

Eczema Area and Severity Index-90 (EASI-90) Responder Rates With Abrocitinib and Relationship With Quality of Life (QoL) and Itch in Patients With Moderate-to-Severe Atopic Dermatitis (AD): Results From a Randomized, Phase 3 Clinical Trial

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Disclosures

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JADE MONO-1: Baseline Characteristics Consistent with Other Trials in Patients with Moderate-to-Severe AD

Introduction

- Abrocitinib is an oral once-daily JAK1 selective inhibitor under investigation for the treatment of AD
- In a phase 3 trial (NCT03349060; JADE MONO-1), abrocitinib was well tolerated and effective in patients with moderate-to-severe AD¹

Objectives

- To assess EASI-90 (≥90% improvement) responder rates in JADE MONO-1
- To explore the relationship between EASI-90 response and pruritus and QoL outcomes

Methods

- Randomized, double-blind, placebo-controlled trial of abrocitinib (200 mg or 100 mg) versus placebo
- Patients aged ≥12 years with AD ≥1 year
 - Moderate-to-severe AD (IGA ≥3, EASI ≥16, %BSA ≥10, PP-NRS ≥4)
 - Inadequate response or intolerance to topical medication, or needed systemic therapy to control AD
- Pruritus outcomes
 - **PP-NRS4**: ≥4-point improvement in PP-NRS
 - **PP-NRS 0/1**: PP-NRS score of 0 or 1 (ie, little-to-no itch)
- QoL outcome
 - **DLQI/CDLQI band descriptors** (ie, effect on patient's life: 0-1 = no effect, 2-5 = small effect, 6-10 = moderate effect, 11-20 = very large effect, 21-30 = extremely large effect)²

Baseline Characteristics

	Total N=387	Placebo N=77	100 mg N=156	200 mg N=154
Age, mean (SD), y	32.5 (16.0)	31.5 (14.4)	32.6 (15.4)	33.0 (17.4)
Age group, n (%)				
<18 y	84 (21.7)	17 (22.1)	34 (21.8)	33 (21.4)
%BSA, mean (SD)	49.8 (23.6)	47.4 (22.7)	50.8 (23.4)	49.9 (24.4)
Disease duration, median (range), y	19.8 (1-69)	18.8 (2-66)	21.3 (1-69)	18.9 (1-65)
IGA, n (%)				
Moderate (3)	229 (59.2)	46 (59.7)	92 (59.0)	91 (59.1)
Severe (4)	158 (40.8)	31 (40.3)	64 (41.0)	63 (40.9)
EASI, mean (SD)	30.5 (13.6)	28.7 (12.5)	31.3 (13.6)	30.6 (14.1)
PP-NRS, mean (SD)	7.0 (1.9)	7.0 (1.8)	6.9 (2.0)	7.1 (1.9)
DLQI, mean (SD) ^a	14.4 (6.8)	13.9 (7.3)	14.6 (6.5)	14.6 (6.8)
CDLQI, mean (SD) ^b	12.7 (6.2)	13.6 (7.0)	11.7 (6.6)	13.2 (5.5)

%BSA, percentage of body surface area; AD, atopic dermatitis; CDLQI, Children's Dermatology Life Quality Index; DLQI, Dermatology Life Quality Index; EASI, Eczema Area and Severity Index; EASI-90, ≥90% improvement in EASI; IGA, Investigator's Global Assessment; JAK1, Janus kinase 1; PP-NRS, Peak Pruritus Numerical Rating Scale (used with permission of Regeneron Pharmaceuticals, Inc. and Sanofi); QoL, quality of life.

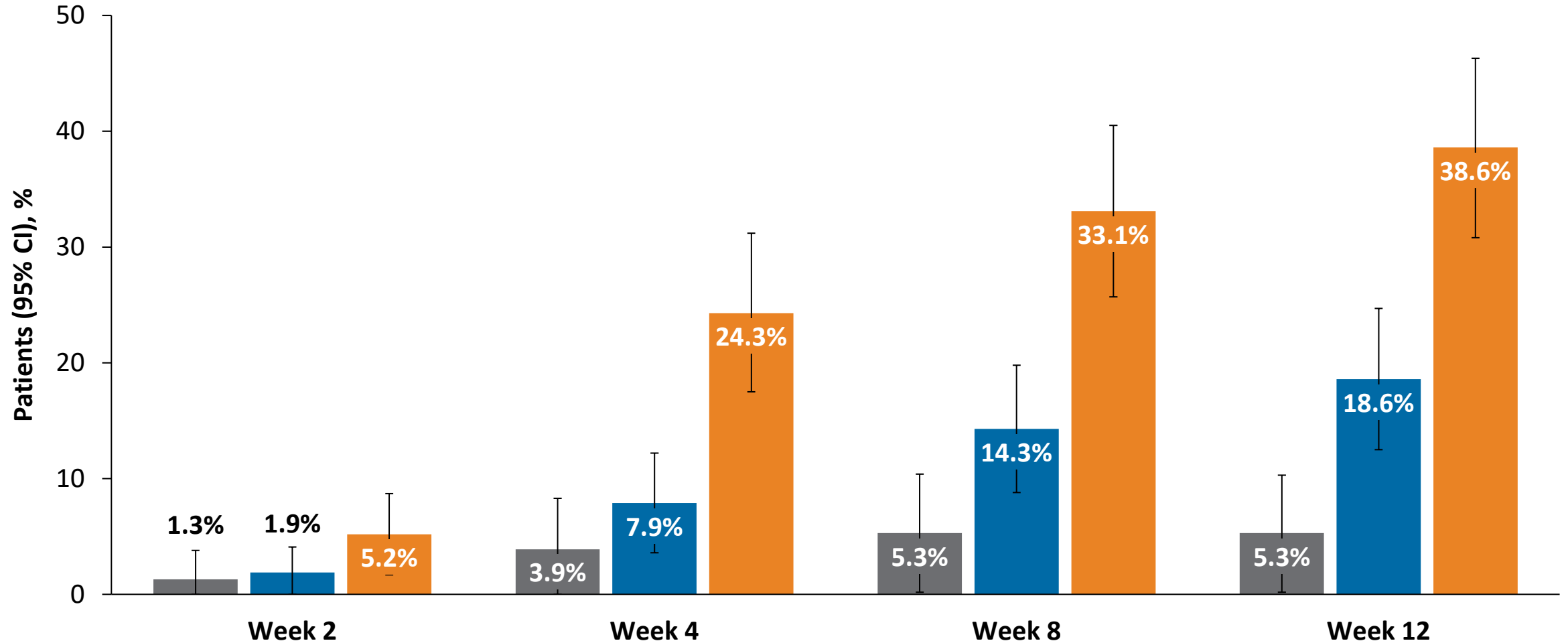
^aFor patients ≥18 years. ^bFor patients <18 years.

1. Simpson E et al. Presented at: 28th EADV Congress; October 9-13, 2019; Madrid, Spain. 2. Hongbo Y et al. *J. Invest. Dermatol.* 2005;125:659-664.

JADE MONO-1: Robust EASI-90 Response Seen With Abrocitinib

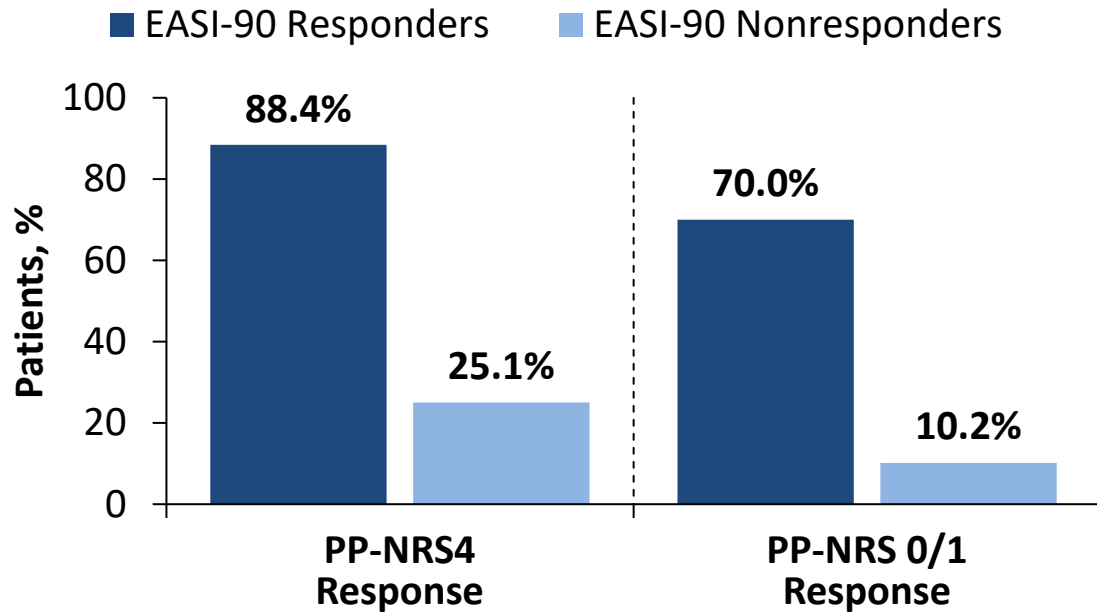
EASI-90 Response

■ Placebo ■ 100 mg ■ 200 mg

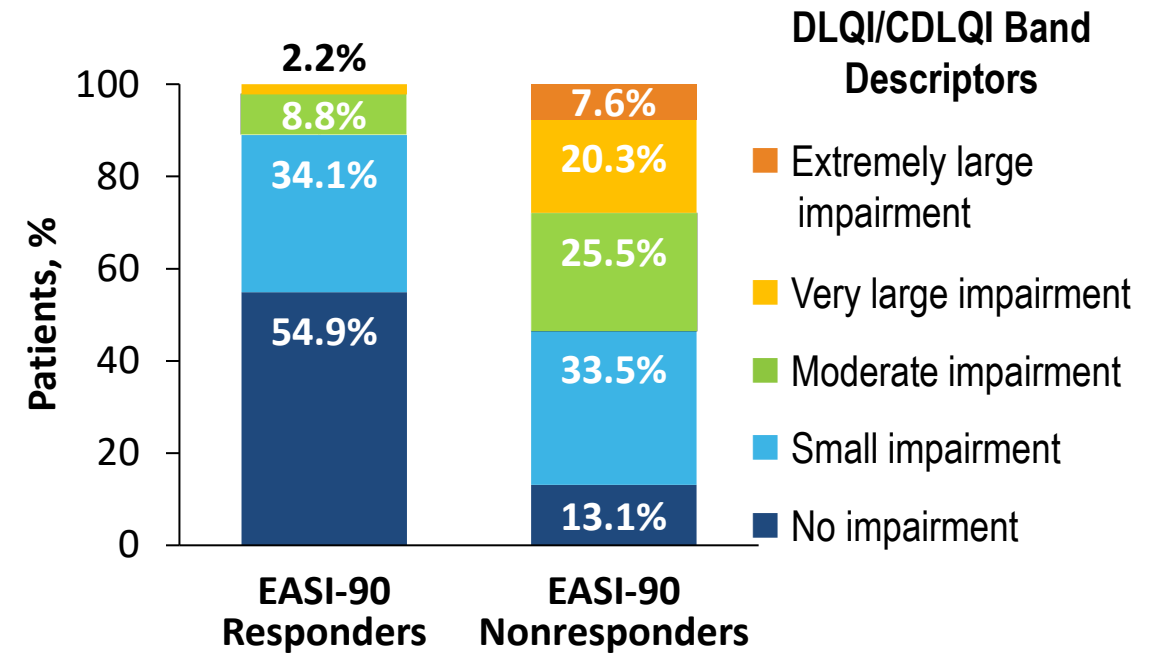


JADE MONO-1: Patients Who Achieve EASI-90 Response Are More Likely to Achieve an Itch-Free State and Have Small or No Impairment in QoL

PP-NRS Outcomes for EASI-90 Responders Versus Nonresponders at Week 12



Impairment in QoL for EASI-90 Responders Versus Nonresponders at Week 12



Conclusions

- Abrocitinib was well tolerated with incidence of serious AEs and treatment discontinuations because of treatment-related AEs comparable to or less than the placebo group¹
- Abrocitinib treatment was associated with significantly higher EASI-90 responder rates than for placebo
- EASI-90 responders at week 12 were more likely to experience a clinically meaningful improvement in itch, little-to-no itch, and low impairment in QoL than nonresponders were

CDLQI, Children's Dermatology Life Quality Index; DLQI, Dermatology Life Quality of Index; EASI-90, ≥90% improvement from baseline in Eczema Area and Severity Index; PP-NRS 0/1, Peak Pruritus Numerical Rating Scale score of 0 or 1; PP-NRS4, ≥4-point improvement in Peak Pruritus Numerical Rating Scale; QoL, quality of life.

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