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Treatment Earlier in Atopic Dermatitis Disease Duration Improves Patient Response to Abrocitinib

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Disclosures: J. Gutermuth has served as a speaker and/or advisor for Almirall, AbbVie, Beiersdorf, Eli Lilly and Company, Janssen, LEO Pharma, La Roche-Posay, Nestlé, Pierre Fabre, Pfizer, Regeneron, Sanofi Genzyme, Thermo Fisher Scientific, and PeerVoice. **E. Guttman-Yassky** is an advisory board member for Pfizer, Asana BioSciences (received honorarium), Celgene, Dermira, Galderma, Glenmark, MedImmune, Novartis, Regeneron, Sanofi Genzyme, Stiefel/GSK, and Vitae; a consultant for Pfizer, AbbVie, Almirall (received honorarium), Anacor, Asana BioSciences, Celgene, Dermira, Eli Lilly and Company, Galderma, Glenmark, Kyowa Kirin, LEO Pharma, MedImmune, Mitsubishi Tanabe, Novartis, Regeneron, Sanofi Genzyme, Stiefel/GSK, and Vitae; and an investigator for Celgene, Eli Lilly and Company (received grants to institution), LEO Pharma, MedImmune, and Regeneron. **S. Weidinger** is a speaker, advisory board member, and/or investigator for AbbVie, Almirall, Boehringer Ingelheim, Eli Lilly and Company, Galderma, GSK, LEO Pharma, Pfizer, Regeneron, and Sanofi; and has received institutional research grants from LEO Pharma, Pfizer, and Sanofi. **A. Selfridge, M. Zhang,** and **M. Watkins** are employees and shareholders of Pfizer.

Presented at the American Academy of Dermatology Conference; March 27-31, 2026; Denver, Colorado

Editorial/medical writing support under the guidance of authors was provided by Kathleen Proudfoot, PhD, of Nucleus Global, New York, NY, USA, and was funded by Pfizer Inc., New York, NY, USA, in accordance with Good Publication Practice (GPP 2022) guidelines (Ann Intern Med. 2022; 10.7326/M22-1460).

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Background, Objective, and Methods

Background

- Atopic dermatitis (AD) is a common, chronic, inflammatory skin disorder that is characterized by recurrent eczematous skin lesions and pruritus with heterogeneous skin manifestations, symptoms, and severity[1,2]
- Abrocitinib is an oral, once-daily, Janus kinase (JAK)1-selective inhibitor approved for the treatment of adults and adolescents with moderate-to-severe AD[3-5]
- Little is known whether earlier AD diagnosis and treatment intervention could improve patient outcomes

Objective

- To conduct a post hoc analysis assessing the impact of AD disease duration since initial diagnosis on response to abrocitinib

Methods

- Patients from six phase 2b/3 clinical trials received placebo or abrocitinib (100 or 200 mg) as monotherapy or in combination with topical therapies and were stratified by AD disease duration since initial diagnosis (≤3 vs >3 years)[6-11]
- Efficacy endpoints included EASI-75 and EASI-90 over 12 weeks
- PROs included ≥4-point reductions from baseline in PP-NRS and DLQI (for adults) scores over 12 weeks
- Safety was assessed via TEAE monitoring

EASI-75, ≥75% improvement from baseline in Eczema Area and Severity Index score; EASI-90, ≥90% improvement from baseline in Eczema Area and Severity Index score; PP-NRS, Peak Pruritus Numerical Rating Scale; PRO, patient-reported outcome; DLQI, Dermatology Life Quality Index; TEAE, treatment-emergent adverse event.

ClinicalTrials.gov identifiers: NCT02780167 (phase 2b); NCT03349060 (JADE MONO-1); NCT03575871 (JADE MONO-2); NCT03720470 (JADE COMPARE); NCT03796676 (JADE TEEN); NCT04345367 (JADE DARE).

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Demographics and Baseline Characteristics

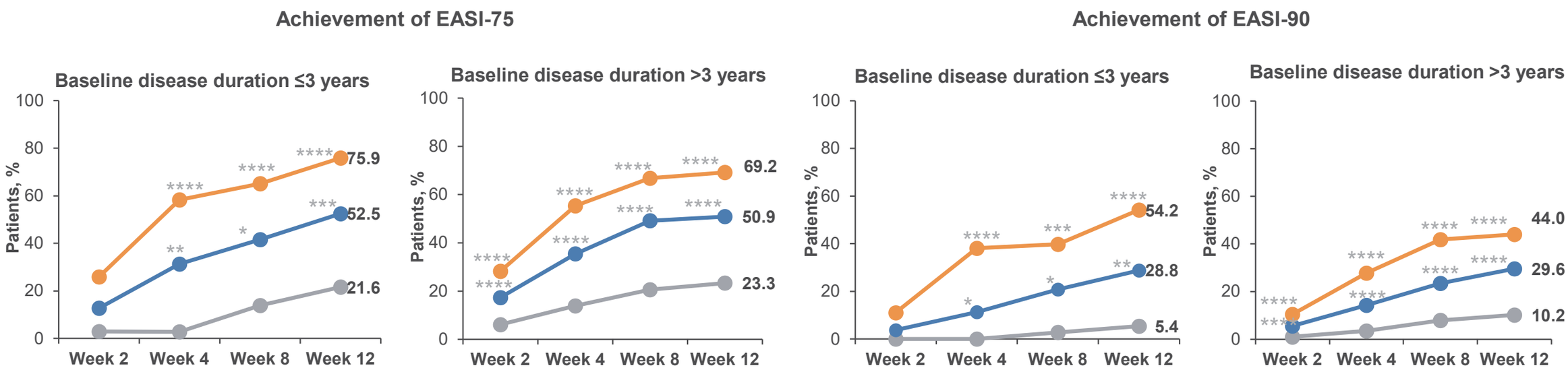
Characteristic	Baseline Disease Duration ≤3 Years			Baseline Disease Duration >3 Years		
	Placebo (n=38)	Abrocitinib 100 mg QD (n=80)	Abrocitinib 200 mg QD (n=84)	Placebo (n=400)	Abrocitinib 100 mg QD (n=623)	Abrocitinib 200 mg QD (n=962)
Age, years, n (%)						
<18	9 (23.7)	18 (22.5)	19 (22.6)	111 (27.8)	128 (20.5)	123 (12.8)
18 to <65	24 (63.2)	52 (65.0)	54 (64.3)	277 (69.3)	469 (75.3)	788 (81.9)
≥65	5 (13.2)	10 (12.5)	11 (13.1)	12 (3.0)	26 (4.2)	51 (5.3)
Mean (SD)	36.6 (20.6)	38.2 (19.6)	37.6 (19.5)	30.9 (15.4)	33.0 (15.5)	33.9 (15.5)
Mean duration since AD onset, years (SD)	2.0 (0.6)	1.8 (0.6)	1.8 (0.6)	21.6 (13.7)	24.0 (15.1)	23.7 (14.1)
IGA, %						
Moderate	71.1	72.5	73.8	62.8	61.2	60.7
Severe	28.9	27.5	26.2	37.3	38.8	39.3
EASI, median (Q1, Q3)	22.0 (18.0, 33.0)	21.8 (18.0, 33.1)	21.7 (17.4, 29.2)	25.2 (19.7, 37.0)	26.5 (20.0, 38.6)	26.0 (19.8, 36.6)
Mean baseline PP-NRS score (SD)	7.4 (1.7)	7.2 (1.9)	7.3 (1.7)	7.1 (1.8)	7.1 (1.8)	7.3 (1.8)
Prior topical agents only, n (%)	28 (73.7)	50 (62.5)	53 (63.1)	236 (59.0)	347 (55.7)	528 (54.9)
Prior nonbiologic systemic agents, n (%)[a]	8 (21.1)	30 (37.5)	30 (35.7)	160 (40.0)	268 (43.0)	425 (44.2)
Biologic agents, n (%)[a]	1 (2.6)	0	1 (1.2)	19 (4.8)	34 (5.5)	39 (4.1)

- Patient age distribution at baseline varied between the disease duration ≤3 years and >3 years cohorts; more patients in the <18 and ≥65 age groups were in the disease duration ≤3 years cohort
- A larger proportion of patients with disease duration ≤3 years had baseline IGA scores of moderate disease severity than those with disease duration >3 years
  - A lower percentage of these patients with disease duration ≤3 years had prior exposure to previous systemic therapeutics, including biologics

AD, atopic dermatitis; EASI, Eczema Area and Severity Index; IGA, Investigator's Global Assessment; PP-NRS, Peak Pruritus Numerical Rating Scale; Q, quartile; QD, once daily.
[a]Within the nonbiologic systemic or biologic category, patients could be counted more than once for each medication type they had prior experience with.

Shorter Disease Duration Was Associated With Greater Proportions of Patients Achieving Skin Clearance With Abrocitinib 200 mg

- Larger proportions of patients with disease duration ≤3 years who received abrocitinib 200 mg achieved EASI-75 at Week 12 vs placebo than patients with >3 years vs placebo
  - Notably, patients with shorter disease duration were more likely to achieve a deeper response (EASI-90) with abrocitinib 200 mg vs placebo
- Abrocitinib 100-mg responses at Week 12 were consistent across both duration cohorts

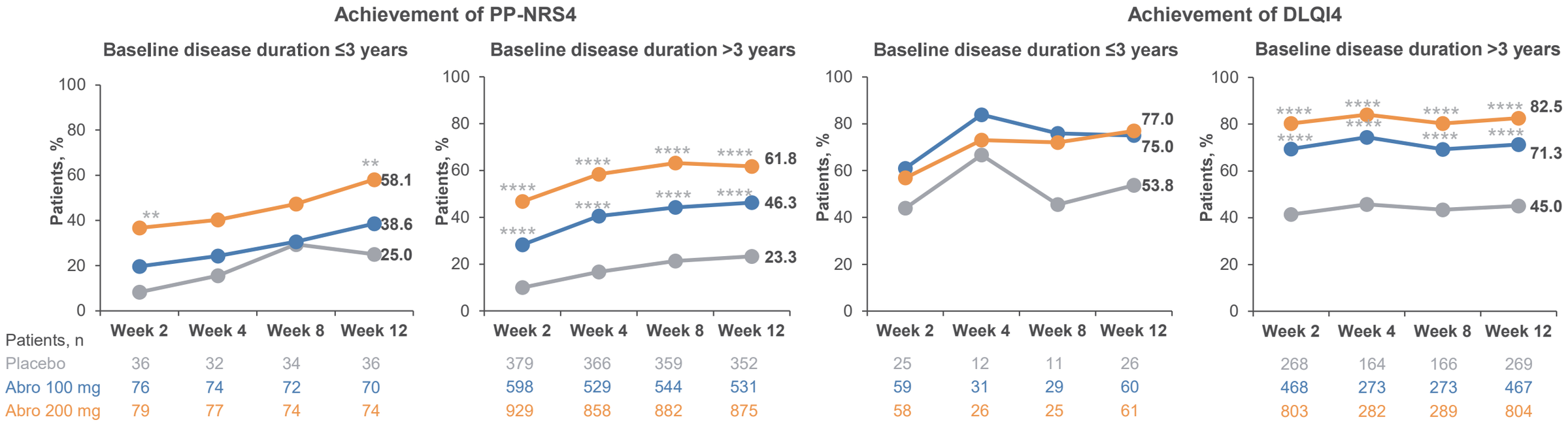


Patients, n	Baseline disease duration ≤3 years				Baseline disease duration >3 years				Baseline disease duration ≤3 years				Baseline disease duration >3 years			
	Week 2	Week 4	Week 8	Week 12	Week 2	Week 4	Week 8	Week 12	Week 2	Week 4	Week 8	Week 12	Week 2	Week 4	Week 8	Week 12
Placebo	35	36	36	37	392	396	394	391	35	36	36	37	392	396	394	391
Abro 100 mg	79	80	77	80	608	607	612	609	79	80	77	80	608	607	612	609
Abro 200 mg	81	84	83	83	955	946	949	943	81	84	83	83	955	946	949	943

Abro, abrocitinib; EASI-75, ≥75% improvement from baseline in Eczema Area and Severity Index; EASI-90, ≥90% improvement from baseline in Eczema Area and Severity Index.
*P<0.05; **P<0.01; ***P<0.001; ****P<0.0001. Two-sided P values represent the difference from placebo and were calculated using the Cochran-Mantel-Haenszel method adjusted by randomization strata (study, baseline disease severity, and age category).

Patient-Reported Outcomes and Safety Were Comparable Between Groups

- PROs varied between treatment and baseline disease duration cohorts



Patients, n	Achievement of PP-NRS4								Achievement of DLQI4							
	Baseline disease duration ≤3 years				Baseline disease duration >3 years				Baseline disease duration ≤3 years				Baseline disease duration >3 years			
	Week 2	Week 4	Week 8	Week 12	Week 2	Week 4	Week 8	Week 12	Week 2	Week 4	Week 8	Week 12	Week 2	Week 4	Week 8	Week 12
Placebo	36	32	34	36	379	366	359	352	25	12	11	26	268	164	166	269
Abro 100 mg	76	74	72	70	598	529	544	531	59	31	29	60	468	273	273	467
Abro 200 mg	79	77	74	74	929	858	882	875	58	26	25	61	803	282	289	804

- TEAEs were largely consistent across both duration cohorts (**Supplementary Material**, accessed via QR code)

Conclusion

- These data suggest that patients with shorter AD duration clinically benefited from abrocitinib 200 mg, while patient-reported outcomes were consistent between groups. Treatment responses with abrocitinib 100 mg were consistent between duration cohorts
- Further studies are needed to better understand microbiome, barrier integrity and inflammatory-mediator levels and associated potential immunologic differences impacting itch and skin clearance in patients with shorter versus longer AD durations to improve treatment strategies, and long-term disease control

Abro, abrocitinib; AD, atopic dermatitis; DLQI4, ≥4-point reduction from baseline in Dermatology Life Quality Index (for adults); PP-NRS4, ≥4-point reduction from baseline in Peak Pruritus Numerical Rating Scale; PRO, patient-reported outcome; TEAE, treatment-emergent adverse event.
**P<0.01; ****P<0.0001. Two-sided P values represent the difference from placebo and were calculated using the Cochran-Mantel-Haenszel method adjusted by randomization strata (study, baseline disease severity, and age category).