Improvement in Patient-Reported Symptoms and Quality of Life With Abrocitinib Versus Dupilumab in Adults With Moderate-to-Severe Atopic Dermatitis Who Received Background Topical Therapy: Results of a 26-Week, Randomized, Head-to-Head Trial

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Disclosures

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Introduction and Methods

Background

Abrocitinib was superior to dupilumab in providing itch relief at week 2 (primary endpoint) and reducing the area and severity of AD at weeks 4 and 16 (primary and key secondary endpoints) in adults with moderate-to-severe AD in the head-to-head JADE DARE trial

Objective

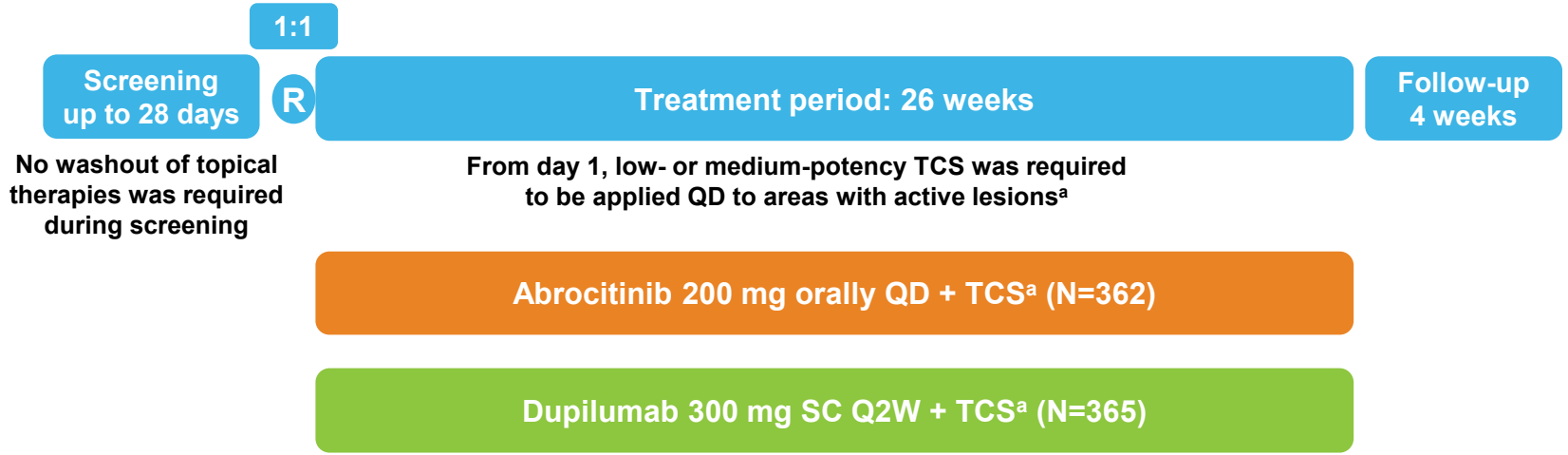
To summarize patient-reported signs, symptoms, and dermatologic HRQoL in patients from the phase 3b JADE DARE trial

JADE DARE Study Design

Multicenter, phase 3b, randomized, double-blind, double-dummy, active-controlled trial (NCT04345367)

Eligibility Criteria

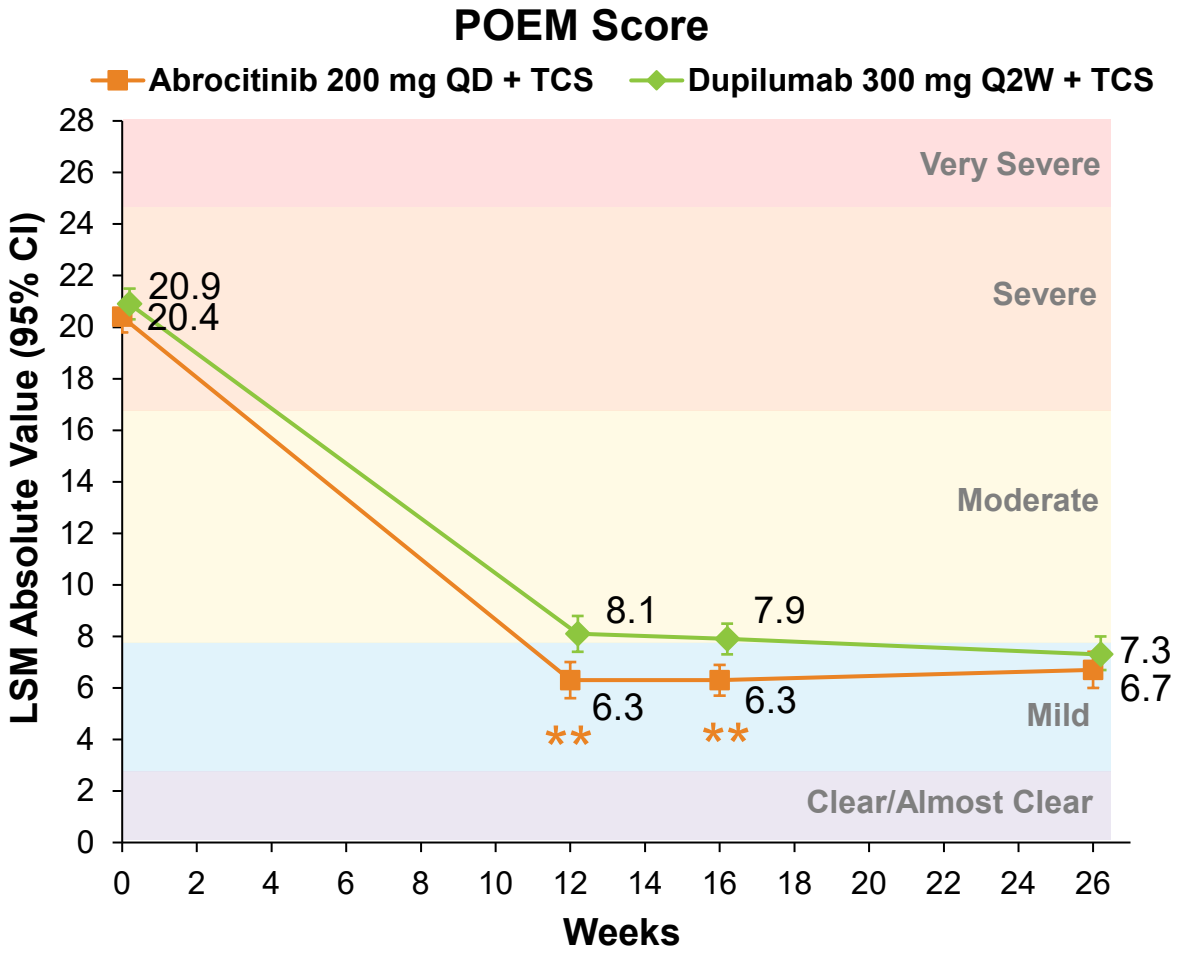
- Adults (≥18 years of age) with AD for ≥6 months
- Moderate-to-severe AD (IGA ≥3; EASI ≥16; %BSA affected ≥10; PP-NRS ≥4)
- Inadequate response to topical medication or a requirement for systemic therapy to control AD

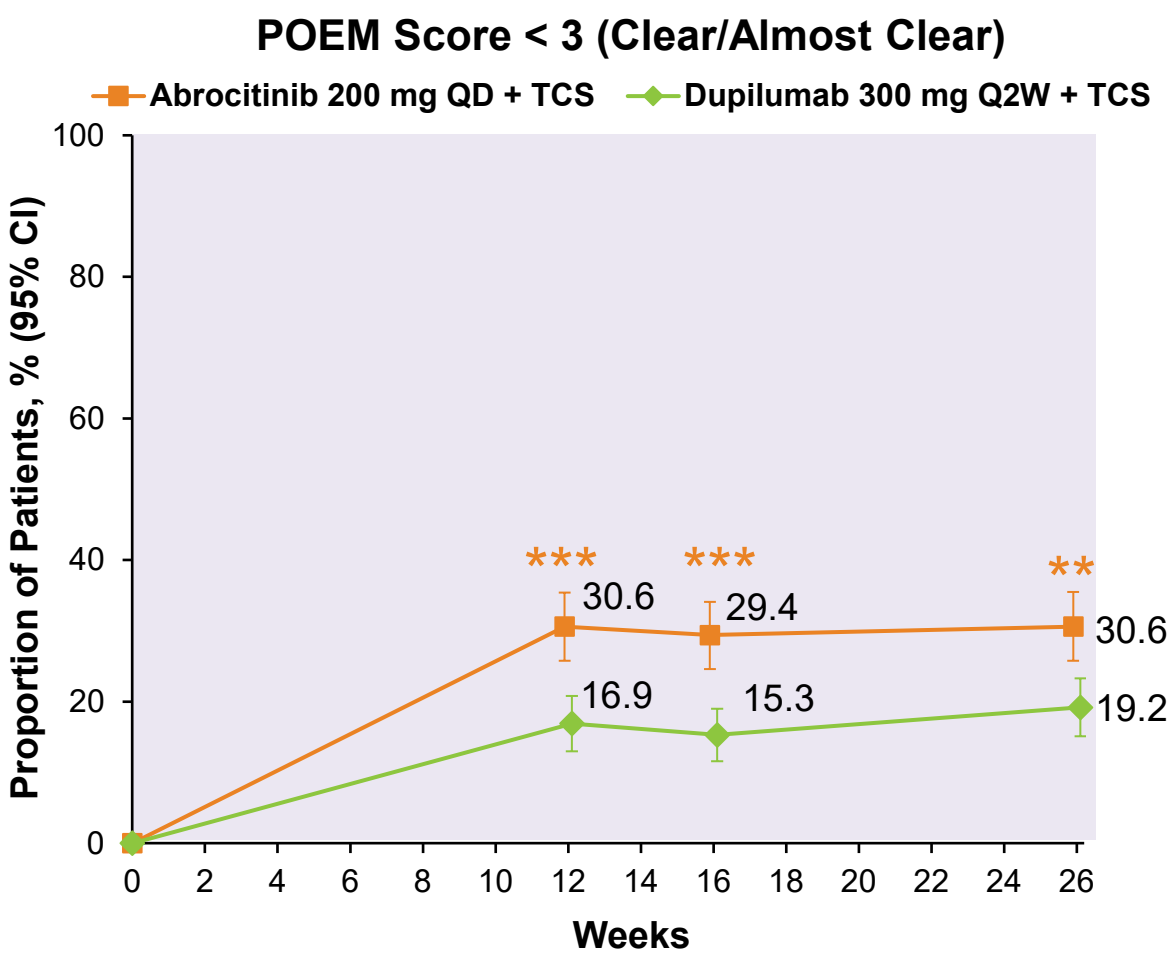


AD, atopic dermatitis; %BSA, percentage of body surface area; EASI, Eczema Area and Severity Index; HRQoL, health-related quality of life; IGA, Investigator's Global Assessment; PP-NRS, Peak Pruritus Numerical Rating Scale; Q2W, once every other week; QD, once daily; R, randomization; SC, subcutaneously; TCS, topical corticosteroid(s).

[a]Topical calcineurin inhibitors or a phosphodiesterase-4 inhibitor were permitted to be used instead of TCS in body areas of thin skin or if continued treatment with TCS was considered unsafe. Nonmedicated topical emollients were required to be applied at least twice daily to all body areas affected with AD.

Proportion of Patients Reporting Clearance of AD Signs and Symptoms Was Higher With Abrocitinib Than With Dupilumab





LSM, least squares mean; POEM, Patient-Oriented Eczema Measure.

**P<0.01, ***P<0.0001. P values are not controlled for multiplicity.

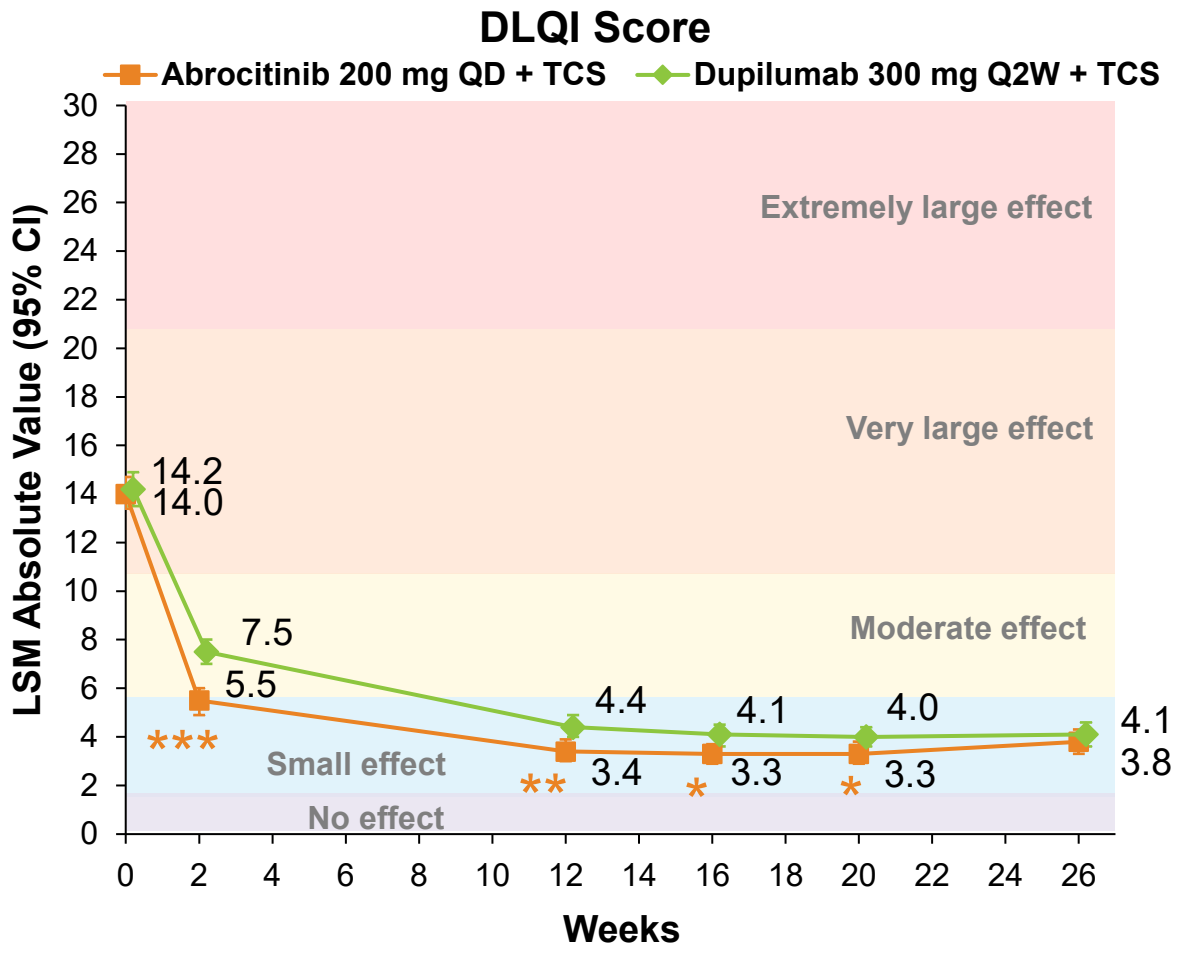
POEM scores range from 0 to 28; a score of 0 to 2 indicates clear/almost clear, 3 to 7 indicates mild, 8 to 16 indicates moderate, 17 to 24 indicates severe, and 25 to 28 indicates very severe (Charman et al. *Br J Dermatol*. 2013;169:1326-32).

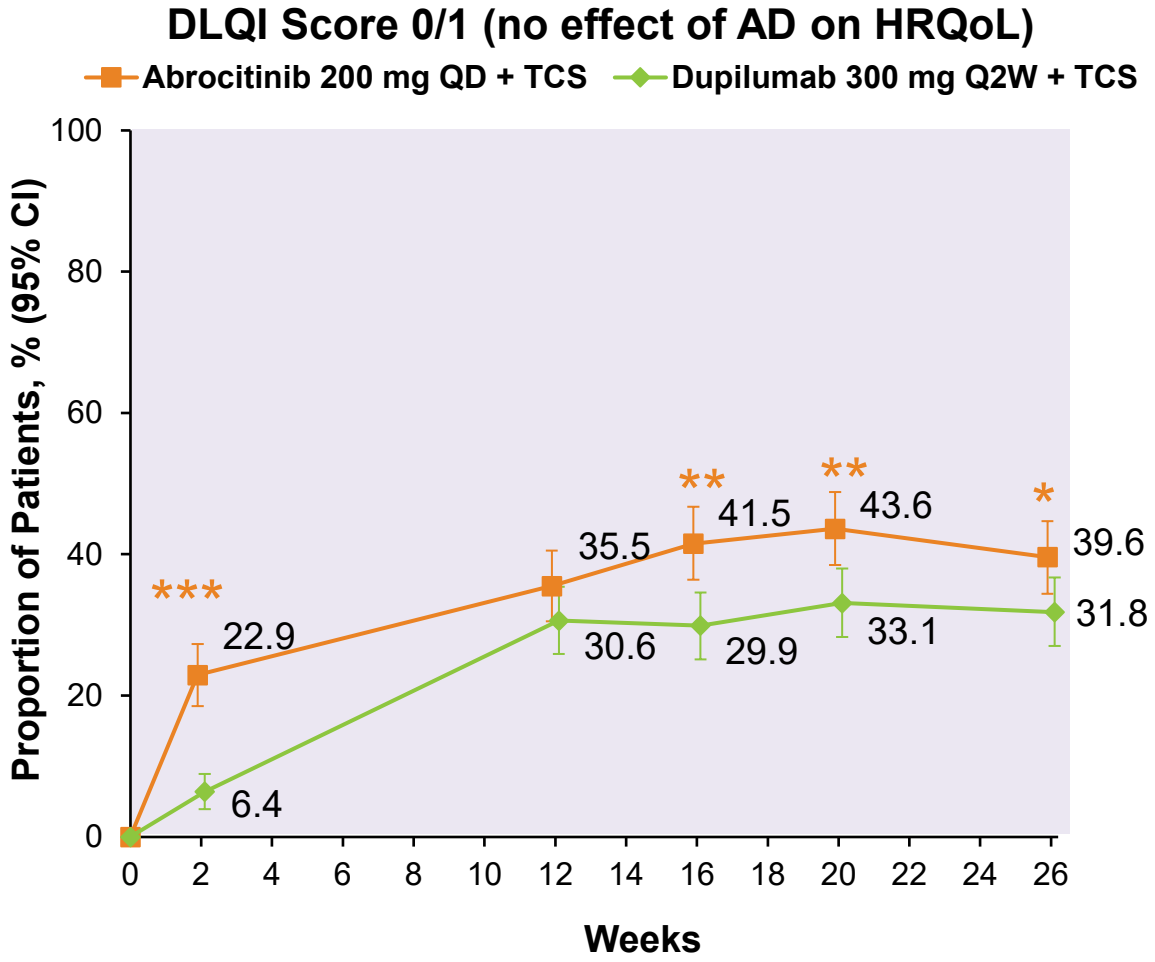
A 4-point improvement in POEM is considered the minimal clinically important difference (Schram et al. *Allergy*. 2012;67:99-106).

POEM scores in each treatment group were analyzed using mixed model for repeated measures, with fixed factors of treatment, visit, treatment by visit interaction, baseline disease severity, and an unstructured covariance matrix. Data were analyzed in the full analysis set (all randomly assigned patients who received ≥1 dose of study medication). Data collected after dropout or the use of rescue therapy were censored.

Proportions of patients with POEM scores of <3 in each treatment group were analyzed in the full analysis set (all randomly assigned patients who received ≥1 dose of study medication) with baseline POEM scores of ≥3. If a patient withdrew from the study or used rescue therapy, the patient was counted as a nonresponder after that point. P values were calculated using the Cochran-Mantel-Haenszel method adjusted by baseline disease severity.

Proportion of Patients Reporting No Effect of AD on Their Dermatologic Health-Related Quality of Life Was Higher With Abrocitinib Than With Dupilumab





DLQI, Dermatology Life Quality Index.

*P<0.05, **P<0.01, ***P<0.0001. P values are not controlled for multiplicity.

DLQI scores range from 0 to 30; a score of 0 or 1 indicates no effect, 2 to 5 indicates a small effect, 6 to 10 indicates a moderate effect, 11 to 20 indicates a very large effect, and 21 to 30 indicates an extremely large effect (Basra et al. *Br J Dermatol.* 2008;159:997-1035).

A 4-point improvement in DLQI score is considered the minimal clinically important difference (Basra et al. *Dermatology.* 2015;230:27-33).

DLQI scores in each treatment group were analyzed using mixed model for repeated measures contained fixed factors of treatment, visit, treatment by visit interaction, baseline disease severity, and an unstructured covariance matrix. Data were analyzed in the full analysis set (all randomly assigned patients who received ≥1 dose of study medication). Data collected after dropout or the use of rescue therapy were censored.

Proportions of patients with DLQI scores of 0 or 1 in each treatment group were analyzed in the full analysis set (all randomly assigned patients who received ≥1 dose of study medication) with baseline DLQI scores of ≥2. If a patient withdrew from the study or used rescue therapy, the patient was counted as a nonresponder after that point. P values were calculated using the Cochran-Mantel-Haenszel method adjusted by baseline disease severity.

Conclusions

- In patients with moderate-to-severe AD receiving background medicated topical therapy, abrocitinib treatment for up to 26 weeks was associated with greater improvements in patient-reported signs, symptoms, and dermatologic HRQoL than dupilumab
  - Proportion of patients achieving a clearance of AD signs and symptoms (“clear/almost clear” per POEM) was significantly higher for abrocitinib versus dupilumab across all time points
  - Proportion of patients reporting no effect of AD on their dermatologic HRQoL was significantly higher for abrocitinib versus dupilumab across all time points except for week 12

Significance was assessed at a nominal level of 0.05 or 5%; there were no adjustments for multiplicity.