Efficacy of Abrocitinib in Patients Based on Prior Biologic Treatment History: A Post Hoc Analysis of JADE MONO-1, JADE MONO-2, and JADE REGIMEN

Emma Guttman-Yassky, MD, PhD,[1] Melinda Gooderham, MSc, MD, FRCPC,[2,3,4] Michael R. Ardern-Jones, MD, PhD,[5,6] Mahreen Ameen, MD,[7] Bob Geng, MD,[8] Pinaki Biswas, PhD,[9] Ankur Bhambri, DO,[10] Justine Alderfer, PharmD,[10] Melissa Watkins, PhD[9]

[1]Icahn School of Medicine at Mount Sinai, New York, NY, USA; [2]SKiN Centre for Dermatology, Peterborough, ON, Canada; [3]Queen's University, Kingston, ON, Canada; [4]Probity Medical Research, Waterloo, ON, Canada; [5]Clinical Experimental Sciences, Faculty of Medicine, University of Southampton, Southampton, United Kingdom; [6]Department of Dermatology, Southampton University Hospitals NHS Foundation Trust, Southampton, United Kingdom; [7]Royal Free London NHS Foundation Trust, London, United Kingdom; [8]University of California San Diego School of Medicine, San Diego, CA, USA; [9]Pfizer Inc., New York, NY, USA; [10]Pfizer Inc., Collegeville, PA, USA

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Background and Objective

Background

- Moderate-to-severe AD is characterized by intense pruritus, skin lesions, and significant impact on quality of life, often requiring systemic therapies due to poor response to topical treatments[1,2]
- Conventional systemic agents such as immunosuppressants and corticosteroids can be limited by side effects and may be unsuitable for long-term use, indicating a need for alternative treatment options with more targeted approaches[2,3]
- The oral JAK1 inhibitor, abrocitinib, and injectable biologic therapies, such as dupilumab, target key pathways involved in AD pathogenesis, potentially offering greater efficacy and more favorable safety profiles compared with conventional systemics[4]
  - Previous analyses have suggested that prior use of conventional systemic or biologic therapies did not affect the efficacy or safety of abrocitinib in patients with moderate-to-severe AD[5,6]
  - Further exploration is needed to determine whether the reason for discontinuation of prior biologic therapy impacts abrocitinib efficacy

Objective

- To assess the efficacy of abrocitinib in patients with moderate-to-severe AD with and without a history of biologic therapy discontinuation due to lack of efficacy or intolerance

AD, atopic dermatitis; JAK1, Janus kinase 1.

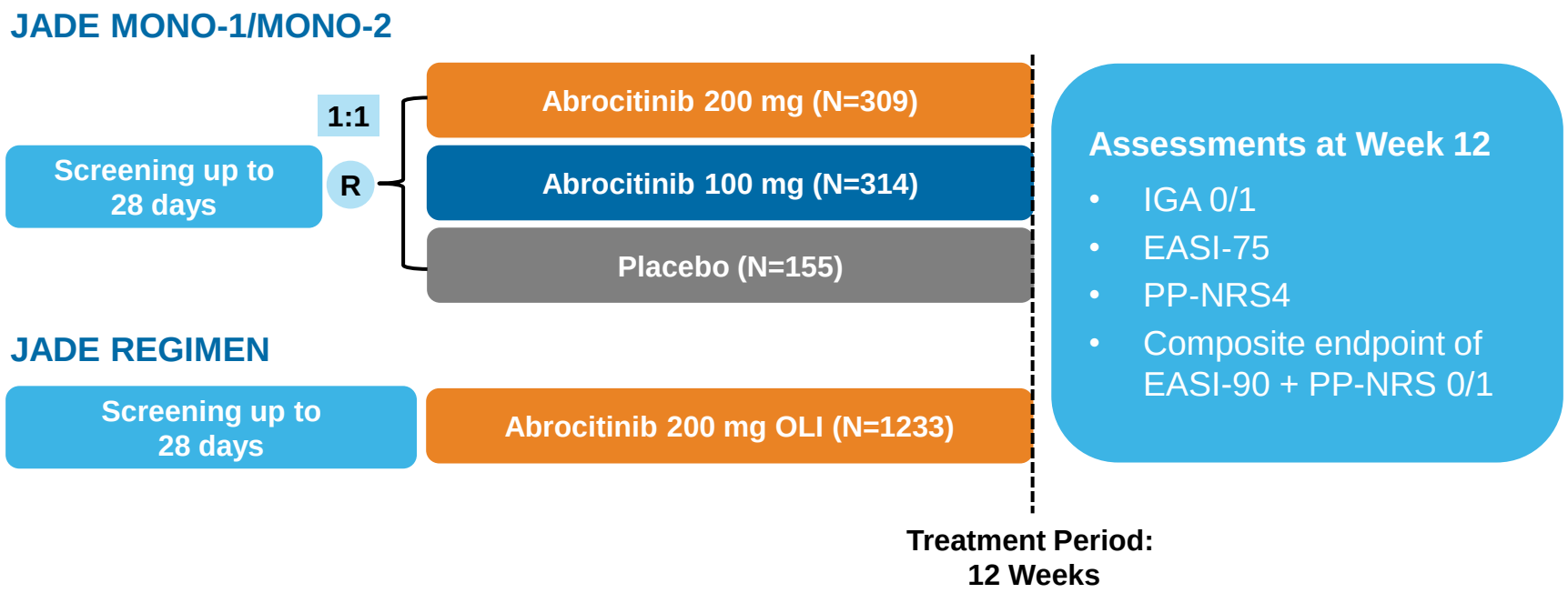
1. Boguniewicz M et al. *Ann Allergy Asthma Immunol.* 2018;120(1):10-22. 2. Simpson EL et al. *J Am Acad Dermatol*. 2017;77(4):623-633. 3. Sidbury R et al. *J Am Acad Dermatol*. 2014;71(2):327-349. 4. Iznardo H et al. *Pharmaceutics*. 2023;15(2):385. 5. Gooderham MJ et al. *JEADV Clin Pract*. 2023;2(4):753-763. 6. Gooderham MJ et al. Presented at: Society for Investigative Dermatology (SID) Annual Meeting; May 18-21, 2022; Portland, OR.

Study Design and Assessments

- This post hoc analysis included pooled data from patients aged ≥12 years with moderate-to-severe AD treated with abrocitinib or placebo as monotherapy in the phase 3 JADE MONO-1 and MONO-2 trials[1,2]
  - Data from patients treated with abrocitinib 200 mg in the induction period of JADE REGIMEN[3] were examined separately

Eligibility Criteria

- Adolescent and adult patients (≥12 years) with AD ≥1 year
- Moderate-to-severe AD (IGA ≥3; EASI ≥16; %BSA ≥10; PP-NRS ≥4)
- Inadequate response, or intolerance to topical medication, or requirement for systemic therapy to control AD



- Patients were stratified according to biologic treatment history before abrocitinib initiation into biologic naive, biologic discontinued (nonresponse), biologic discontinued (intolerance [JADE REGIMEN only]), and biologic discontinued (nonresponse/intolerance) subgroups

%BSA, percentage body surface area; AD, atopic dermatitis; EASI, Eczema Area and Severity Index; EASI-75, ≥75% improvement from baseline in EASI; EASI-90, ≥90% improvement from baseline in EASI; IGA, Investigator's Global Assessment; IGA 0/1, IGA score of 0 (clear) or 1 (almost clear); OLI, open-label induction; PP-NRS, Peak Pruritus Numerical Rating Index; PP-NRS4, ≥4-point improvement from baseline in PP-NRS; PP-NRS 0/1, PP-NRS score of o (no itch) or 1 (very little itch); R, randomization.

PP-NRS used with permission from Regeneron Pharmaceuticals, Inc., and Sanofi.

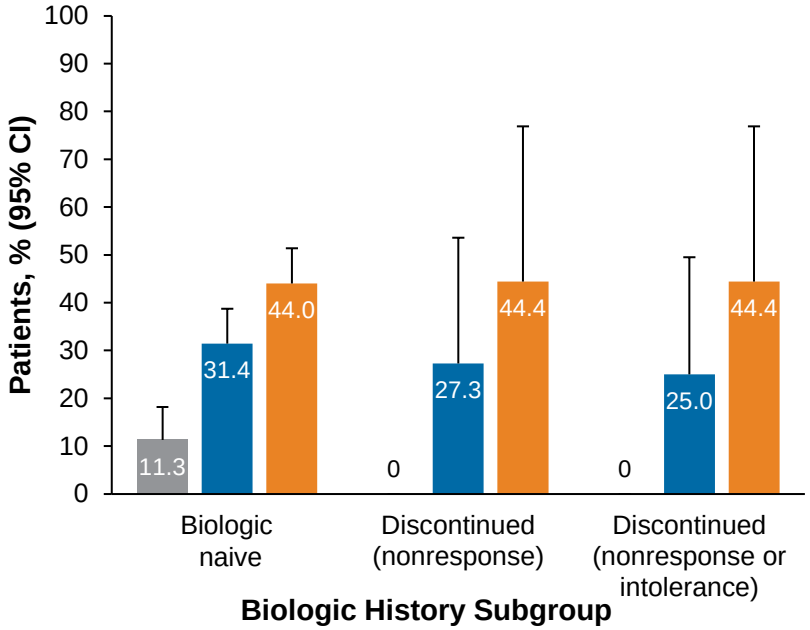
ClinicalTrials.gov Identifiers: NCT03349060 (MONO-1); NCT03575871 (MONO-2); NCT03627767 (REGIMEN).

1. Simpson EL et al. *Lancet*. 2020;396(10246):255-266. 2. Silverberg JI et al. *JAMA Dermatol*. 2020;156(8):863-873. 3. Blauvelt A et al. *J Am Acad Dermatol*. 2022;86(1):104-112.

Efficacy of Abrocitinib Stratified by Biologic Treatment History: Monotherapy Pool

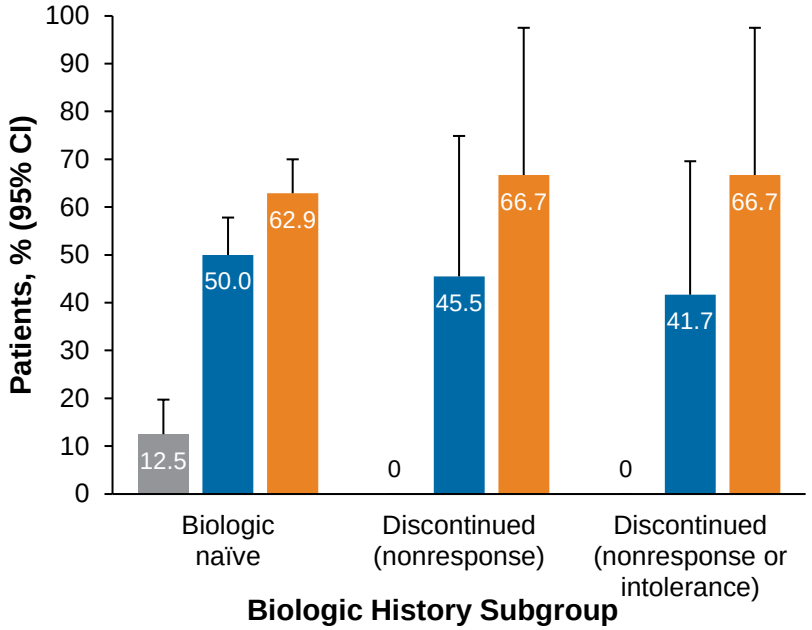
- In the monotherapy pool, 708, 24, and 26 patients comprised the biologic-naive, discontinued-nonresponse, and discontinued-nonresponse/intolerance subgroups, respectively
- At Week 12, efficacy response rates were greater with abrocitinib monotherapy than placebo, regardless of biologic treatment history
  - Substantial proportions of patients who received abrocitinib 200 mg in the JADE REGIMEN induction period achieved IGA 0/1, EASI-75, and PP-NRS4 across subgroups (Supplementary Material, accessible via QR code)

IGA 0/1



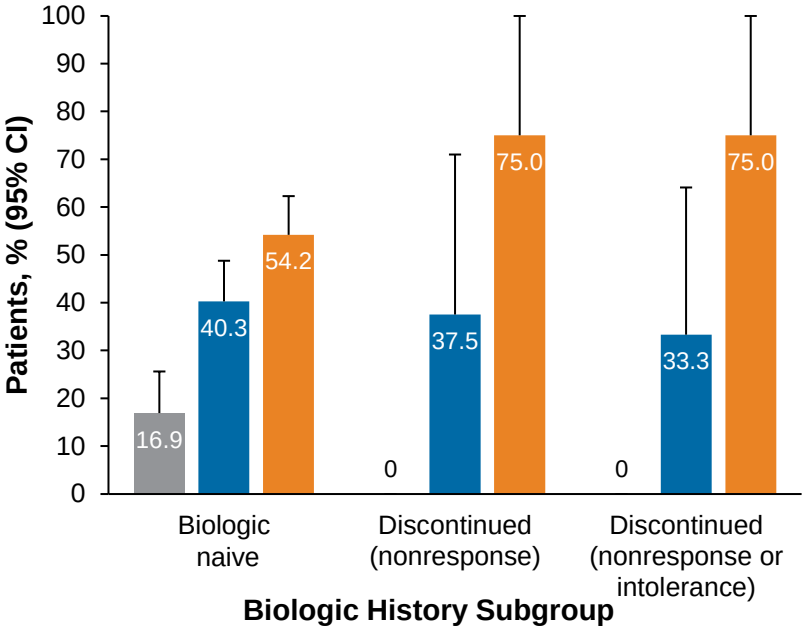
n	9	49	77	0	3	4	0	3	4
N	80	156	175	4	11	9	5	12	9

EASI-75



n	10	78	110	0	5	6	0	5	6
N	80	156	175	4	11	9	5	12	9

PP-NRS4



n	12	52	78	0	3	6	0	3	6
N	71	129	144	4	8	8	4	9	8

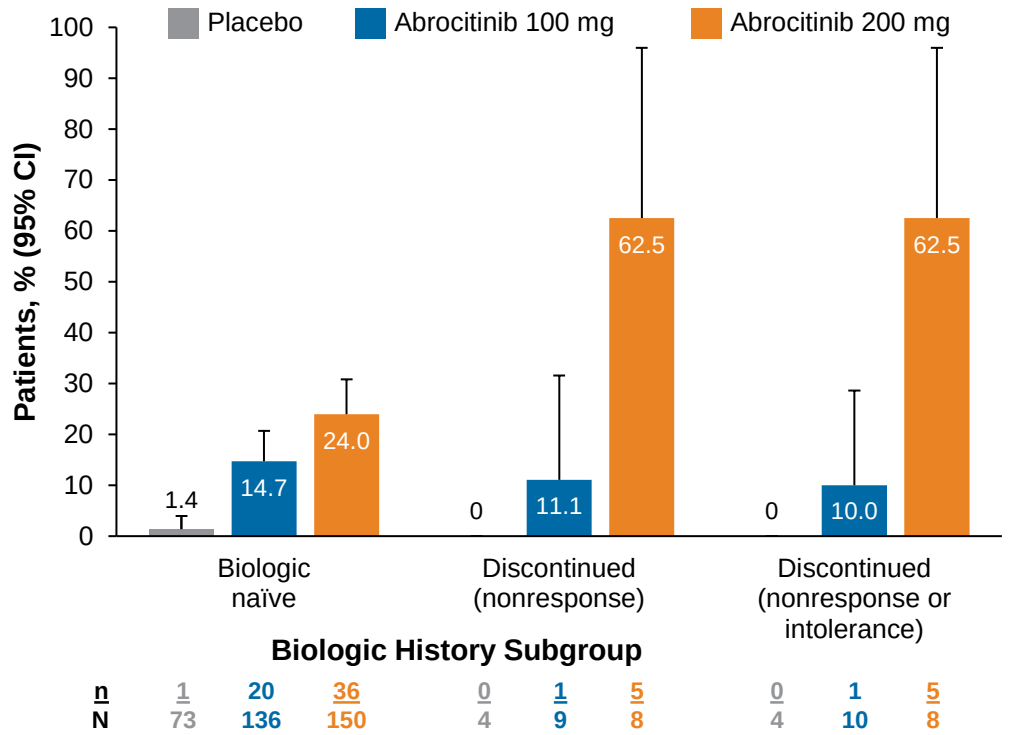
Placebo Abrocitinib 100 mg Abrocitinib 200 mg

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); PP-NRS4, ≥4-point improvement from baseline in Peak Pruritus Numerical Rating Index.

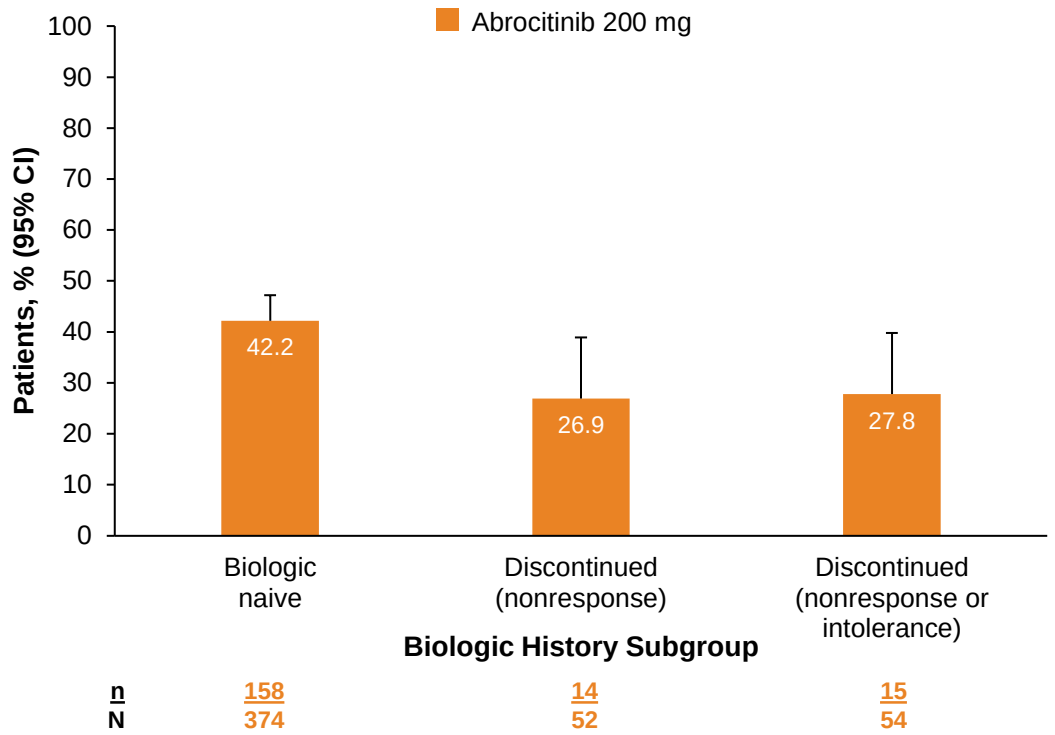
Efficacy of Abrocitinib Stratified by Biologic Treatment History: Achievement of EASI-90 + PP-NRS 0/1

- At Week 12, substantial proportions of patients treated with abrocitinib 200 mg in both the monotherapy pool and JADE REGIMEN induction period achieved the composite endpoint of EASI-90 + PP-NRS 0/1 across subgroups

Monotherapy Pool



JADE REGIMEN Induction Period



AD, atopic dermatitis; EASI-90, ≥90% improvement from baseline in Eczema Area and Severity Index; PP-NRS 0/1, Peak Pruritus Numerical Rating Scale score of 0 (no itch) or 1 (very little itch).

Conclusion

- Abrocitinib monotherapy was efficacious in patients with moderate-to-severe AD, regardless of biologic treatment history or reason for biologic discontinuation