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ORIGINAL ARTICLE

Impact of oral abrocitinib on signs, symptoms and quality of life among adolescents with moderate-to-severe atopic dermatitis: an analysis of patient-reported outcomes

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Abstract

Background A significant improvement in clinical signs was demonstrated with abrocitinib relative to placebo in adolescents with moderate-to-severe atopic dermatitis (AD) in three phase 3, randomized, double-blinded, placebo-controlled studies (JADE TEEN [ClinicalTrials.gov, NCT03796676], JADE MONO-1 [NCT03349060] and JADE MONO-2 [NCT03575871]).

Objectives To evaluate the impact of abrocitinib on patient-reported signs/symptoms, including sleep loss and quality of life among adolescents with moderate-to-severe AD.

Methods JADE TEEN, JADE MONO-1 and JADE MONO-2 were conducted in the Asia-Pacific region, Europe and North America and included patients aged 12–17 years with moderate-to-severe AD and inadequate response to ≥ 4 consecutive weeks of topical medication or treatment with systemic therapy for AD. Patients were randomly assigned (1 : 1 : 1, JADE TEEN; 2 : 2 : 1, JADE MONO-1/-2) to receive once-daily oral abrocitinib (200 or 100 mg) or placebo for 12 weeks in combination with topical therapy (JADE TEEN) or as monotherapy (JADE MONO-1/-2). Data from adolescent patients in JADE MONO-1/-2 were pooled for these analyses.

Results At week 12, more adolescents treated with abrocitinib (200 or 100 mg) vs. placebo achieved a ≥ 4 -point improvement from baseline in the Patient-Oriented Eczema Measure in JADE TEEN (83.9% and 77.0% vs. 60.2%) and JADE MONO-1/-2 (83.0% and 69.4% vs. 43.5%) and a ≥ 6 -point improvement from baseline in the Children's Dermatology Life Quality Index in JADE TEEN (73.8% and 67.5% vs. 56.5%) and JADE MONO-1/-2 (70.0% and 57.1% vs. 19.0%). Significant improvements in SCORing Atopic Dermatitis Visual Analog Scale for sleep loss scores were demonstrated with abrocitinib vs. placebo at weeks 2-12 in JADE TEEN and JADE MONO-1/-2.

Conclusions Patient-reported signs/symptoms, including reduction of sleep loss and quality of life, were substantially improved with abrocitinib monotherapy or combination therapy relative to placebo in adolescents with moderate-to-severe AD.

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Conflict of interest

M.J. Cork is/has been a clinical trial investigator for Pfizer, Atopix, Galapagos, Hyphens, Johnson & Johnson, Kymab, LEO Pharma, L'Oreal/La Roche-Posay, Novartis, Regeneron and Sanofi-Genzyme and an advisory board member, consultant and/or invited lecturer for Pfizer, AbbVie, Amlar, Astellas, Atopix, Boots, Dermavant, Galapagos, Galderma, Hyphens, Johnson & Johnson, Kymab, LEO Pharma, L'Oreal/La Roche-Posay, Menlo Therapeutics, Novartis, Oxagen, Procter & Gamble, Reckitt Benckiser, Regeneron and Sanofi-Genzyme. A. McMichael is/has been a consultant for Pfizer, Galderma, Concert, Incyte, Arcutis, AbbVie, Procter & Gamble and Lilly. She has received research grants from Concert, Incyte, Arcutis and Procter & Gamble. J. Teng has served as a consultant and clinical trial investigator for Pfizer. H. Valdez, R. Rojo, G. Chan, F. Zhang, D.E. Myers and M. DiBonaventura are employees and shareholders of Pfizer Inc.

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Introduction

Atopic dermatitis (AD) is a common, chronic and relapsing inflammatory skin condition characterized by pruritus, eczematous lesions and dry skin.^{1,2} Globally, AD prevalence in adolescents is ~20%.¹ Among US adolescents aged 13–17 years with AD, it is estimated that 62.5% have mild AD, 29.5% have moderate AD and 8.0% have severe AD.^{3,4}

Worldwide, AD has the highest disability-adjusted life-years burden of all skin diseases.⁵ Moderate-to-severe AD in adults is associated with high disease burden, including pruritus, pain, sleep disturbance, mental health problems and reduced quality of life (QoL).^{6–9} Although there is a lack of extensive data on the AD burden specifically in adolescents,¹⁰ it is clear that AD adversely affects QoL, with increasing AD severity worsening QoL.^{11,12} Specifically, adolescents with AD are more likely to suffer from psychosocial and mental health problems,^{13–15} including sleep disturbance,¹² depression and anxiety disorders,^{13–16} lower quality of interpersonal relationships^{12,17} and interference with physical activities.^{12,18} Given the considerable disease burden of AD, it is important to assess patient-reported signs/symptoms and QoL when evaluating treatment response in adolescents.^{11,19,20}

Once-daily oral abrocitinib, a Janus kinase 1-selective inhibitor, was effective and well tolerated in phase 3 monotherapy studies in patients aged ≥ 12 years with moderate-to-severe AD (JADE MONO-1 [NCT03349060] and JADE MONO-2 [NCT03575871])^{21,22} and in adults aged ≥ 18 years in combination with background topical medications for active lesions in JADE COMPARE (NCT03720470).²³ A phase 3 study in adolescents (JADE TEEN [NCT03796676]) evaluated the efficacy and safety of abrocitinib in patients with moderate-to-severe AD who received background topical medications.²⁴

Here, we report the impact of abrocitinib on patient-reported signs/symptoms and QoL among adolescents with moderate-to-severe AD in the JADE TEEN and JADE MONO-1 and MONO-2 studies.

Methods

Ethical conduct

These studies were conducted in compliance with ethical principles from the Declaration of Helsinki and in compliance with all International Council for Harmonisation Good Clinical Practice Guidelines. All local regulatory requirements were followed. This research was approved by the institutional review board or ethics committee at each study site. All patients and/or their legal guardians provided written informed consent.

Study design and key patient eligibility criteria

JADE TEEN JADE TEEN was a phase 3, randomized, double-blind, placebo-controlled, parallel-group multicentre study

conducted between 18 February 2019 and 8 April 2020 and included adolescents aged 12–17 years with AD (according to Hanifin and Rajka diagnostic criteria) that was moderate to severe (affected body surface area $\geq 10\%$, Investigator's Global Assessment [IGA] score ≥ 3 , Eczema Area and Severity Index [EASI] score ≥ 16 and Peak Pruritus Numerical Rating Scale score ≥ 4 [used with permission of Regeneron Pharmaceuticals, Inc., Tarrytown, NY, USA and Sanofi SA, Paris, France]) and a history (within the last 6 months) of inadequate response to treatment with medicated topical therapy or requirement for systemic therapy to control AD. Full study details have been published previously.²⁴

JADE MONO-1/-2 JADE MONO-1/-2 were phase 3, randomized, double-blind, placebo-controlled, parallel group, multicentre studies: MONO-1 was conducted between 7 December 2017 and 26 March 2019, and MONO-2 was conducted between 29 June 2018 and 13 August 2019. These studies included adolescents and adults aged ≥ 12 years (body weight ≥ 40 kg) with chronic (≥ 1 year) AD (according to Hanifin and Rajka diagnostic criteria) that is moderate to severe (affected body surface area $\geq 10\%$, IGA score ≥ 3 , EASI score ≥ 16 and Peak Pruritus Numerical Rating Scale score ≥ 4) and a history (within 6 months) of inadequate response to treatment with medicated topical therapy or requirement for systemic therapy to control AD. Full study details have been published previously.^{21,22}

Randomization and treatments

JADE TEEN Patients were randomly assigned 1 : 1 : 1 to receive once-daily oral abrocitinib 200 mg, abrocitinib 100 mg or placebo for 12 weeks. Randomization was stratified by baseline disease severity (moderate [IGA score of 3] vs. severe [IGA score of 4]). Patients were required to apply non-medicated topical emollients at least twice daily to all body surface areas affected with AD in the 7 days before study day 1 and throughout the study. Patients were required to apply medicated topical therapy once daily to areas with active lesions, starting on day 1 and throughout the study, and for 7 days after lesion clearance. Permitted medicated topical therapies included medium-potency topical corticosteroids for body areas that were considered suitable for use and low-potency topical corticosteroids for body areas of thin skin (face, neck, intertriginous and genital areas, areas of skin atrophy, etc.). Topical calcineurin inhibitors or a phosphodiesterase inhibitor were permitted to be used instead of topical corticosteroids in body areas of thin skin with active lesions or if continued use of topical corticosteroids of any potency was considered unsafe.

JADE MONO-1/-2 Patients were randomly assigned 2 : 2 : 1 to receive once-daily oral abrocitinib 200 mg, abrocitinib 100 mg or placebo for 12 weeks. Randomization was stratified by baseline disease severity (moderate [IGA score of 3] vs. severe [IGA score

of 4]) and age <18 or ≥18 years. Topical non-medicated emollients were permitted but not required during the study.

Patient-reported outcomes included in this analysis

Patient-Oriented Eczema Measure (POEM) is a 7-item assessment of the frequency of AD signs and symptoms recalled over the past week.²⁵ POEM scores range from 0 to 28, with higher scores representing greater disease severity: 0–2 represents clear/almost clear, 3–7 mild, 8–16 moderate, 17–24 severe and 25–28 very severe.²⁵ A ≥ 4-point improvement is very likely to represent a clinically important change in children (1–15 years) with moderate-to-severe AD.²⁶ A ≥ 6-point improvement is considered to represent a clinically meaningful change in adolescents (12–17 years) with moderate-to-severe AD.²⁷

Children's Dermatology Life Quality Index (CDLQI) is a 10-item assessment of the effect of dermatologic disease on QoL in the past week.²⁸ CDLQI scores range from 0 to 30, with higher scores representing larger impact on QoL; 0–1 represents no effect, 2–6 a small effect, 7–12 a moderate effect, 13–18 a very large effect and 19–30 an extremely large effect.²⁸ A ≥ 6-point improvement in CDLQI is considered a clinically meaningful change in adolescents (12–17 years) with moderate-to-severe AD.²⁷

Pruritus and Symptoms Assessment for Atopic Dermatitis (PSAAD) is an 11-item patient-reported symptom diary that assesses AD symptoms in the past 24 h.²⁹ PSAAD scores range from 0 (least severe) to 10 (most severe).²⁹ A clinically important response in PSAAD is estimated to be 1 point.²⁹

The Night Time Itch Scale (NTIS) severity item assesses the worst itching due to AD during the most recent night's sleep. NTIS severity scores range from 0 ('no itch') to 10 ('worst itch imaginable'). NTIS severity data were available only from JADE MONO-2 and JADE TEEN. A ≥ 4-point improvement is considered clinically meaningful in this analysis.

SCORing Atopic Dermatitis (SCORAD) Visual Analog Scale (VAS) sleep loss is a single-item VAS of sleep loss due to AD in the past three nights before evaluation.³⁰ SCORAD VAS sleep loss scores range from 0 (none) to 10 (worst).³⁰

Statistical analyses

Efficacy was analysed in all adolescent patients who received ≥ 1 dose of study medication. JADE MONO-1/-2 data were pooled and presented separately from those of JADE TEEN.

For JADE TEEN, least squares mean scores were assessed using mixed-model repeated measures with fixed factors of treatment group, visit, treatment-by-visit interaction, baseline disease severity and an unstructured covariance matrix. The proportion of patients achieving response thresholds in each treatment group was reported. Differences between abrocitinib and placebo treatment groups were summarized by the weighted average of difference by randomization stratum using the normal approximation of binomial proportions. The confidence

interval for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0% or 100% responders). The *P* value was calculated using the Cochran-Mantel-Haenszel method adjusted by randomization strata. Testing of endpoints was performed at the nominal 5% significance level and not controlled for multiplicity.

For JADE MONO-1/-2 pooled adolescent data, statistical analyses followed a similar methodology to JADE TEEN. All binary endpoints were analysed using the Cochran-Mantel-Haenszel method adjusted by baseline disease severity and study (JADE MONO-1 and JADE MONO-2). All continuous endpoints were analysed using mixed-model repeated measures, which included factors (fixed effects) for treatment group, visit, treatment-by-visit interaction, study and baseline disease severity. *P* values for the pooled adolescent data were not controlled for multiplicity.

Results

Baseline demographics and disease characteristics

Adolescents in JADE TEEN and JADE MONO-1/-2 had a median age of 15 years; 57.5% and 60.5%, respectively, were aged 15–17 years (Table S1, Supporting Information). Mean AD duration was 10.0 years in JADE TEEN and 12.9 years in JADE MONO-1/-2. In JADE TEEN, 61.4% had moderate AD (IGA 3) and 38.6% had severe AD (IGA 4), whereas equal proportions of adolescents in JADE MONO-1/-2 had moderate and severe AD as per IGA (50.8% vs. 49.2%). Mean EASI score was 29.9 in JADE TEEN and 33.1 among adolescents in JADE MONO-1/-2.

Patient-Oriented Eczema Measure

Baseline mean POEM scores in adolescents in JADE TEEN and JADE MONO-1/-2 were suggestive of severe disease (i.e. 17–24). Specifically, in JADE TEEN, the POEM scores were 19.2, 19.5 and 19.8 in the abrocitinib 200 mg, abrocitinib 100 mg and placebo groups, respectively, and 17.8, 18.3 and 19.4, respectively, in the pooled adolescent population from JADE MONO-1/-2.

In JADE TEEN, the proportion of patients achieving a ≥ 4-point improvement from baseline in POEM was higher in both abrocitinib groups compared with placebo at weeks 2, 4, 8 and 12 (Fig. S1a, Supporting Information). In the pooled adolescent population from JADE MONO-1/-2, the proportion was higher for the abrocitinib 200 mg group compared with placebo at weeks 2, 4, 8 and 12 and for the abrocitinib 100 mg group compared with placebo at weeks 4 and 12 (Fig. S1b, Supporting Information).

In JADE TEEN, the proportion of patients achieving a deeper response of ≥ 6-point improvement from baseline in POEM was higher in both abrocitinib groups compared with placebo at weeks 2, 4, 8 and 12 (Fig. 1a). The proportion in the pooled adolescent population from JADE MONO-1/-2 was higher for the abrocitinib 200 mg group compared with placebo at weeks 2, 4, 8 and 12 and for the abrocitinib 100 mg group compared with placebo at week 4 (Fig. 1b).

In JADE TEEN, the proportion of patients achieving a POEM score of 0-7 (clear/almost clear or mild) was higher for abrocitinib 200 mg compared with placebo at weeks 2, 4, 8 and 12 and for abrocitinib 100 mg compared with placebo at weeks 4, 8 and 12 (Fig. 2a). In the pooled adolescent population from JADE MONO-1/-2, the proportion was higher for both abrocitinib groups compared with placebo at weeks 2, 4, 8 and 12 (Fig. 2b).

Children's Dermatology Life Quality Index

Baseline mean CDLQI scores in adolescents from JADE TEEN and JADE MONO-1/-2 were within a range (7–18) indicative that AD had a 'moderate effect' to a 'very large effect' on patients' lives. Specifically in JADE TEEN, CDLQI scores were 13.6, 14.3 and 14.0 in the abrocitinib 200 mg, abrocitinib 100 mg and placebo groups, respectively, and 13.1, 12.4 and 12.5, respectively, in the pooled adolescent population from JADE MONO-1/-2.

In JADE TEEN, the proportion of patients achieving a ≥ 6 -point improvement from baseline in CDLQI was higher for the abrocitinib 200 mg group compared with placebo at weeks 4, 8 and 12, and for the abrocitinib 100 mg group compared with placebo at week 8 (Fig. 3a). In the pooled adolescent population from JADE MONO-1/-2, the proportion was higher for the abrocitinib 200 mg group compared with placebo at weeks 2, 4, 8 and 12, and for the abrocitinib 100 mg group compared with placebo at weeks 4, 8 and 12 (Fig. 3b).

In JADE TEEN, the proportion of patients achieving a CDLQI score of 0-6 (no or small effect) was higher for abrocitinib 200 mg compared with placebo at weeks 2, 4, 8 and 12 and for abrocitinib 100 mg compared with placebo at weeks 4, 8 and 12 (Fig. 4a). In the pooled adolescent population from JADE MONO-1/-2, the proportion was higher for abrocitinib 200 mg compared with placebo at weeks 4, 8 and 12 (Fig. 4b).

Pruritus and Symptoms Assessment for Atopic Dermatitis

Baseline mean PSAAD scores in JADE TEEN were 4.8, 4.9 and 5.0 in the abrocitinib 200 mg, abrocitinib 100 mg and placebo groups, respectively, and 4.9, 4.9 and 5.4, respectively, in the pooled adolescent population from JADE MONO-1/-2.

In JADE TEEN, the proportion of patients with ≥ 1 -point improvement from baseline in PSAAD was higher for abrocitinib 200 mg compared with placebo at weeks 1-12 and for abrocitinib 100 mg compared with placebo at weeks 3-11 (Fig. 5a). The proportion in the pooled adolescent population from JADE MONO-1/-2 was higher for abrocitinib 200 mg compared with placebo at weeks 1-12 and for abrocitinib 100 mg compared with placebo at weeks 1, 4-7 and 12 (Fig. 5b).

Night Time Itch Scale severity

Baseline mean NTIS severity scores in JADE TEEN were 6.5, 6.3 and 6.6 in the abrocitinib 200 mg, abrocitinib 100 mg and placebo groups, respectively, and 6.5, 7.2 and 7.0, respectively, in the adolescent population from JADE MONO-2.

In JADE TEEN, the proportion of patients with ≥ 4 -point improvement from baseline in NTIS severity was higher for abrocitinib 200 mg compared with placebo at weeks 2, 4, 8 and 12, and for abrocitinib 100 mg compared with placebo at week 2 (Fig. S2a, Supporting Information). The proportion in the adolescent population from JADE MONO-2 (NTIS data were not collected in JADE MONO-1) was higher for abrocitinib 200 mg compared with placebo at weeks 2, 4, 8 and 12 (Fig. S2b, Supporting Information).

SCORing Atopic Dermatitis visual analog scale sleep loss

Baseline mean SCORAD VAS sleep loss scores in JADE TEEN were 5.6, 5.3 and 5.7 in the abrocitinib 200 mg, abrocitinib 100 mg and placebo groups, respectively, and 5.1, 5.6 and 5.9, respectively, in the pooled adolescent population from JADE MONO-1/-2.

In JADE TEEN and the pooled adolescent population from JADE MONO-1/-2, least squares mean SCORAD VAS sleep loss was lower for both abrocitinib groups compared with placebo at weeks 2, 4, 8 and 12 (Fig. 6a,b).

Other patient-reported outcomes

Patient-reported outcomes according to the Patient Global Assessment are reported in the Fig. S3a,b (Supporting Information).

Discussion

JADE TEEN was the first randomized, double-blind, placebo-controlled phase 3 trial of abrocitinib that specifically focused on the adolescent age group of patients with moderate-to-severe AD.²⁴ Inclusion of the pooled adolescent subpopulation from JADE MONO-1/-2 trials^{21,22} confirmed the findings of the analyses from JADE TEEN. Clinically meaningful improvements in patient-reported signs/symptoms, including sleep loss and QoL, were detected with abrocitinib used with or without concomitant topical medicated therapy vs. placebo as early as week 2 and generally maintained at week 12.

POEM is recommended by the Harmonising Outcome Measures for Eczema initiative as the core outcome instrument for measuring patient-reported symptoms in AD trials.³¹ Adolescent patients entering these phase 3 studies were severely burdened by their AD, as indicated by their mean baseline POEM scores. The rapid (by week 2) and consistent improvements in POEM with the use of abrocitinib relative to placebo observed in JADE TEEN are clinically meaningful for this adolescent patient population. A ≥ 4 -point improvement in POEM is considered to represent a clinically important change in children (1–15 years)²⁶ and a ≥ 6 -point improvement in adolescents (12–17 years) with moderate-to-severe AD.²⁷

AD in adolescence is linked to psychosocial and mental health burden^{13–15} and worsened QoL.^{11,12} Consideration of

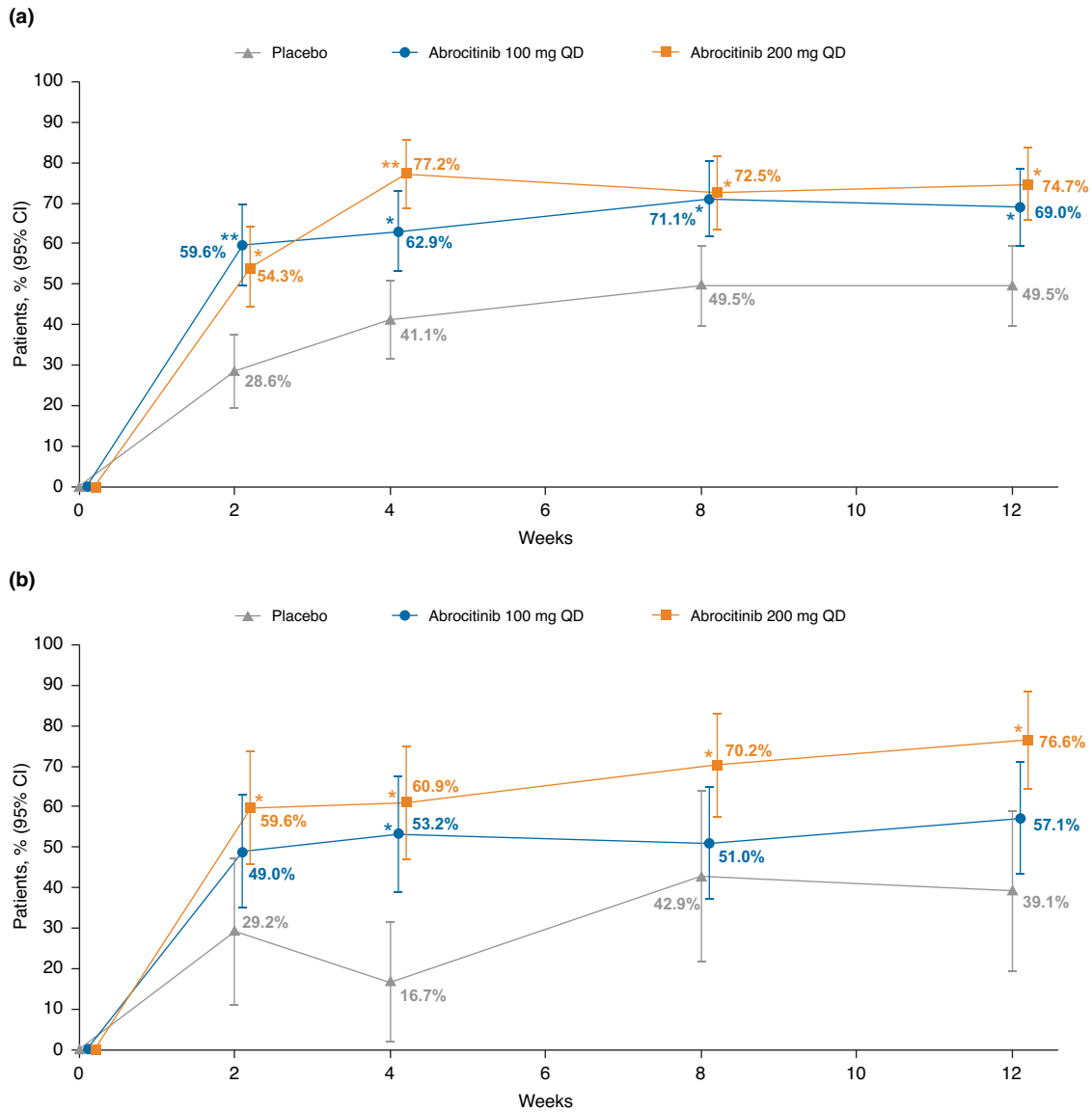


Figure 1 Proportion of patients achieving a ≥ 6 -point improvement from baseline in POEM over time in (a) JADE TEEN and (b) pooled adolescent population from JADE MONO-1/-2. * $P < 0.05$, ** $P < 0.0001$. Conclusion of statistical significance was not controlled for multiplicity. Assessed among patients with ≥ 6 points at baseline. CI, confidence interval; POEM, Patient-Oriented Eczema Measure; QD, once daily.

QoL is important in the assessment of treatment response in adolescent patients with AD,¹¹ and the Harmonising Outcome Measures for Eczema initiative recommends the CDLQI for monitoring QoL of children with AD in clinical studies. Adolescent patients included in these analyses reported a moderate to very large effect of AD on their QoL at baseline; significant improvements in QoL were demonstrated from

weeks 4 to 12 with abrocitinib 200 mg relative to placebo in terms of the proportion of patients meeting the ≥ 6 -point improvement threshold that is considered a clinically meaningful change in QoL in adolescents with moderate-to-severe AD.²⁷

Adolescents report major sleeping difficulties caused by AD,^{12,32} including trouble falling asleep and night-time and

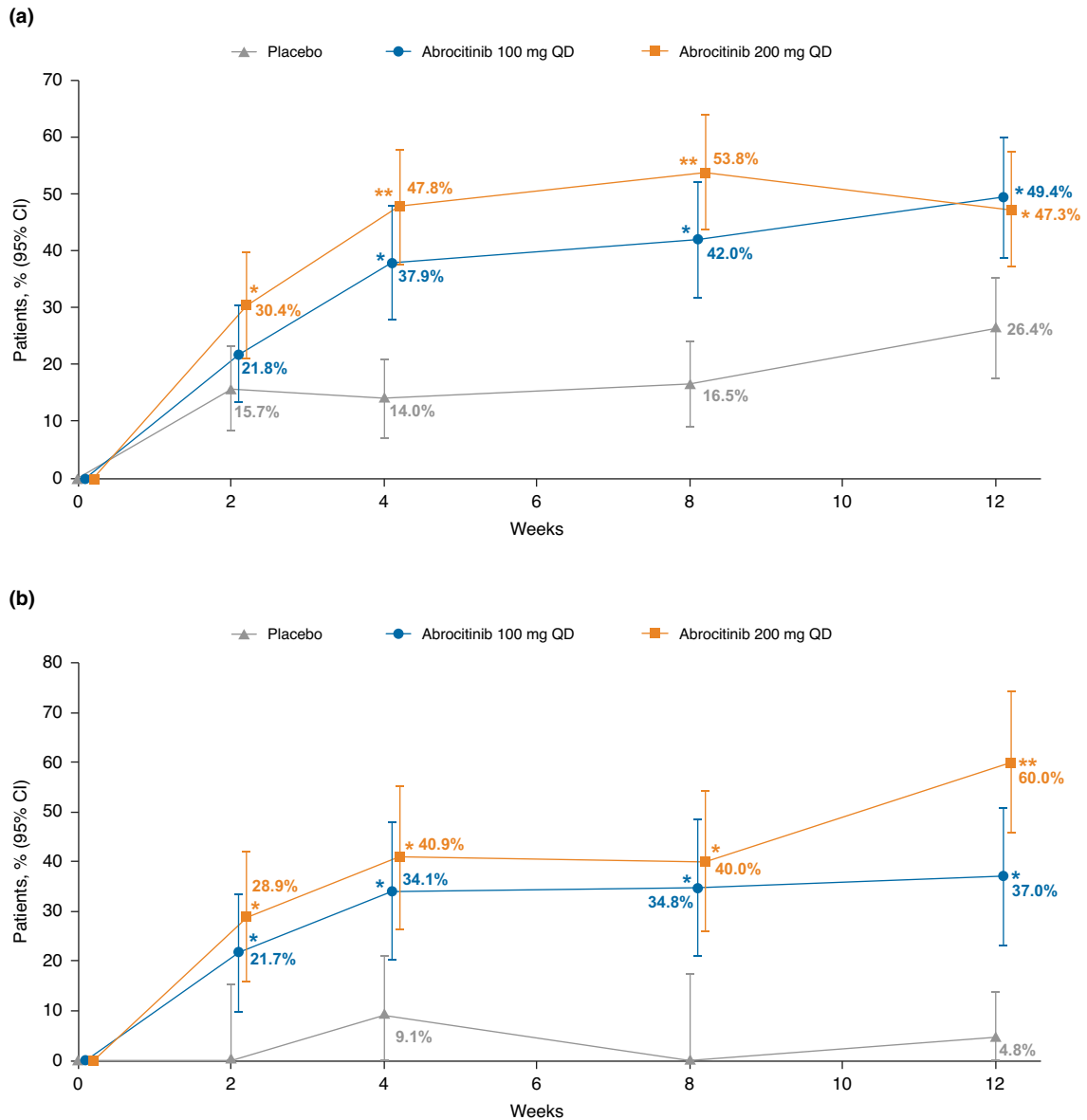


Figure 2 Proportion of patients achieving POEM score of 0-7 (clear/almost clear or mild) over time in (a) JADE TEEN and (b) pooled adolescent population from JADE MONO-1/-2. * $P < 0.05$, ** $P < 0.0001$. Conclusion of statistical significance was not controlled for multiplicity. Assessed among patients with ≥ 8 points at baseline. CI, confidence interval; POEM, Patient-Oriented Eczema Measure; QD, once daily.

early morning awakenings, with daytime drowsiness as a consequence.³³ As such, high importance is placed on AD treatments that improve sleep.³⁴ Although there is no established threshold for clinically meaningful improvement in SCORAD VAS sleep loss, it is likely that the sleep improvements demonstrated with abrocitinib in both studies from weeks 2 to 12 are clinically relevant to adolescents. In JADE TEEN, mean baseline scores of ~ 5.5 on a scale from 0 (none) to 10 (worst) indicated moderate

sleep loss due to AD in the adolescent patient population. At week 12, scores in the abrocitinib groups had reduced to ~ 2.0 , indicating minimal sleep loss.

The high 'placebo' response rate in JADE TEEN is likely multifactorial in nature; these factors include increased adherence to concomitant topical medications and use of emollients compared with what is observed in the clinic^{20,35} (patients were on background topical medications) and possibly less

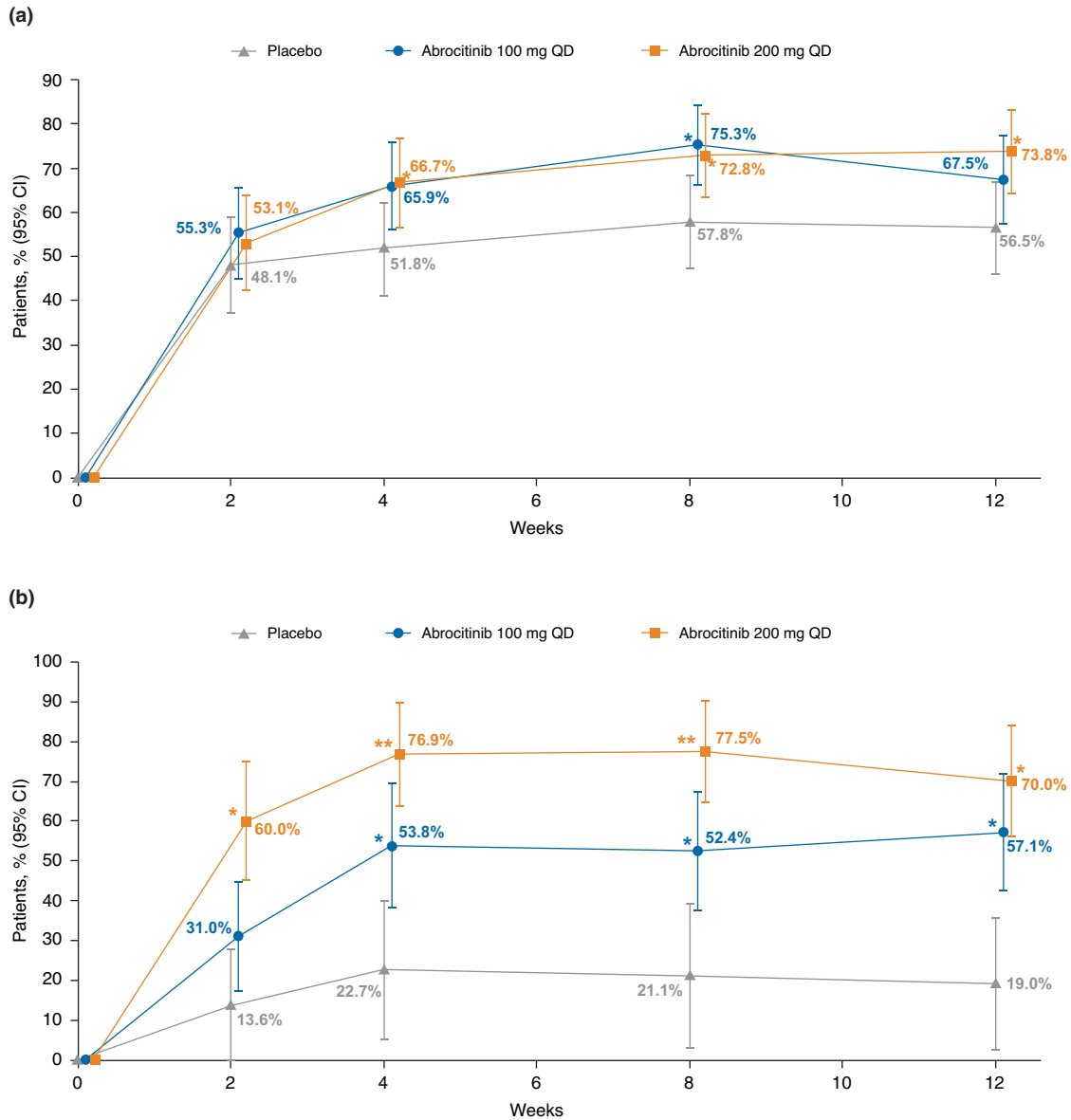


Figure 3 Proportion of patients with ≥ 6 -point improvement from baseline in CDLQI over time in (a) JADE TEEN and (b) pooled adolescent population from JADE MONO-1/-2. * $P < 0.05$, ** $P < 0.0001$. Conclusion of statistical significance was not controlled for multiplicity. Assessed among patients with ≥ 6 points at baseline. CDLQI, Children’s Dermatology Life Quality Index; CI, confidence interval; QD, once daily.

experience with topical corticosteroids (disease duration was shorter in JADE TEEN). Children have a higher ratio of body surface area to weight and immature skin barrier function, and therefore, may have a higher systemic exposure to topical drugs than adults,³⁶ further enhancing response rates in the placebo arm.

Although this article focused exclusively on patient-reported outcomes, it should be noted that abrocitinib also had an acceptable safety profile among adolescent patients in JADE TEEN and JADE MONO-1/-2,^{21,22,24} and although adolescents are at high risk of acne, it was reported in a low percentage of abrocitinib-treated patients ($\leq 5.3\%$).

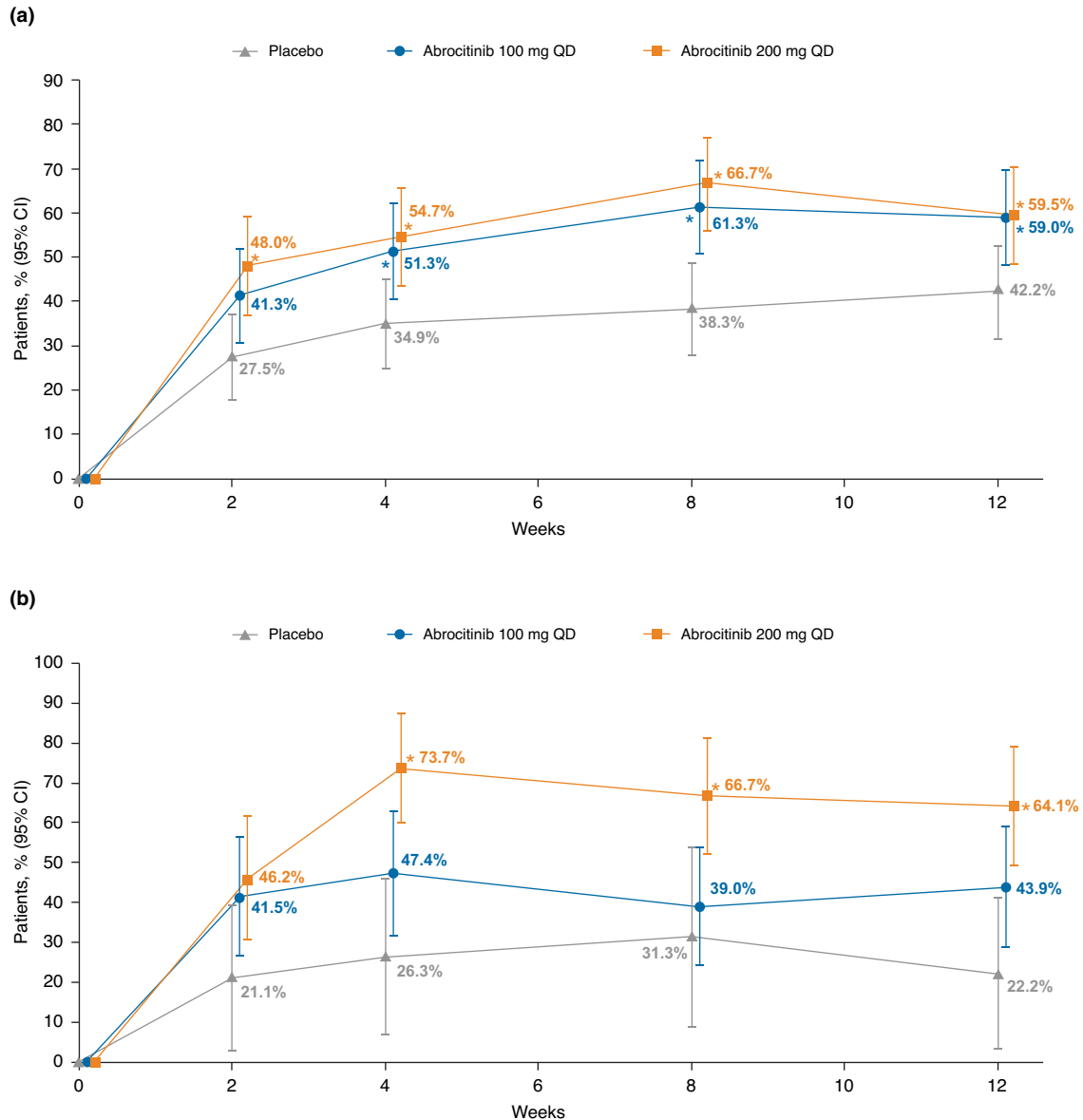


Figure 4 Proportion of patients achieving a CDLQI score of 0-6 (no or small effect) over time in (a) JADE TEEN and (b) pooled adolescent population from JADE MONO-1/-2. * $P < 0.05$, ** $P < 0.0001$. Conclusion of statistical significance was not controlled for multiplicity. Assessed among patients with ≥ 7 points at baseline. CDLQI, Children's Dermatology Life Quality Index; CI, confidence interval; QD, once daily.

Limitations of the current study include that this was a *post hoc* analysis without control for the multiplicity of statistical comparisons. Assessments were limited by duration (12 weeks), and for some measures the effect of abrocitinib had not plateaued by week 12. Durability of response needs to be examined in longer-term studies. Furthermore,

there are potential differences between patients who elect or are eligible to participate in clinical trials vs. real-world settings.

In conclusion, abrocitinib substantially improved patient-reported signs/symptoms, including sleep loss and QoL, in adolescents with moderate-to-severe AD.

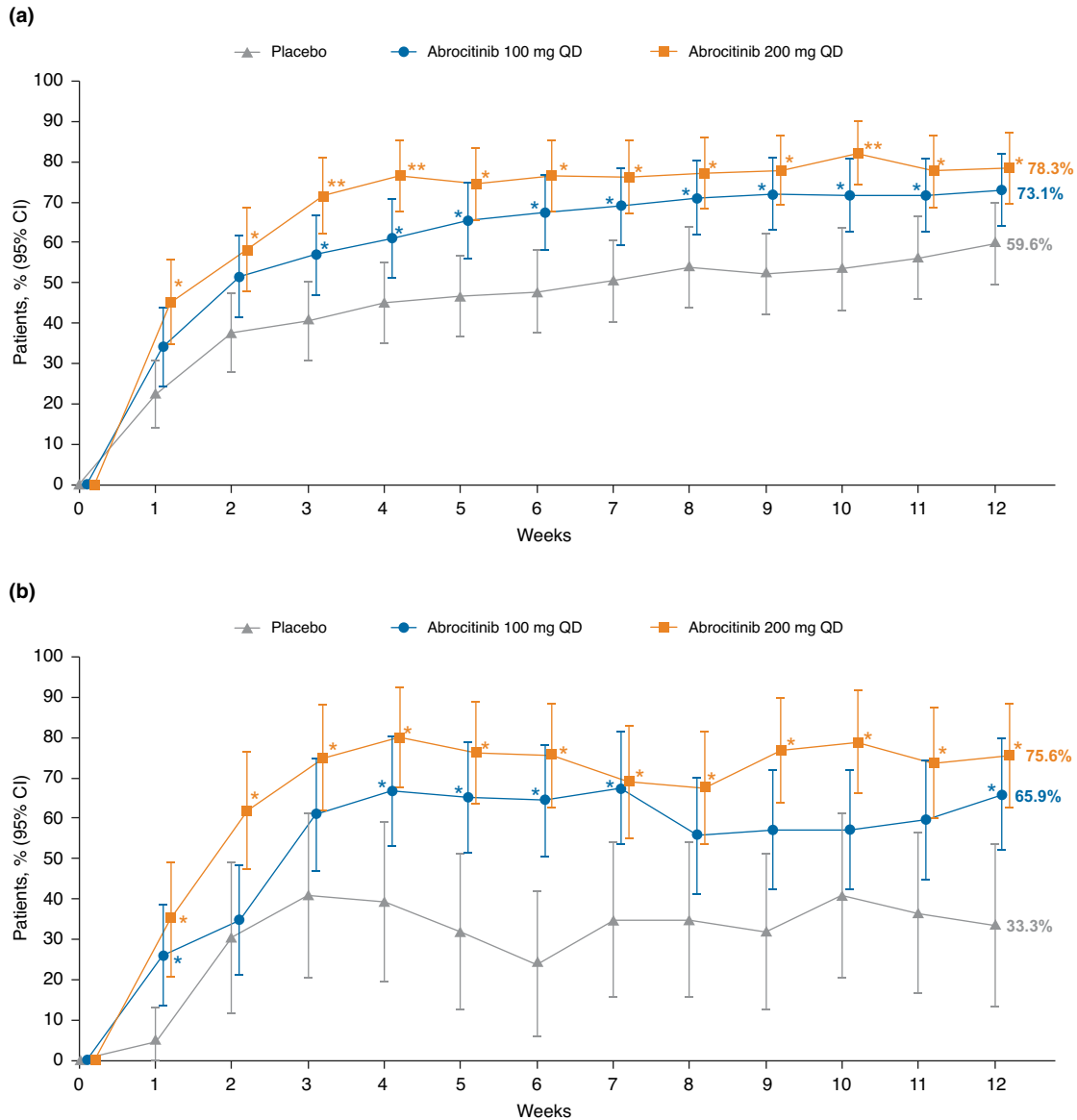


Figure 5 Proportion of patients with ≥ 1 -point improvement from baseline in PSAAD over time in (a) JADE TEEN and (b) pooled adolescent population from JADE MONO-1/-2. * $P < 0.05$, ** $P < 0.0001$. Conclusion of statistical significance was not controlled for multiplicity. Assessed among patients with ≥ 1 point at baseline. CI, confidence interval; PSAAD, Pruritus and Symptoms Assessment for Atopic Dermatitis; QD, once daily.

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Data availability statement

Upon request, and subject to certain criteria, conditions and exceptions (see <https://www.pfizer.com/science/clinical-trials/trial-data-and-results> for more information), Pfizer will provide access to individual de-identified participant data from Pfizer-sponsored global interventional clinical studies conducted for medicines, vaccines and medical devices (1) for indications that

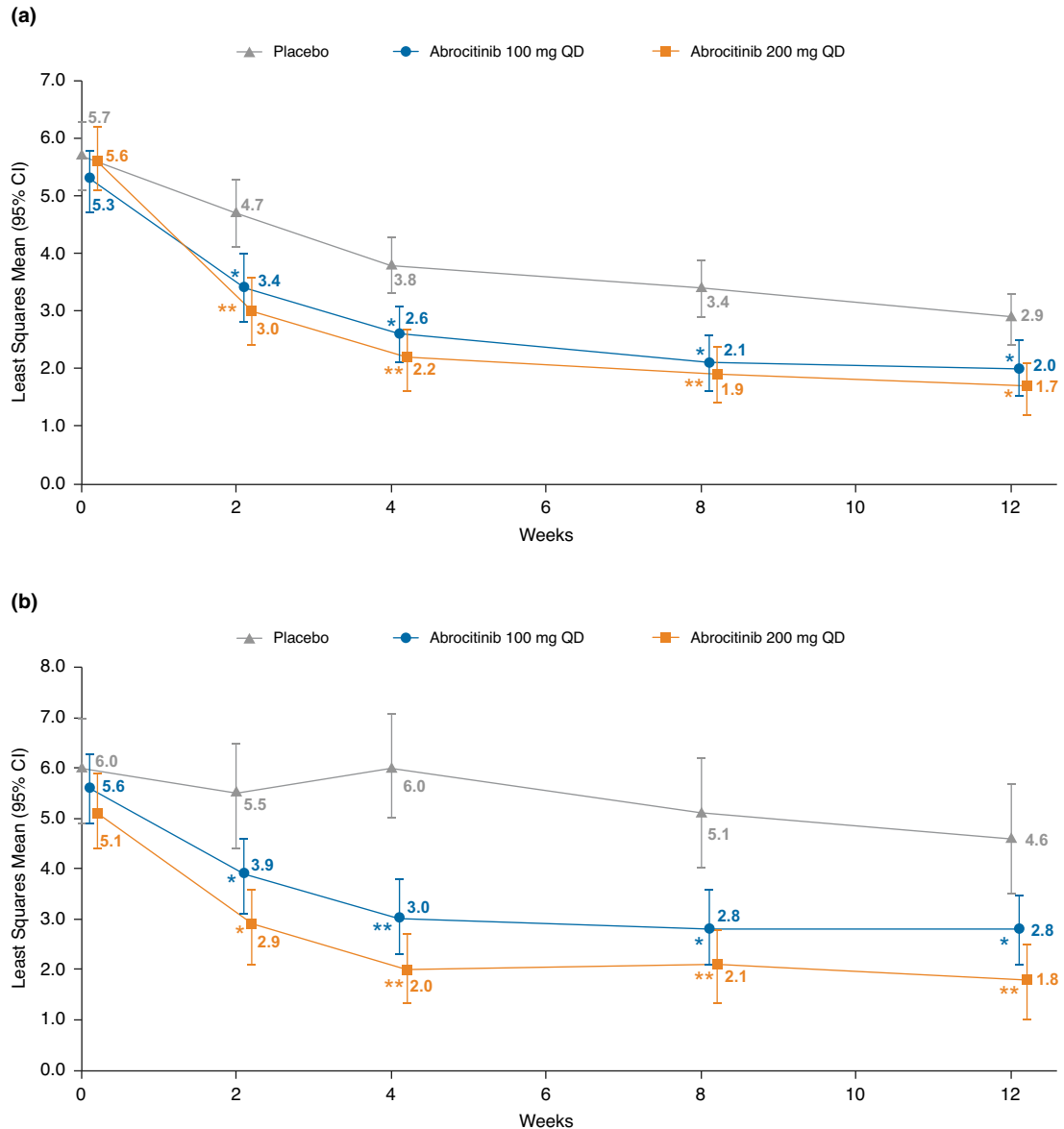


Figure 6 SCORAD VAS sleep loss over time in (a) JADE TEEN and (b) pooled adolescent population from JADE MONO-1/-2. * $P < 0.05$, ** $P < 0.0001$. Conclusion of statistical significance was not controlled for multiplicity. CI, confidence interval; QD, once daily; SCORAD, SCORing Atopic Dermatitis; VAS, Visual Analog Scale.

have been approved in the US and/or EU or (2) in programs that have been terminated (i.e. development for all indications has been discontinued). Pfizer will also consider requests for the protocol, data dictionary and statistical analysis plan. Data may be requested from Pfizer trials 24 months after study completion. The de-identified participant data will be made available to researchers whose proposals meet the research criteria and other conditions, and for which an exception does not apply, via a

secure portal. To gain access, data requestors must enter into a data access agreement with Pfizer.

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Supporting information

Additional Supporting Information may be found in the online version of this article:

File S1. Patient Global Assessment results.

Table S1. Baseline demographics and disease characteristics of adolescents in JADE TEEN and the pooled adolescent population from JADE MONO-1/-2.

Figure S1. Proportion of patients achieving a ≥ 4 -point improvement from baseline in Patient-Oriented Eczema Measure (POEM) over time in (a) JADE TEEN and (b) pooled adolescent population from JADE MONO-1/-2.

Figure S2. Proportion of patients with ≥ 4 -point improvement from baseline in Night Time Itch Scale (NTIS) severity over time

in (a) JADE TEEN and (b) adolescent population from JADE MONO-2.

Figure S3. Proportion of patients achieving clear or almost clear and with ≥ 2 -point improvement from baseline in Patient Global Assessment (PtGA) over time in (a) JADE TEEN and (b) pooled adolescent population from JADE MONO-1/-2.