Treatment Patterns and Efficacy in Biologic-Exposed and Biologic-Naive Patients With Moderate-to-Severe Atopic Dermatitis: JADE REAL Post Hoc Analysis

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SYNOPSIS

- Atopic dermatitis (AD) is a chronic inflammatory skin disorder with heterogeneous skin manifestations often requiring long-term, systemic treatment in patients with moderately to severely active disease that is not adequately controlled by topical agents[1,2]
  - The heterogenous nature of the disease necessitates flexibility in tailoring treatment regimens to manage changes in the signs and symptoms of AD over time, a practice rarely permitted in clinical trials used to inform the treatment and management of AD
- Abrocitinib, an oral Janus kinase (JAK) 1–selective inhibitor, is approved at the recommended doses of 100 and 200 mg once daily to treat moderate-to-severe AD in adult and adolescent patients[3,4]
- Many patients initiating abrocitinib in the real world have received prior biologic therapy[5-7] but are underrepresented in clinical trials[4,8]
- JADE REAL (NCT04564755) was a real-world–simulating, global, open-label, expanded access protocol (EAP) study with the primary objective of providing early access to abrocitinib for patients for whom available and approved topical and systemic medications for AD were inadequate
  - This unique study design simulated a real-world clinical setting by incorporating both clinical trial characteristics and real-world elements, including permitting dose changes
- This post hoc analysis of the JADE REAL study examined abrocitinib treatment patterns and exploratory efficacy outcomes by prior biologic exposure (biologic-exposed and biologic-naive)
- Both biologic-exposed and biologic-naive patients experienced improvements in Eczema Area and Severity Index (EASI) total score, percentage of body surface area (%BSA) involvement, Peak Pruritus Numerical Rating Scale (PP-NRS) total score, and Patient-Oriented Eczema Measure (POEM) total score from baseline to Week 72
- Very few patients in either group required concomitant rescue medications
- Results from this post hoc analysis indicate that abrocitinib flexible dosing enabled optimized treatment for patients with moderate-to-severe AD, including biologic-naive patients as well biologic-exposed patients, who are a difficult-to-treat population

OBJECTIVE

- To examine abrocitinib treatment patterns and exploratory efficacy outcomes by prior biologic exposure (biologic-exposed and biologic-naive) in a post hoc analysis of the JADE REAL study

METHODS

- The global EAP was initiated in 2020 and concluded in 2024; it included patients aged ≥12 years with moderate-to-severe AD
- Patients initiated daily abrocitinib 100 or 200 mg, per investigator discretion, with dose switching allowed throughout the study to simulate the real-world use of JAK inhibitors; topical AD medications were permitted
  - Per investigator discretion, the dose could be changed throughout the treatment period (first dose escalation of 100 to 200 mg due to inadequate patient response after ≥4 weeks of treatment)
- Baseline patient characteristics, including prior biologic use (exposed and naive), abrocitinib treatment patterns, and use of concomitant rescue medications, were collected
- Exploratory efficacy outcomes included EASI total score, %BSA involvement, PP-NRS total score (used with permission from Regeneron Pharmaceuticals, Inc., and Sanofi), and POEM total score at all scheduled timepoints
- Baseline was defined at the last measurement collected on or prior to Day 1 (first day of abrocitinib treatment)
- Exploratory efficacy outcomes are summarized descriptively from baseline to Week 72, with no formal hypothesis testing
  - Data were collected beyond Week 72; however, due to low patient numbers, data are analyzed to Week 72

RESULTS

Baseline characteristics

- Overall, 89 biologic-exposed and 223 biologic-naive patients were included (**Table 1**)
- Demographic and disease characteristics were similar between groups
  - Of biologic-exposed and biologic-naive patients, respectively, 74 (83.1%) and 171 (76.7%) were aged ≥18 to <65 years, 70 (78.7%) and 147 (65.9%) were White, and 51 (57.3%) and 116 (52.0%) were male
  - At baseline, 32 biologic-exposed (36.0%) and 82 biologic-naive (36.8%) patients had severe disease per Investigator Global Assessment (IGA)

Table 1. Baseline Demographics and Disease Characteristics

		All Patients N=312	Biologic-Exposed n=89	Biologic-Naive n=223
Age, years	Mean (SD)	38.0 (18.5)	40.9 (18.1)	36.8 (18.5)
	Median (IQR)	32.0 (22.5-53.0)	39.0 (25.0-53.0)	31.0 (22.0-52.0)
	≥12 to <18, n (%)	33 (10.6)	5 (5.6)	28 (12.6)
	≥18 to <65, n (%)	245 (78.5)	74 (83.1)	171 (76.7)
	≥65, n (%)	34 (10.9)	10 (11.2)	24 (10.8)
Sex, n (%)	Female	145 (46.5)	38 (42.7)	107 (48.0)
	Male	167 (53.5)	51 (57.3)	116 (52.0)
Race, n (%)	Asian	44 (14.1)	7 (7.9)	37 (16.6)
	Black or African American	43 (13.8)	10 (11.2)	33 (14.8)
	White	217 (69.6)	70 (78.7)	147 (65.9)
	Other[a]	8 (2.6)	2 (2.2)	6 (2.7)
EASI total score, mean (SD)		22.4 (12.7)	20.1 (12.3)	23.3 (12.8)
%BSA involvement, mean (SD)		34.4 (21.4)	32.5 (21.4)	35.1 (21.4)
PP-NRS total score, mean (SD)		7.4 (2.0)	7.2 (2.2)	7.5 (2.0)
POEM total score, mean (SD)		20.1 (5.6)	19.7 (5.7)	20.2 (5.6)
IGA, n (%)	Moderate	198 (63.5)	57 (64.0)	141 (63.2)
	Severe	114 (36.5)	32 (36.0)	82 (36.8)

%BSA, percentage of body surface area; EASI, Eczema Area and Severity Index; IGA, Investigator Global Assessment; POEM, Patient-Oriented Eczema Measure; PP-NRS, Peak Pruritus Numerical Rating Scale.
[a]Other includes Native Hawaiian or Other Pacific Islander, multiracial or not reported.

Treatment patterns

- A higher proportion of biologic-exposed patients received an initial dose of abrocitinib 200 mg (61 [68.5%]) compared with biologic-naive patients (131 [58.7%]; **Table 2**)
- A higher proportion of biologic-exposed patients had ≥1 dose change in both initial dose groups (initial dose: 100 mg, 15 [53.6%]; 200 mg, 27 [44.3%]) compared with biologic-naive patients (100 mg, 27 [29.3%]; 200 mg, 46 [35.1%]; **Table 2**)
- Median (IQR) abrocitinib treatment duration was similar in biologic-exposed and biologic-naive patients (351.0 [259.0-500.0] and 378.0 [246.0-510.0] days, respectively)
- Few biologic-exposed (6 [6.7%]) and biologic-naive (10 [4.5%]) patients required concomitant rescue treatments

Table 2. Treatment Patterns

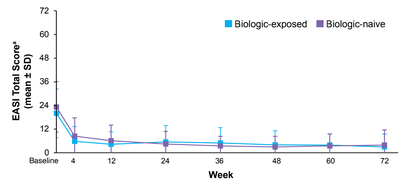
	All Patients N=312	Biologic-Exposed n=89	Biologic-Naive n=223
Patients who started on 100 mg QD,[a] n (%)	120 (38.5)	28 (31.5)	92 (41.3)
Continuous dosing[b]	78 (65.0)	13 (46.4)	65 (70.7)
≥1 Dose change from initial dose[b]	42 (35.0)	15 (53.6)	27 (29.3)
1 Dose change[c]	30 (71.4)	9 (60.0)	21 (77.8)
>1 Dose change[c]	12 (28.6)	6 (40.0)	6 (22.2)
Patients who started on 200 mg QD,[a] n (%)	192 (61.5)	61 (68.5)	131 (58.7)
Continuous dosing[d]	119 (62.0)	34 (55.7)	85 (64.9)
≥1 Dose change from initial dose[d]	73 (38.0)	27 (44.3)	46 (35.1)
1 Dose change[c]	40 (54.8)	13 (48.1)	27 (58.7)
>1 Dose change[c]	33 (45.2)	14 (51.9)	19 (41.3)

QD, once daily.
Missing doses and 0 doses were excluded before counting.
[a]Percentages are based on N. [b]Percentages are based on patients who started on 100 mg QD. [c]Percentages are based on patients with ≥1 dose change from initial dose. [d]Percentages are based on patients who started on 200 mg QD.

Efficacy

- Mean (SD) EASI total score improved from baseline to Week 72 in both biologic-exposed (20.1 [12.3] to 3.0 [6.6]) and biologic-naive (23.3 [12.8] to 3.9 [7.8]) patients (**Figure 1**)
  - The mean (SD) percent change from baseline at Week 72 in EASI total score in biologic-exposed and -naive patients was −84.5% (32.6%; n=30) and −80.2% (49.1%; n=77)

Figure 1. EASI Total Score in Biologic-Exposed and Biologic-Naive Patients From Baseline to Week 72

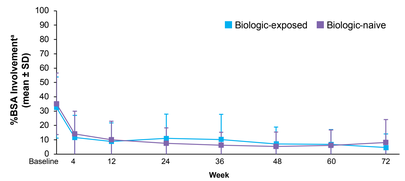


Observed (n)	Baseline	4	12	24	36	48	60	72
Biologic-exposed	89	89	88	86	75	63	45	30
Biologic-naive	223	217	208	189	171	149	121	77

EASI, Eczema Area and Severity Index. [a]The maximum value for EASI total score is 72.

- Mean (SD) %BSA involvement improved from baseline to Week 72 in both biologic-exposed (32.5% [21.4%] to 4.6% [9.5%]) and biologic-naive (35.1% [21.4%] to 8.2% [16.0%]) patients (**Figure 2**)
  - The mean (SD) percent change from baseline at Week 72 for %BSA involvement in biologic-exposed and -naive patients was −86.6% (25.8%; n=30) and −73.5% (57.3%; n=77)

Figure 2. %BSA Involvement in Biologic-Exposed and Biologic-Naive Patients From Baseline to Week 72

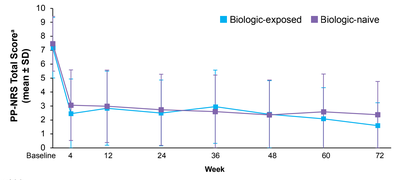


Observed (n)	Baseline	4	12	24	36	48	60	72
Biologic-exposed	89	89	88	86	75	63	45	30
Biologic-naive	223	217	208	189	171	149	121	77

%BSA, percentage of body surface area. [a]The maximum value for %BSA involvement is 100%.

- Mean (SD) PP-NRS total score improved from baseline to Week 72 in both biologic-exposed (7.2 [2.2] to 1.6 [1.6]) and biologic-naive (7.5 [2.0] to 2.4 [2.4]) patients (**Figure 3**)
  - The mean (SD) change from baseline at Week 72 in PP-RRS total score in biologic-exposed and -naive patients was −6.0% (2.9%; n=30) and −5.1% (2.7%; n=78)

Figure 3. PP-NRS Total Score in Biologic-Exposed and Biologic-Naive Patients From Baseline to Week 72

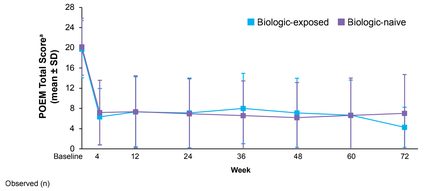


Observed (n)	Baseline	4	12	24	36	48	60	72
Biologic-exposed	89	89	88	86	75	63	45	30
Biologic-naive	223	217	208	189	171	148	121	78

PP-NRS, Peak Pruritus Numerical Rating Scale. [a]The maximum value for PP-NRS total score is 10.

- Mean (SD) POEM total score improved from baseline to Week 72 in both biologic-exposed (19.7 [5.7] to 4.3 [4.0]) and biologic-naive (20.2 [5.6] to 7.0 [7.7]) patients (**Figure 4**)
  - The mean (SD) change from baseline at Week 72 in POEM total score in biologic-exposed and -naive patients was −14.9% (6.8%; n=30) and −13.0% (8.3%; n=78)

Figure 4. POEM Total Score in Biologic-Exposed and Biologic-Naive Patients From Baseline to Week 72



Observed (n)	Baseline	4	12	24	36	48	60	72
Biologic-exposed	89	89	88	86	75	63	45	30
Biologic-naive	223	217	208	189	171	149	121	78

POEM, Patient-Oriented Eczema Measure. [a]The maximum value for POEM total score is 28.

CONCLUSIONS

- Both biologic-exposed and -naive patients with moderate-to-severe AD receiving abrocitinib in JADE REAL experienced substantial improvements in EASI total score, %BSA involvement, PP-NRS total score, and POEM total score from baseline to Week 72
- Very few patients in either group required concomitant rescue medications
- The flexible dosing of abrocitinib enabled optimized treatment strategies for patients with moderate-to-severe AD, including biologic-naive patients as well biologic-exposed patients, who are a difficult-to-treat population[5,9,10]

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DISCLOSURES

M.J.G. has received grants, personal fees, honoraria, and/or nonfinancial support from Pfizer Inc., AbbVie, Amgen, AkrosPharma, Arcutis, AnaptysBio, Aristea, Bristol Myers Squibb, Boehringer Ingelheim, Celgene, Dermavant, Dermira, Eli Lilly and Company, Galderma, JAMP Pharma, Janssen, Kyowa Kirin, LEO Pharma, MedImmune, Merck, Moonlake, Meiji, Nektar, Novartis, Roche, Sanofi Genzyme, Regeneron Pharmaceuticals, Sun Pharma, UCB, Ventyx, and Bausch Health. **R.C.** has been an advisor, speaker, and/or consultant for Pfizer Inc., AbbVie, Arena, Arcutis, Incyte, Regeneron Pharmaceuticals, and Sanofi Genzyme. **Y.O.** has received honoraria and consulting feed from Kyowa Kirin Co., Ltd., Bristol-Myers Squibb Company, J Janssen Pharmaceutical K.K., Nippon Boehringer Ingelheim Co., Ltd, AbbVie GK, Sanofi K.K., Amgen Inc., Eli Lilly Japan K.K.; honoraria from UCB Japan Co. Ltd., Maruho Co., Ltd; and grants from Sun Pharma Japan Ltd. **I.L.** is an employee of IQVIA, who were paid contractors to Pfizer Inc. for providing statistical support and for the development of this poster. **H.K., S.C.,** and **C.T.** are employees of Pfizer Inc., and may own stock/stock options in Pfizer Inc.

ACKNOWLEDGEMENTS

Editorial/medical writing support under the guidance of authors was provided by Nucleus Global, an Inizio Company, San Francisco, CA, 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). This study was funded by Pfizer Inc.

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Presented at The Fall Clinical Dermatology Conference; October 23-26, 2025; Las Vegas, Nevada