Sustained On- and Off-Treatment Disease Control in Patients With Moderate-To-Severe Atopic Dermatitis Following 12-Week Open-Label Once-Daily Abrocitinib 200 mg: Post-Hoc Analysis of the Phase 3 JADE REGIMEN Study

Emma Guttman-Yassky,[1] Thomas Bieber,[2,3] Jan Gutermuth,[4,5] Kenji Kabashima,[6] Stephan Weidinger,[7] Andreas Wollenberg,[8,9,10] Irina Lazariciu,[11] Gerado Encinas,[12] Marina Mikheil,[13] Melissa Watkins[14]

[1]Icahn School of Medicine at Mount Sinai, New York, NY, USA; [2]Deptartment of Dermatology and Allergy, Ludwig-Maximilian Universits Hospital, Munich, Germany; [3]Christine Kühne-Center for Allergy Research and Education, Medicine Campus, Davos, Switzerland; [4]Skin Immunology & Immune Tolerance (SKIN) Research Group, Vrije Universiteit Brussel, Brussels, Belgium; [5]Universitair Ziekenhuis Brussel, Vrije Universiteit Brussel, Brussels, Belgium; [6]Graduate School of Medicine, Kyoto University, Kyoto, Japan; [7]University Hospital Schleswig-Holstein, Kiel, Germany; [8]University Hospital Augsburg, Augsburg, Germany; [9]Ludwig Maximilian University, Munich, Germany; [10]Comprehensive Centre for Inflammation Medicine, University of Lübeck, Lübeck, Germany; [11]IQVIA, Kirkland, QC, Canada; [12]Pfizer SA de CV, Mexico City, Mexico; [13]Pfizer Inc., Collegeville, PA, USA; [14]Pfizer Inc, New York, NY, USA

BACKGROUND

- The importance of achieving disease remission in atopic dermatitis (AD) is increasingly recognized, but the concept of disease remission has not been explicitly tested in clinical trials[1,2]
- A major obstacle has been a lack of consensus in how best to clinically define disease remission[1]
  - Definitions of flare itself vary widely, with 22 different definitions reported in the literature[3,4]
  - For example, the European Task Force on Atopic Dermatitis defined remission as a "period without flare of at least 8 weeks duration without anti-inflammatory treatment (irritant/allergen avoidance and emollient use not included)"[5]
  - Others have sub-classified remission into 'deep remission' (patient asymptomatic due to complete disease inactivity), 'long-term remission' (absence of disease activity for at least 1 year), and 'therapy-free remission' (no need for ongoing medical treatment)[6]
- Abrocitinib is an oral, once-daily, selective Janus kinase (JAK) 1 inhibitor approved for the treatment of adults and adolescents with moderate-to-severe AD[7]
  - In the phase 3 JADE REGIMEN trial, patients received 40-weeks of double-blind maintenance therapy with once-daily abrocitinib 200/100 mg or placebo, following 12 weeks of open-label once-daily abrocitinib 200 mg induction therapy[8]

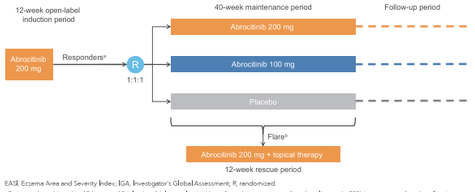
OBJECTIVE

- Outcomes from JADE REGIMEN (NCT03627767) were examined to explore the potential for patients with moderate-to-severe atopic dermatitis to achieve sustained on- and off-treatment disease control with abrocitinib treatment

METHODS

- In JADE REGIMEN, patients received 12 weeks of open-label once-daily abrocitinib 200 mg induction therapy, and responders (defined as Investigator's Global Assessment [IGA] score of 0/1 with ≥2-point reduction from baseline and ≥75% improvement from baseline in Eczema Area and Severity Index [EASI]) were then randomized to 40 weeks double-blind maintenance therapy with once-daily abrocitinib 200 mg, abrocitinib 100 mg, or placebo (**Figure 1**)
  - Patients who experienced a flare (≥50% loss of week 12 EASI response and new IGA score ≥2) during the maintenance period entered a 12-week open-label rescue period (abrocitinib 200 mg + topical therapy)
- Patients in this analysis were categorized by whether or not they experienced a disease flare during the maintenance period
  - Patients randomized to placebo who did not flare during the maintenance period were considered to have achieved an off-treatment state of disease control
- Assessments included EASI, Peak Pruritus Numerical Rating Scale (PP-NRS), IGA, and Dermatology Life Quality Index (DLQI)
- All data are reported as observed

Figure 1. Study Design and Cohorts



EASI, Eczema Area and Severity Index; IGA, Investigator's Global Assessment; R, randomized.

[a] Patients who achieved an IGA score of 0 (clear) or 1 (almost clear) with a ≥2-grade improvement from baseline and ≥75% improvement from baseline in EASI after 12 weeks of treatment with abrocitinib 200 mg.

[b] Patients who experienced a flare (≥50% loss of week 12 EASI response and new IGA score ≥2) during the maintenance period of JADE REGIMEN entered a 12-week open-label rescue period (abrocitinib 200 mg + topical medicated treatment).

RESULTS

Patient Populations

- Overall, 798 patients were responders at the end of the 12-week induction period
- Of these, 266 were randomized to abrocitinib 200 mg, 265 to abrocitinib 100 mg, and 267 to placebo for the 40-week maintenance period
  - During the maintenance period, 44 (16.5%), 105 (39.6%), and 207 (77.5%) patients randomized to abrocitinib 200 mg, 100 mg, or placebo, respectively, experienced a flare
- Baseline characteristics were similar among patients who did and did not experience a protocol-defined flare during the maintenance period across treatment arms (**Table 1**)

Table 1. Baseline Characteristics

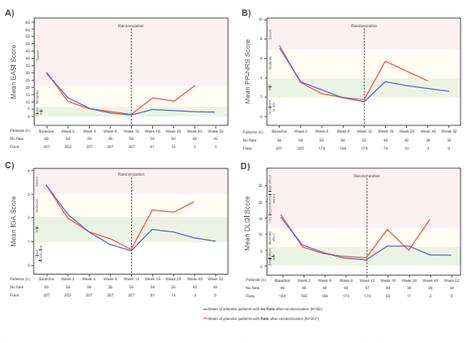
	Placebo		Abrocitinib 100 mg QD		Abrocitinib 200 mg QD	
	No Flare (N=60)	Flare (N=207)	No Flare (N=160)	Flare (N=105)	No Flare (N=222)	Flare (N=44)
Age, years Mean (SD)	30.4 (14.3)	32.3 (14.3)	32.4 (15.8)	31.8 (13.6)	32.6 (15.8)	31.0 (12.9)
Category, n (%)						
<18	12 (20.0)	37 (17.9)	28 (17.5)	21 (20.0)	40 (18.0)	7 (15.9)
18 to <65	46 (76.6)	164 (79.2)	124 (77.5)	82 (78.1)	170 (76.6)	37 (84.1)
≥65	2 (3.3)	6 (2.9)	8 (5.0)	2 (1.9)	12 (5.4)	0
Sex, n (%)						
Male	30 (50.0)	111 (53.6)	86 (53.8)	62 (59.0)	123 (55.4)	27 (61.4)
Female	30 (50.0)	96 (46.4)	74 (46.3)	43 (41.0)	99 (44.6)	17 (38.6)
Disease duration, years						
Mean (SD)	19.7 (14.7)	21.0 (15.0)	19.7 (14.5)	21.6 (14.0)	21.1 (15.4)	22.8 (13.7)
IGA, n (%)						
Moderate	40 (66.7)	137 (66.2)	101 (63.1)	60 (57.1)	139 (62.6)	31 (70.5)
Severe	20 (33.3)	70 (33.8)	59 (36.9)	45 (42.9)	83 (37.4)	13 (29.5)
EASI						
Mean (SD)	29.7 (12.2)	30.3 (12.2)	29.6 (11.8)	31.8 (11.9)	30.5 (12.6)	29.8 (10.9)
%BSA						
Mean (SD)	43.6 (19.8)	47.2 (20.6)	45.0 (20.5)	51.1 (21.9)	47.8 (22.1)	49.6 (21.5)
PP-NRS	n=59	n=207	n=160	n=105	n=222	n=44
Mean (SD)	7.1 (1.6)	7.4 (1.8)	7.2 (1.6)	7.3 (1.5)	7.3 (1.8)	7.5 (1.4)
DLQI	n=46	n=164	n=132	n=84	n=178	n=35
Mean (SD)	15.4 (6.5)	16.1 (6.6)	15.2 (6.3)	16.2 (6.3)	16.5 (6.9)	16.7 (6.4)

%BSA, percentage of body surface area; DLQI, Dermatology Life Quality Index; EASI, Eczema Area and Severity Index; IGA, Investigator's Global Assessment; PP-NRS, Peak Pruritus Numerical Rating Scale; QD, once daily

Maintenance of response

- Among patients who did not flare after being randomized to placebo for the maintenance period, mean EASI, PP-NRS, IGA, and DLQI scores remained stable and either clear or mild for 40 weeks (**Figure 2**)
  - A summary of EASI, PP-NRS, and IGA categories during the maintenance period in flare-free patients randomized to placebo is shown in **Figure 3**, confirming that the majority of these patients were experiencing mild to no symptoms
  - This indicates that their disease course initially achieved on-treatment disease control, which was maintained after coming off-treatment
- No clustering in patient response was observed during the initial 12 weeks of open-label abrocitinib 200 mg treatment across all available data that could help differentiate patients who would or would not subsequently flare post randomization

Figure 2. Patients Randomized to Placebo (Dose Withdrawal): Mean A) EASI, B) PP-NRS, C) IGA, and D) DLQI Response Rates

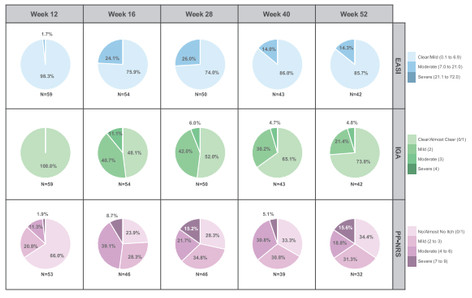


DLQI, Dermatology Life Quality Index; EASI, Eczema Area and Severity Index; IGA, Investigator's Global Assessment; PP-NRS, Peak Pruritus Numerical Rating Scale.

Includes all patients who were responders to 12-weeks open label abrocitinib and then randomized to placebo for 40-weeks maintenance.

Color banding is defined as follows: EASI (0.1 to 6.9 = clear/mild; 7.0 to 21.0 = moderate, 21.1 to 72.0 = severe); IGA (0 to 1 = clear or almost clear; 2 = mild, 3 = moderate, 4 = severe); PP-NRS (0 to 1 = no/almost no itch, 2 to 3 = mild, 4 to 6 = moderate, 7 to 9 = severe); DLQI (0 to 6 = small effect/mild, 6 to 11 = moderate effect, 11 to 30 = very large/extremely large effect/severe).

Figure 3. Summary of EASI, PP-NRS, and IGA Categories During Maintenance in the JADE REGIMEN Study for Patients Randomized to Placebo Without Flare

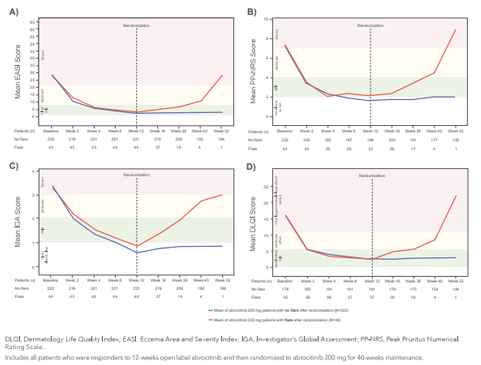


EASI, Eczema Area and Severity Index; IGA, Investigator's Global Assessment; PP-NRS, Peak Pruritus Numerical Rating Scale.

Includes all patients who were responders to 12-weeks open label abrocitinib, were then randomized to placebo for 40 weeks maintenance and did not meet the criteria for protocol-defined flare.

- For patients who did not flare after continuing abrocitinib 200 mg (**Figure 4**) or down-dosing to abrocitinib 100 mg (**Figure 5**), mean EASI, PP-NRS, IGA, and DLQI scores also remained stable and either clear/mild for 40 weeks
  - This indicates that their disease course had achieved on-treatment disease control

Figure 4. Patients Randomized to Abrocitinib 200 mg: Mean A) EASI, B) PP-NRS, C) IGA, and D) DLQI Response Rates

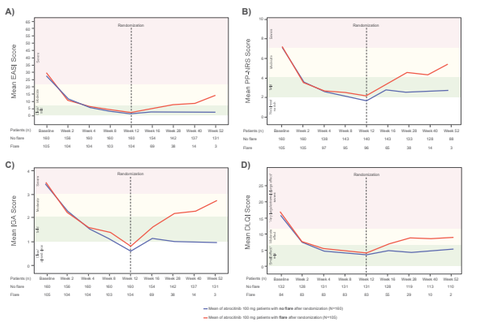


DLQI, Dermatology Life Quality Index; EASI, Eczema Area and Severity Index; IGA, Investigator's Global Assessment; PP-NRS, Peak Pruritus Numerical Rating Scale.

Includes all patients who were responders to 12-weeks open label abrocitinib and then randomized to abrocitinib 200 mg for 40-weeks maintenance.

Color banding is defined as follows: EASI (0.1 to 6.9 = clear/mild; 7.0 to 21.0 = moderate, 21.1 to 72.0 = severe); IGA (0 to 1 = clear or almost clear; 2 = mild; 3 = moderate; 4 = severe); PP-NRS (0 to 1 = no/almost no itch, 2 to 3 = mild, 4 to 6 = moderate, 7 to 9 = severe); DLQI (0 to 6 = small effect/mild, 6 to 11 = moderate effect, 11 to 30 = very large/extremely large effect/severe).

Figure 5. Patients Randomized to Abrocitinib 100 mg (Dose Reduction): Mean A) EASI, B) PP-NRS, C) IGA, and D) DLQI Response Rates



DLQI, Dermatology Life Quality Index; EASI, Eczema Area and Severity Index; IGA, Investigator's Global Assessment; PP-NRS, Peak Pruritus Numerical Rating Scale.

Includes all patients who were responders to 12-weeks open label abrocitinib and then randomized to abrocitinib 100 mg for 40-weeks maintenance.

Color banding is defined as follows: EASI (0.1 to 6.9 = clear/mild; 7.0 to 21.0 = moderate, 21.1 to 72.0 = severe); IGA (0 to 1 = clear or almost clear; 2 = mild; 3 = moderate; 4 = severe); PP-NRS (0 to 1 = no/almost no itch, 2 to 3 = mild, 4 to 6 = moderate, 7 to 9 = severe); DLQI (0 to 6 = small effect/mild, 6 to 11 = moderate effect, 11 to 30 = very large/extremely large effect/severe).

CONCLUSIONS

- This post hoc analysis of JADE REGIMEN demonstrated that therapy-free disease control is possible in a proportion of patients with moderate-to-severe AD following only 12 weeks of active treatment with abrocitinib 200 mg
- Sustained on-treatment disease control was also demonstrated among patients down-dosed to abrocitinib 100 mg following induction therapy
- For patients who have experienced on-treatment disease control, dose interruption or pausing treatment following a response to induction therapy might be considered
- Future studies may identify which patient characteristics or biomarkers could predict which patients may achieve sustained off-treatment disease control and benefit from a dose interruption or pausing

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DISCLOSURES

E. Guttman-Yassky is an advisory board member for Pfizer Inc., Asana Biosciences, Celgene, Dermira, Galderma, Glenmark, Medimmune, Novartis, Regeneron, Sanofi, Stiefel/GlaxoSmithKline, and Vitae (honorarium); a consultant for Pfizer Inc., AbbVie, Almirall, Anacor, Asana Biosciences, Celgene, Dermira, Galderma, Eli Lilly and Company, Glenmark, Kiowa Kirin, LEO Pharma, Medimmune, Mitsubishi Tanabe, Novartis, Regeneron, Sanofi, Stiefel/GlaxoSmithKline, and Vitae (honorarium); and an investigator for Celgene, Eli Lilly and Company, LEO Pharma, Medimmune, and Regeneron (grants to institution).

T. Bieber is a speaker and/or consultant and/or Investigator for AbbVie, Affibody, Almirall, Amagma, AnaptysBio, AOBiom, Anergis, Apogee, Arena, Aristea, Artax, Asana Biosciences, ASLAN pharma, Astria, Attovia, Bayer Health, Biofilm control, BioVerSys, Böhringer-Ingelheim, Bristol-Myers Squibb, BYOME Labs, Connect Pharma, Daichi-Sanyko, Dermavant, DICE Therapeutics, Domain Therapeutics, DS Pharma, EQRx, Galderma, Galapagos, Glenmark, GSK, Incyte, Innovaderm, Janssen, Kirin, Kymab, LEO, LG Chem, Lilly, L'Oréal, MSD, Medac, Micreos, Nektar, Nextech, Novartis, Numab, OM-Pharma, Ornavi, Overtone, Pfizer, Pierre Fabre, Q32bio, RAPT, Samsung Bioepis, Sanofi/Regeneron, TIRmed, UCB, Union Therapeutics, UPStream Bio, and YUHAN. He is the founder and chairman of the board of the non-profit biotech "Davos Biosciences AG" within the international Kühne-Foundation and founder of the consulting firm "Bieber Dermatology Consulting."

J. Gutermuth has conducted clinical trials and/or has been an advisory board member and/or speaker for AbbVie, Almirall, Eli Lilly and Company, Galderma, Janssen, LEO Pharma, Pfizer, Regeneron, and Sanofi and Genzyme.

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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.

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