Time to efficacy outcomes among biologic-naive and -exposed patients with moderate-to-severe atopic dermatitis: A post-hoc analysis of JADE REAL

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SYNOPSIS

- Atopic dermatitis (AD) is a chronic inflammatory skin disorder with heterogeneous symptoms, severity, disease course, and burden[1,2]
- For patients with moderately to severely active disease that is not adequately controlled by topical agents, systemic treatment is often needed[1,2]
  - The heterogenous nature of AD necessitates flexible and individualized treatment approaches, but such tailored treatment is rarely allowed in clinical trials that are used to inform the treatment and management of AD
- Abrocitinib, an oral Janus kinase (JAK) 1-selective inhibitor, is approved for treating moderate-to-severe AD in patients aged ≥12 years at the recommended doses of 100 and 200 mg once daily[3,4]
- In real-world clinical practice, many patients initiating abrocitinib have previously received treatment with biologics,[5-7] but this group is under-represented in clinical trials[4,8]
- JADE REAL (NCT04564755) was a global, open-label, expanded access protocol (EAP) study that provided access to abrocitinib for patients for whom available and approved topical and systemic medications for AD were inadequate
  - This study incorporated both clinical trial and real-world elements, including permitting dose changes to simulate a real-world setting
- This post-hoc analysis of JADE REAL evaluated time to response for exploratory efficacy outcomes among all patients and stratified by prior biologic exposure (biologic-exposed and naive)
- The proportion of patients achieving EASI-75, EASI-90, and EASI-100 responses increased over time, with similar outcomes observed in both biologic-naive and biologic-exposed groups, and nearly half of patients achieved the stringent endpoints of EASI-100 response and EASI-90 + PP-NRS 0/1 response by Week 48
- Overall, flexible dosing of abrocitinib allowed for tailored therapy management for patients with moderate-to-severe AD, with similar efficacy outcomes observed among both biologic-naive and biologic-exposed patients

OBJECTIVE

- To evaluate time to response for efficacy outcomes overall and by prior biologic exposure (biologic-exposed and -naive) in a post-hoc analysis of the JADE REAL study

METHODS

- The JADE REAL global EAP study included patients with moderate-to-severe AD who were ≥12 years of age
- Patients received abrocitinib (100 or 200 mg daily) at investigator discretion, with dose adjustments allowed to simulate real-world use of JAK inhibitors; topical medications for AD were permitted
  - The dose could be changed throughout the treatment period per investigator discretion with the first dose increase permitted at ≥4 weeks of abrocitinib treatment; dose reduction could occur at any time
  - Patients completed study visits at Weeks 4 and 12, then every 12 weeks until abrocitinib became available in their country, until the study sponsor terminated the study in that country, or for individual reasons for discontinuation
- Baseline patient demographics and clinical characteristics were collected, including prior use of biologic treatments
- Time to response for the exploratory efficacy outcomes of ≥75% improvement from baseline in Eczema Area and Severity Index (EASI-75), ≥90% improvement from baseline in EASI (EASI-90), ≥100% improvement from baseline in EASI (EASI-100), and EASI-90 + Peak Pruritus-Numerical Rating Scale (PP-NRS) 0/1 were analyzed overall and by prior biologic exposure (exposed and naive)
  - The probability of EASI-75, EASI-90, EASI-100, and EASI-90 + PP-NRS 0/1 response was assessed at Weeks 4, 12, 24, 36, 48, 60 and 72

RESULTS

Baseline characteristics

- Analyses included 309 patients overall, with 89 and 223 in the biologic-exposed and -naive groups, respectively
- Demographic and disease characteristics were similar between groups (**Table 1**)
  - Among all, biologic-exposed, and biologic-naive patients, respectively, similar proportions were aged ≥18 to <65 years (78.5%, 83.1%, and 76.7%); were White (69.6%, 78.7%, and 65.9%); and were male (53.5%, 57.3%, and 52.0%)
  - At baseline, 36.5% of all patients, 36.0% of biologic-exposed patients, and 36.8% of biologic-naive patients had severe disease per Investigator Global Assessment (IGA)

Table 1. Baseline Characteristics

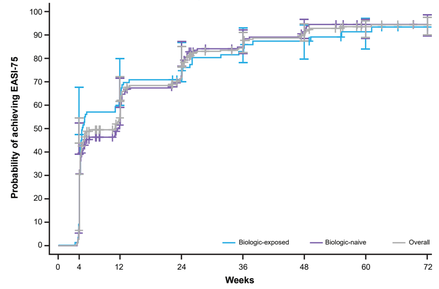
	All patients N=312	Biologic-exposed n=89	Biologic-naive n=223
Age, years			
Mean (SD)	38.0 (18.5)	40.9 (18.1)	36.8 (18.5)
Median (Q1, Q3)	32.0 (22.5, 53.0)	39.0 (25.0, 53.0)	31.0 (22.0, 52.0)
≥ 12 to < 18, n (%)	33 (10.6)	5 (5.6)	28 (12.6)
≥ 18 to < 65, n (%)	245 (78.5)	74 (83.1)	171 (76.7)
≥ 65, n (%)	34 (10.9)	10 (11.2)	24 (10.8)
Sex, n (%)			
Male	167 (53.5)	51 (57.3)	116 (52.0)
Female	145 (46.5)	38 (42.7)	107 (48.0)
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*	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, mean (SD)	7.4 (2.0)	7.2 (2.2)	7.5 (2.0)
POEM, 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, 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.
*Other includes Native Hawaiian or Other Pacific Islander, Multiracial or not reported.

Time to response

- Overall, 48.9% (95% CI, 43.5%-54.6%) of all patients achieved EASI-75 response by Week 4; 66.8% (61.5%-72.1%) achieved EASI-75 by Week 12 and 94.4% (89.8%-97.4%) by Week 72 (**Figure 1**)
  - The median time to achieve EASI-75 response overall was 78.0 (34.0-85.0) days
- Similar proportions of biologic-exposed and -naive patients achieved EASI-75 response by Week 4 (57.3% [47.3%-67.7%] vs 45.5% [39.1%-52.3%]), Week 12 (70.8% [61.2%-79.8%] vs 65.3% [58.8%-71.7%]), and Week 60 (92.1% [83.9%-97.1%] vs 93.3% [88.4%-96.7%]; **Figure 1**)

Figure 1. Time to achieve EASI-75 response

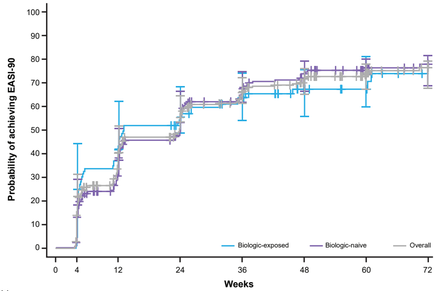


No. at risk								
Biologic-exposed	89	86	34	23	12	8	4	1
Biologic-naive*	220	214	95	50	21	11	3	2
Overall	309	300	129	73	33	19	7	3

*Three biologic-naive patients lacked post-baseline EASI data to calculate improvement from baseline

- Overall, 26.2% (21.7%-31.5%) of all patients achieved EASI-90 response by Week 4; 45.9% (40.5%-51.7%) achieved EASI-90 by Week 12 and 70.8 % (65.2%-76.2%) by Week 48 (**Figure 2**)
  - The overall median time to achieve EASI-90 response was 168.0 (91.0-170.0) days
- Similar proportions of biologic-exposed and -naive patients achieved EASI-90 response by Week 4 (33.7% [24.9%-44.5%] vs 23.2% [18.1%-29.3%]), Week 12 (51.7% [41.8%-62.4%] vs 43.6% [37.2%-50.6%]), and Week 60 (71.1% [59.9%- 81.4%] vs 74.0% [67.3%-80.2%]; **Figure 2**)

Figure 2. Time to achieve EASI-90 response

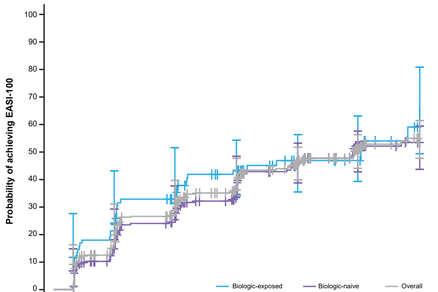


No. at risk								
Biologic-exposed	89	88	55	37	25	16	11	4
Biologic-naive*	220	218	140	97	59	43	26	14
Overall	309	306	195	134	84	59	37	18

*Three biologic-naive patients lacked post-baseline EASI data to calculate improvement from baseline

- Nearly half of all patients and in the biologic-exposed and -naive subgroups achieved EASI-100 by Week 48 (45.6% [39.8%-51.9%], 45.2% [35.3%-56.5%], and 45.8% [38.8%-53.3%], respectively; **Figure 3**)
- Similar proportions of all patients and in the biologic-exposed and -naive subgroups also achieved EASI 100 response by Week 72 (54.5% [47.6%-61.7%], 65.5% [47.6%-61.7%], and 51.4% [43.8%-59.5%], respectively; **Figure 3**)

Figure 3. Time to achieve EASI-100 response

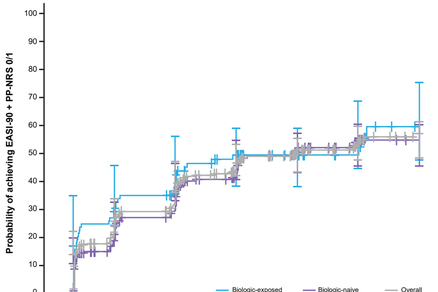


No. at risk								
Biologic-exposed	89	86	70	54	39	26	17	5
Biologic-naive*	220	218	171	141	109	78	52	31
Overall	309	307	241	195	148	104	69	36

*Three biologic-naive patients lacked post-baseline EASI data to calculate improvement from baseline.

- Nearly half of all patients and in the biologic-exposed and -naive subgroups achieved EASI-90 + PP-NRS 0/1 response by Week 48 (49.4% [43.6%-55.6%], 48.1% [38.2%-59.1%], and 50.0% [43.1%-57.5%], respectively; **Figure 4**)
- Similar proportions of all patients and in the biologic-exposed and -naive subgroups also achieved EASI-90 + PP-NRS 0/1 response by Week 72 (54.6% [48.2%-61.2%], 61.2% [47.4%-75.1%], and 52.7% [45.5%-60.3%], respectively; **Figure 4**)

Figure 4. Time to achieve EASI-90 + PP-NRS 0/1 response



No. at risk								
Biologic-exposed	89	88	65	50	34	23	16	7
Biologic-naive*	220	218	161	131	94	68	47	30
Overall	309	306	226	181	128	91	63	37

*Three biologic-naive patients lacked post-baseline EASI data to calculate improvement from baseline

CONCLUSIONS

- Among patients with moderate-to-severe AD receiving abrocitinib in JADE REAL, the proportion of patients achieving response was similar and increased over time overall and by prior biologic exposure (biologic-exposed and -naive) for all efficacy endpoints examined
- Nearly half of all patients achieved the stringent endpoints of EASI-100 and EASI-90 + PP-NRS 0/1 response before 1 year (by Week 48) of abrocitinib treatment
- Overall, flexible dosing of abrocitinib enabled versatile, tailored management for patients with moderate-to-severe AD

REFERENCES

1. Chovatiya R, et al. *J Drugs Dermatol.* 2022;21(2):172-176.
2. Langan SM, et al. *Lancet.* 2020;396(10247):345-360.
3. Cibinqo (abrocitinib). Prescribing information.Pfizer Labs; 2023.
4. Simpson EL, et al. *Lancet.* 2020;396(10246):255-266.
5. Olydam JI, et al. *J Eur Acad Dermatol Venereol.* 2023;37(12):2537-2542.
6. Ibba L, et al. *J Clin Med.* 2025;14(9)
7. Armario-Hita JC, et al. *Int J of Dermatol.* 2024;63(11)
8. Silverberg JI, et al. *JAMA Dermatol.* 2020;156(8):863-873.

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