (28.2%) were categorised as having SoC (abrocitinib 200 mg, n=91; dupilumab 300 mg, n=114), and 522 (71.8%) were categorised as White (abrocitinib 200 mg: n=271; dupilumab 300 mg: n=251; **Table 1**)
- Among patients with SoC, the majority were Asian (70.7%), and 24.9% were Black or African American
- Baseline disease characteristics were generally balanced between treatment groups independent of skin colour

Table 1. Baseline Demographics and Disease Characteristics

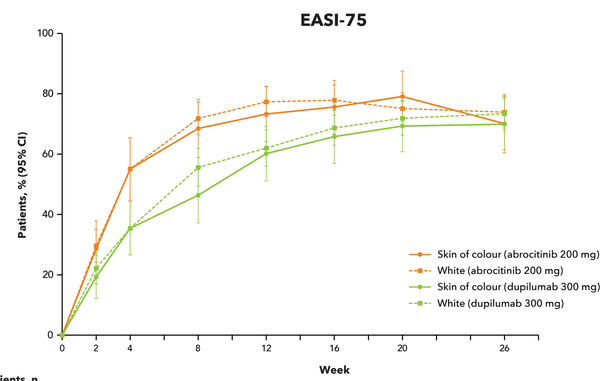
Characteristic	Skin of Colour			White		
	Abrocitinib 200 mg (n=91)	Dupilumab 300 mg (n=114)	Total (n=205)	Abrocitinib 200 mg (n=271)	Dupilumab 300 mg (n=251)	Total (n=522)
Age, mean (SD), years	32.3 (11.7)	33.8 (12.2)	33.2 (12.0)	38.1 (15.2)	36.2 (13.7)	37.2 (14.5)
Male, n (%)	54 (59.3)	68 (59.6)	122 (59.5)	139 (51.3)	136 (54.2)	275 (52.7)
Race, n (%)						
American Indian or Alaska Native	1 (1.1)	0	1 (1.5)	0	0	0
Asian	62 (68.1)	83 (72.8)	145 (70.7)	0	0	0
Black or African American	25 (27.5)	26 (22.8)	51 (24.9)	0	0	0
Multiracial	0	3 (2.6)	3 (1.5)	0	0	0
Native Hawaiian or Other Pacific Islander	1 (1.1)	0	1 (1.5)	0	0	0
White	0	0	0	269 (99.3)	248 (98.8)	517 (99.0)
Not reported	2 (2.2)	2 (1.8)	4 (2.0)	2 (0.7)	3 (1.2)	5 (1.0)
Ethnicity, n (%)						
Hispanic or Latino	4 (4.4)	4 (3.5)	8 (3.9)	26 (9.6)	23 (9.2)	49 (9.4)
Not Hispanic or Latino	86 (94.5)	109 (95.6)	195 (95.1)	245 (90.4)	228 (90.8)	473 (90.6)
BMI, mean (SD) kg/m^2	27.0 (6.7)	26.6 (7.8)	26.8 (7.3)	26.5 (5.5)	26.9 (6.0)	26.7 (5.7)
%BSA, mean (SD)	43.0 (20.8)	41.1 (20.5)	41.9 (20.6)	42.3 (19.7)	43.3 (21.7)	42.8 (20.7)
EASI at baseline, mean (SD)	27.7 (11.6)	27.4 (11.2)	27.5 (11.4)	28.3 (11.4)	28.4 (12.2)	28.3 (11.8)
IGA at baseline, n (%)						
Moderate	52 (57.1)	61 (53.5)	113 (55.1)	164 (60.5)	159 (63.3)	323 (61.9)
Severe	39 (42.9)	53 (46.5)	92 (44.9)	107 (39.5)	92 (36.7)	199 (38.1)
PP-NRS, mean (SD)	7.4 (1.5)	7.5 (1.6)	7.5 (1.6)	7.5 (1.6)	7.3 (1.6)	7.4 (1.6)
DLQI, mean (SD)	15.2 (7.1)	14.1 (6.5)	14.6 (6.8)	13.7 (6.6)	14.3 (6.2)	13.9 (6.4)

%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.

Efficacy Assessments

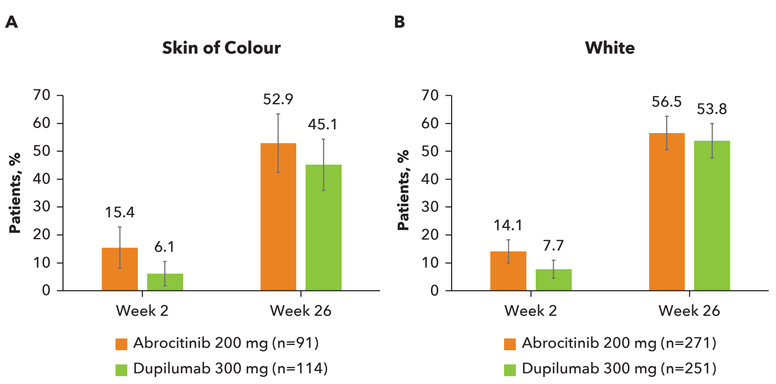
- A higher proportion of patients with SoC receiving abrocitinib 200 mg than those receiving dupilumab 300 mg achieved an EASI-75 response (28.6% vs 19.3%; **Figure 2**), IGA 0/1 (15.4% vs 6.1%; **Figure 3**), and EASI-90 + PP-NRS 0/1 (4.4% vs 0.9%; **Figure 4**) by Week 2
  - Similar findings were reported for White patients (EASI-75: 29.6% vs 22.2%; IGA 0/1: 14.1% vs 7.7%; EASI-90 + PP-NRS 0/1: 6.3% vs 1.2%)
- The proportions of patients with SoC receiving abrocitinib 200 mg who achieved an EASI-75 response at Week 26 were similar to those receiving dupilumab 300 mg (70.1% vs 69.9%; **Figure 2**)
  - Similar findings were reported for White patients (73.9% vs 73.4%)
- At Week 26, 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 colour (**Figures 3 and 4**)

Figure 2. Patients Achieving EASI-75 Response Among Those With SoC and White Patients



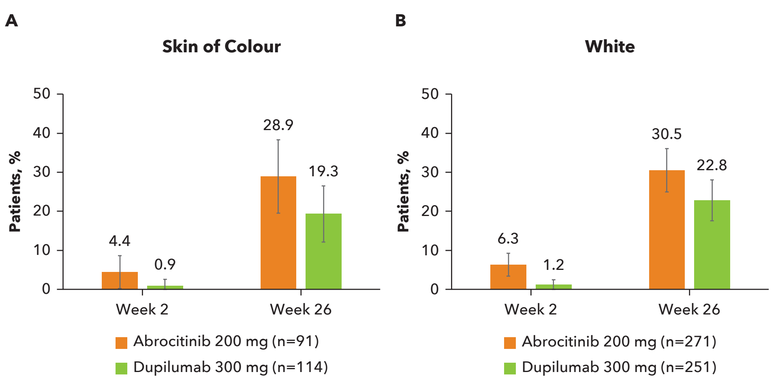
EASI-75, ≥75% improvement from baseline in Eczema Area and Severity Index; SoC, skin of colour.

Figure 3. Achievement of IGA 0/1 Response at Weeks 2 and 26 in (A) Patients With SoC and (B) White Patients



IGA, Investigator's Global Assessment; SoC, skin of colour.

Figure 4. Achievement of EASI-90 + PP-NRS 0/1 at Weeks 2 and 26 in (A) Patients With SoC and (B) White Patients

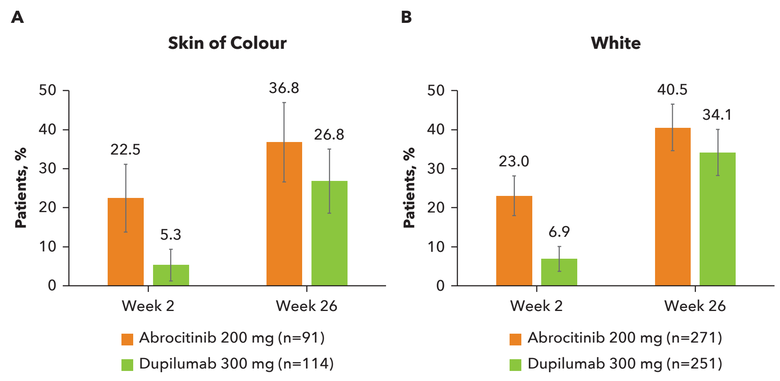


EASI-90, ≥90% improvement from baseline in Eczema Severity and Area Index; PP-NRS, Peak Pruritus Numerical Rating Scale.

Patient-Reported Outcome Assessments

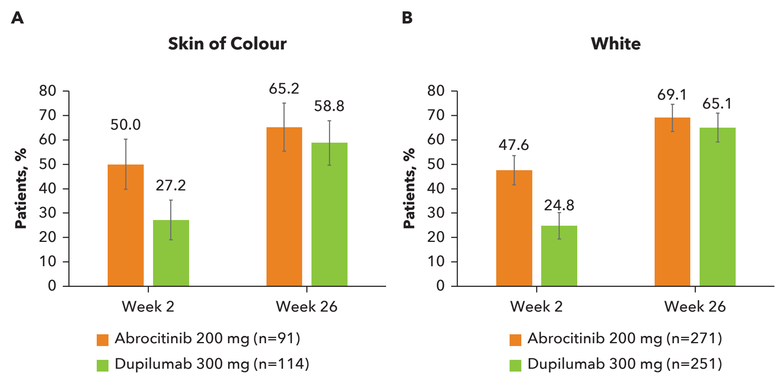
- A higher proportion of patients with SoC receiving abrocitinib 200 mg than those receiving dupilumab 300 mg achieved DLQI 0/1 (22.5% vs 5.3%; **Figure 5**) and PP-NRS4 (50.0% vs 27.2%; **Figure 6**) by Week 2
  - Similar findings were reported for White patients (DLQI 0/1: 23.0% vs 6.9%; PP-NRS4: 47.6% vs 24.8%)
- At Week 26, the proportions achieving DLQI 0/1 and PP-NRS4 were greater in patients receiving abrocitinib 200 mg than in those receiving dupilumab 300 mg among patients with SoC (DLQI: 36.8% vs 26.8%; PP-NRS4: 65.2% vs 58.8%) and White patients (DLQI: 40.5% vs 34.1%; PP-NRS4: 69.1% vs 65.1%)

Figure 5. Achievement of DLQI 0/1 at Weeks 2 and 26 in (A) Patients With SoC and (B) White Patients



DLQI, Dermatology Life Quality Index; SoC, skin of colour.

Figure 6. Achievement of PP-NRS4 at Weeks 2 and 26 in (A) Patients With SoC and (B) White Patients



PP-NRS4, ≥4-point improvement from baseline in Peak Pruritus Numerical Rating Scale; SoC, skin of colour.

Safety

- TEAEs in the abrocitinib 200 mg and dupilumab 300 mg groups were reported by 71.4% and 61.4% of patients with SoC and 74.9% and 67.3% of White patients, respectively (**Table 2**)
  - The percentage of TEAEs leading to discontinuation from the study was low (2%-3% in each group)
- In both treatment groups, 100% of patients who self-identified as having SoC reported no serious adverse events
- In both the SoC and White subgroups, acne and herpes zoster were reported more frequently with abrocitinib 200 mg, while conjunctivitis was reported more frequently with dupilumab 300 mg

Table 2. Summary of Safety Findings

	Skin of Colour		White	
	Abrocitinib 200 mg (n=91)	Dupilumab 300 mg (n=114)	Abrocitinib 200 mg (n=91)	Dupilumab 300 mg (n=114)
TEAEs, n (%)	65 (71.4)	70 (61.4)	203 (74.9)	169 (67.3)
TEAEs leading to discontinuation, n (%)	3 (3.3)	2 (1.8)	9 (3.3)	7 (2.8)
SAEs, n (%)	0	0	2 (1.2)	2 (1.1)
TEAEs of interest, n (%)				
Acne	19 (20.9)	4 (3.5)	27 (10.0)	6 (2.4)
Conjunctivitis	2 (2.2)	5 (4.4)	6 (2.2)	27 (10.8)
Herpes zoster	1 (1.1)	0	8 (3.0)	2 (0.8)

SAE, serious adverse event; TEAE, treatment-emergent adverse event.

CONCLUSIONS

- Across diverse racial/ethnic populations, greater proportions of patients with moderate-to-severe AD achieved efficacy responses with abrocitinib than with dupilumab as early as Week 2 of treatment
- Achievement of efficacy and patient-reported outcomes at Week 26 was generally higher in patients receiving abrocitinib versus dupilumab, across diverse racial/ethnic populations
- The safety profiles of abrocitinib and dupilumab were consistent with previous analyses in the overall population from JADE DARE[16,17]

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DISCLOSURES

PH has been a speaker/investigator for Pfizer Inc., AbbVie, Almirall, Eli Lilly and Company, Galderma, LEO Pharma, Janssen, Novartis, Regeneron, Sandoz, Sanofi, and UCB. **AA** has received grants made to their institution from AbbVie, Amgen, Arcutis, Castle, Dermavant, Incyte, and LEO Pharma; is an advisory board member or consultant for Pfizer Inc., AbbVie, Allergan, Almirall, Alphyn, Amgen, Apogee, Arcutis, Bausch Health, Beiersdorf, Boehringer Ingelheim, Bristol Myers Squibb, Canfield, Castle, Dermavant, Eli Lilly and Company, Galderma, Genentech, Incyte, Janssen, LEO Pharma, L'Oreal, Novartis, Ortho, Regeneron Pharmaceuticals, Sanofi Genzyme, Swiss American, Symrise, UCB, and VisualDx; has served as a speaker for Aerolase, Janssen, L'Oreal, Regeneron Pharmaceuticals, Sanofi Genzyme, and Scientis; has received royalties from Elsevier, Springer, Wiley-Blackwell, and Wolters Kluwer Health; and has received equipment from Aerolase. **KK** has received grants from Japan Tobacco, Kyowa Kirin, LEO Pharma, Mitsubishi Tanabe Pharma, Ono Pharmaceutical, Pola Pharmaceutical, Taiho Pharmaceutical, Torii Pharmaceutical, and The Procter & Gamble Company. **FW** has been an advisor or speaker for Pfizer Inc., AbbVie, LEO Pharma, and Sanofi Genzyme. **RAE** is an owner of Health Services Consulting Corporation and received consultancy fees from Pfizer Inc. in connection with this study. **GB** is an employee of Engineering Ingegneria Informatica and a paid subcontractor to Health Services Consulting Corporation. **AS, PB,** and **MW** are employees and shareholders of Pfizer Inc. ***BE** was an employee of Pfizer Inc. at the time of analysis and is no longer affiliated with Pfizer.

ACKNOWLEDGMENTS

Editorial/medical writing support under the guidance of authors was provided by Coles Keeter, PhD, of Nucleus Global, was provided by Pfizer, Inc. This poster was developed in accordance with Good Publication Practice (GPP 2022) guidelines. Authors had full control of the content and made the final decision on all aspects of this publication.

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Presented at the European Academy of Dermatology & Venereology Congress; September 17-20, 2025; Paris, France.