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Early Achievement of 3- and 6-Month Treat-To-Target Goals After 4 Weeks of Abrocitinib Monotherapy in Patients With Moderate-to-Severe Atopic Dermatitis: A Post Hoc Analysis

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BACKGROUND

- A treat-to-target strategy proposed by experts for adults with moderate-to-severe atopic dermatitis (AD) suggests that treatment target goals at 3 months should be a ≥1-point improvement in patient global assessment (PtGA) score and at least 1 of the following improvements[1]:
  - ≥50% in Eczema Area and Severity Index (EASI-50)
  - ≥50% in SCORing Atopic Dermatitis (SCORAD-50)
  - ≥3 points in Peak Pruritus Numerical Rating Scale (PP-NRS3)
  - ≥4 points in Dermatology Life Quality Index (DLQI4)
  - ≥4 points in Patient-Oriented Eczema Measure (POEM4)
- At 6 months, the proposed treat-to-target goals are a PtGA score of ≤2 and at least 1 of the following[1]:
  - EASI-75 or EASI ≤7
  - SCORAD-75 or SCORAD ≤24
  - PP-NRS ≤4
  - DLQI ≤5
  - POEM ≤7
- Treatment continuation should be considered if the respective PtGA target goal plus at least 1 disease domain target goal is attained[1]
- Findings from clinical trials indicate that treatment with abrocitinib, an oral, once-daily, Janus kinase 1-selective inhibitor, is associated with a rapid improvement in multiple clinical domains[2]
- A strong early response may be a predictor of a later response, as well as of treatment adherence

OBJECTIVES

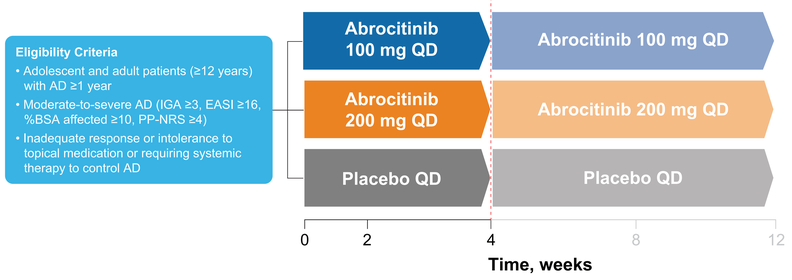
- To estimate the proportions of patients with moderate-to-severe AD who attained 3-month and 6-month treat-to-target goals after only 4 weeks of abrocitinib monotherapy
- To assess itch relief at Week 4 of abrocitinib monotherapy

METHODS

Study Design

- Data were pooled from the JADE pivotal phase 3 clinical trials JADE MONO-1 (NCT03349060)[3] and JADE MONO-2 (NCT03575871),[4] in which patients with moderate-to-severe AD aged ≥12 years were treated with abrocitinib (200 or 100 mg/day) or placebo (**Figure 1**)

Figure 1. JADE MONO-1 and JADE MONO-2 Study Design



%BSA, percentage of body surface area; AD, atopic dermatitis; EASI, Eczema Area and Severity Index; IGA, Investigator's Global Assessment; PP-NRS, Peak Pruritus Numerical Rating Scale (with permission from Regeneron Pharmaceuticals, Inc., and Sanofi); QD, once daily.

Assessments and Statistical Analysis

- In this post hoc analysis, all randomized patients who received at least 1 dose of the study medication were assessed
- Assessments included:
  - Proportions of patients attaining the 3- and 6-month treat-to-target goals at Week 4
    - Only patients with available PtGA, EASI, PP-NRS, and DLQI data at Week 4 were included in this analysis
    - Data are presented as observed and using descriptive statistics
  - Least squares mean changes from baseline in PP-NRS score (with permission from Regeneron Pharmaceuticals, Inc., and Sanofi) were analyzed using a mixed-effects model with repeated measures

RESULTS

Patients

- The data pool included 778 patients (placebo, n=155; abrocitinib 100 mg/day, n=314; abrocitinib 200 mg/day, n=309)
  - Baseline demographics and clinical characteristics were comparable across treatment arms (**Table 1**)
- Of those, 487 patients had available PtGA, EASI, PP-NRS, and DLQI scores at Week 4 (placebo, n=100; abrocitinib 100 mg/day, n=191; abrocitinib 200 mg/day, n=196)

Table 1. Baseline Demographics and Clinical Characteristics

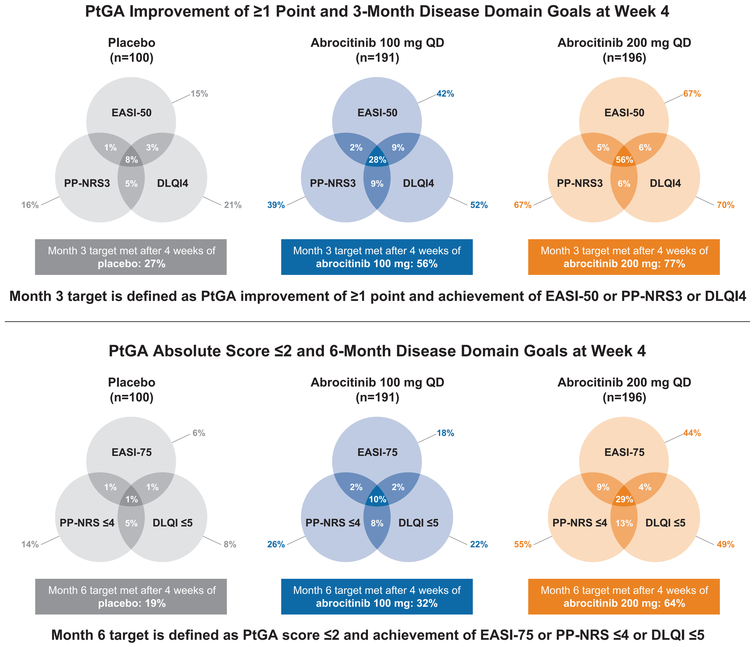
	Placebo n=155	Abrocitinib 100 mg QD n=314	Abrocitinib 200 mg QD n=309
Age, mean ± SD, years	32 ± 14	35 ± 16	33 ± 16
Female, n (%)	59 (38)	130 (41)	140 (45)
Race, n (%)			
White	102 (66)	214 (68)	195 (63)
Other[a]	53 (34)	100 (32)	114 (37)
Weight, mean ± SD, kg	74 ± 18	77 ± 20	75 ± 18
EASI, mean ± SD	28 ± 11	30 ± 12	30 ± 13
PP-NRS, mean ± SD	7 ± 2	7 ± 2	7 ± 2
DLQI, mean ± SD	14 ± 7	15 ± 7	15 ± 6

DLQI, Dermatology Life Quality Index; EASI, Eczema Area and Severity Index; PP-NRS, Peak Pruritus Numerical Rating Scale; QD, once daily.
[a]Patients who identified as Black or African American, Asian, American Indian or Alaskan Native, Native Hawaiian or Other Pacific Islander, multiracial, or did not report their race.

Abrocitinib Efficacy After 4 Weeks of Treatment

- At Week 4, a greater proportion of patients (56% [109/196]) treated with abrocitinib 200 mg/day attained the 3-month treat-to-target goals for simultaneous improvements in PtGA, EASI, PP-NRS, and DLQI, compared with patients who received abrocitinib 100 mg/day (28% [54/191]) or placebo (8% [8/100]); the corresponding values for 6-month treat-to-target goals were 29% (57/196), 10% (20/191), and 1% (1/100), respectively (**Figure 2**)
  - Proportions of patients attaining the 3-month targets were greater with abrocitinib 200 mg/day (77% [150/196]) than with abrocitinib 100 mg/day (56% [107/191]) or placebo (27% [27/100]); these proportions were, respectively, 64% (126/196), 32% (62/191), and 19% (19/100) for the 6-month targets (**Figure 2**)

Figure 2. Proportions of Patients Attaining 3- and 6-Month Treatment Goals at Week 4

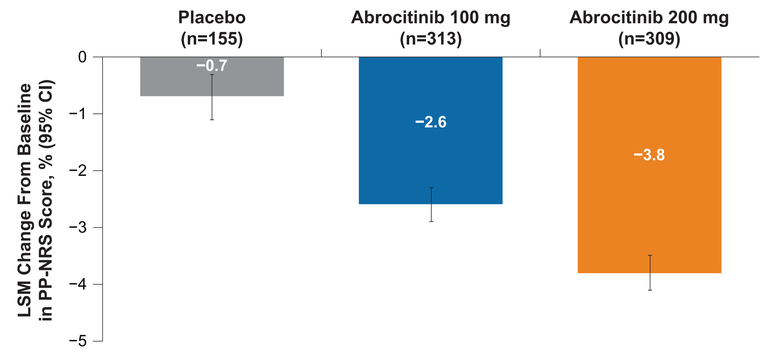


DLQI, Dermatology Life Quality Index; DLQI4; ≥4-point improvement from baseline in DLQI; DLQI ≤5; DLQI score ≤5 (baseline >5); EASI, Eczema Area and Severity Index; EASI-50, ≥50% improvement from baseline in EASI; EASI-75, ≥75% improvement from baseline in EASI; PP-NRS, Peak Pruritus Numerical Rating Scale; PP-NRS3, ≥3-point improvement from baseline in PP-NRS; PP-NRS ≤4, PP-NRS score ≤4 (baseline >4); PtGA, patient global assessment; QD, once daily.
Data reported as observed; includes patients with available PtGA, EASI, PP-NRS, and DLQI scores at Week 4.

Itch Relief After 4 Weeks of Abrocitinib Treatment

- Greater improvements in PP-NRS change from baseline to Week 4 were observed with abrocitinib 200 mg/day than with abrocitinib 100 mg/day or placebo (**Figure 3**)

Figure 3. Changes in PP-NRS From Baseline to Week 4



LSM, least squares mean; MMRM, mixed-effects model with repeated measures; PP-NRS, Peak Pruritus Numerical Rating Scale.
Mean PP-NRS ± SD at baseline was 7 ± 2 for all treatment arms.
All randomized patients who received at least 1 dose of the study medication were assessed.
MMRM contained fixed factors of treatment, week, treatment-by-week interaction, study, baseline disease severity, age category and baseline value and unstructured covariance matrix or compound symmetry covariance matrix.

CONCLUSIONS

- As early as Week 4, a substantial proportion of patients treated with abrocitinib 200 mg or 100 mg monotherapy attained proposed 3-month and 6-month improvement goals in skin lesions, pruritus, and dermatology-related quality of life
- Improvements in itch severity were greater with abrocitinib 200 mg and abrocitinib 100 mg than with placebo at Week 4
- These data suggest that abrocitinib treatment provides rapid relief of signs and symptoms across several clinical domains
- Moreover, currently proposed 3-month and 6-month treatment goals for patients with moderate-to-severe AD could be achieved far earlier with abrocitinib, thus enabling early clinical response assessment

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