

Long-Term Efficacy and Safety of Abrocitinib in Patients With Moderate-to-Severe Atopic Dermatitis Who Had Failed or Were Intolerant to Oral Non-Steroidal Immunosuppressants: Pooled Analysis of JADE Clinical Trials

Michael Ardern-Jones,¹ Mahreen Ameen,² Marjolein de Bruin-Weller,³
Eric Simpson,⁴ Wing Sin Chiu,⁵ Pinaki Biswas,⁶ Gary Chan,⁷
Christopher Koulias,⁸ Stephan Weidinger⁹

¹University of Southampton, Southampton General Hospital, Southampton, UK; ²Royal Free NHS Trust, London, UK; ³University Medical Center Utrecht, Utrecht, Netherlands; ⁴Oregon Health & Science University, Portland, OR, USA; ⁵Pfizer Ltd., Tadworth, Surrey, UK; ⁶Pfizer Inc., New York, NY, USA; ⁷Pfizer Inc., Groton, CT, USA; ⁸Pfizer Hellas S.A., Athens, Greece; ⁹University Hospital Schleswig-Holstein, Kiel, Germany

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Introduction, Objective, and Methods

Background

- Systemic non-steroidal immunosuppressants (NSISS) are frequently used to treat moderate-to-severe AD, but their long-term use is sometimes limited due to insufficient efficacy and/or toxicities and side effects¹
- Abrocitinib, an oral once-daily Janus kinase 1 selective inhibitor, has been shown to be efficacious and well tolerated as monotherapy or in combination with topical therapy in patients with moderate-to-severe AD²⁻⁴
- Impact of failure or intolerance to previous treatment with NSISS on the efficacy and safety of abrocitinib remains to be determined

Objective

- To assess the long-term efficacy and safety of abrocitinib in patients who had failed or were intolerant to prior oral NSISS compared with those without prior use of systemic therapy (ie, received prior topical treatments only) in a pooled post hoc analysis of phase 3 clinical trials

Methods

- Data were pooled from trials in which abrocitinib 100 mg or 200 mg was administered orally once daily as monotherapy (phase 3 JADE MONO-1 and MONO-2; patients ≥ 12 years of age), or in combination with topical therapy (patients ≥ 18 years of age from phase 3 JADE COMPARE who were subsequently enrolled in JADE EXTEND)
- Patients were stratified into subgroups who had failed or were intolerant to ≥ 1 prior oral NSISS and those who were naïve to any prior systemic therapy
- Efficacy was assessed from baseline through week 48, based on achievement of an IGA score of 0 (clear) or 1 (almost clear) and ≥ 2 points improvement from baseline, EASI-75, and ≥ 4 points improvement in PP-NRS4
- AEs were assessed through week 48

AD, atopic dermatitis; AEs adverse events; EASI-75; $\geq 75\%$ improvement in Eczema Area and Severity Index; IGA, Investigator's Global Assessment; NSISS, systemic non-steroidal immunosuppressants; PP-NRS4, ≥ 4 points improvement in Peak Pruritus Numerical Rating Scale.

Clinicaltrials.gov identifiers: NCT03349060 (JADE MONO-1), NCT03575871 (JADE MONO-2), NCT03720470 (JADE COMPARE), NCT03422822 (JADE EXTEND).

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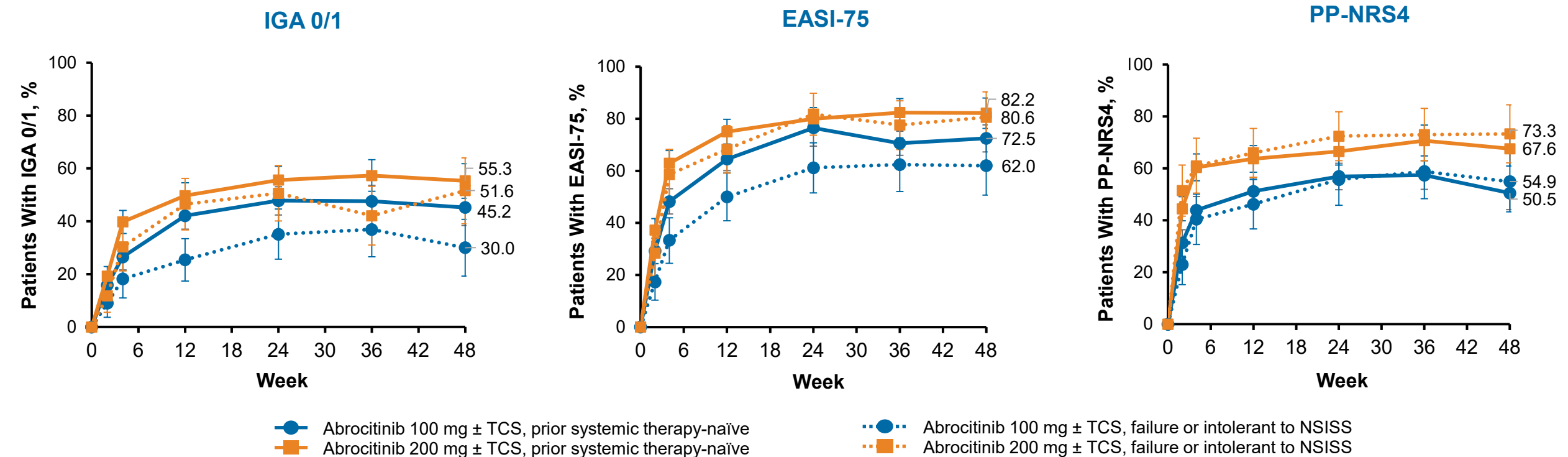
Baseline Characteristics (Full Analysis Set^a)

	Failure and/or intolerance to prior NSISS n=218		Naïve to prior oral systemic therapy n=785	
	Abrocitinib 100 mg ± TCS n=115	Abrocitinib 200 mg ± TCS n=103	Abrocitinib 100 mg ± TCS n=406	Abrocitinib 200 mg ± TCS n=379
Age, years, mean ± SD	31.9 ± 15.2	31.5 ± 14.6	29.8 ± 15.5	30.2 ± 16.7
Sex, female (%)	43 (37.4)	46 (44.7)	193 (47.5)	191 (50.4)
%BSA, mean ± SD	56.1 ± 23.1	60.0 ± 25.0	44.9 ± 21.3	45.2 ± 21.4
IGA score of 4 (severe), n (%)	56 (48.7)	62 (60.2)	117 (28.8)	124 (32.7)
EASI, mean ± SD	34.4 ± 14.5	36.9 ± 15.1	27.5 ± 11.1	28.8 ± 12.4
Duration of disease, mean ± SD	22.3 ± 15.1	22.7 ± 14.2	18.6 ± 14.1	17.9 ± 13.6
POEM, mean ± SD	21.0 ± 5.5	21.0 ± 6.0	19.9 ± 6.1	20.0 ± 6.0
DLQI, mean ± SD	16.9 ± 6.0	16.2 ± 6.3	14.2 ± 6.6	15.2 ± 6.6

%BSA, percentage of body surface area; DLQI, Dermatology Life Quality Index; EASI, Eczema Area and Severity Index; IGA, Investigator's Global Assessment; NSISS, systemic non-steroidal immunosuppressants; POEM, Patient Oriented Eczema Measure; SD, standard deviation; TCS, topical corticosteroids.

^aPatients who withdrew from the study were counted as non-responders.

Improvement in Skin Clearance and Itch



Conclusions

- Abrocitinib as monotherapy or in combination with topical therapy demonstrated rapid skin clearance and itch relief that was sustained through 48 weeks in patients with moderate-to-severe AD who were naïve to any prior systemic therapy, as well as those who had failed or were intolerant to prior oral NSISS
- The safety profile of abrocitinib was similar in both subgroups, and consistent with the overall population
- These results support the use of abrocitinib both as a systemic first-line treatment and in patients where oral NSISS have failed or were intolerant