Patient-Reported Outcomes (PROs) With Abrocitinib Treatment in Patients With Moderate-to-Severe Atopic Dermatitis (AD): Results From a Randomized, Phase 3 Clinical Trial

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Disclosures

JIS is an investigator for AbbVie, Celgene, Eli Lilly, GSK, Kiniksa, LEO Pharma, Menlo Therapeutics, Realm Therapeutics, Regeneron, Roche, and Sanofi; a consultant for Pfizer Inc., AbbVie, Anacor, AnaptysBio, Arena Pharmaceuticals, Asana Biosciences, Dermira, Dermavant, Eli Lilly, Galderma, GSK, Glenmark, Incyte, Kiniksa, LEO Pharma, MedImmune, Menlo Therapeutics, Novartis, Realm Therapeutics, Regeneron, and Sanofi; a speaker for Regeneron and Sanofi; and is on advisory boards for Pfizer Inc., Dermira, LEO Pharma, and Menlo Therapeutics.

ADC is an investigator for AbbVie, Janssen, and Novartis; a consultant for Pfizer Inc., AbbVie, Boehringer Ingelheim, Dexcel Pharma, Eli Lilly, Janssen, Neopharm, Novartis, Rafa, and Sanofi; a speaker for Pfizer Inc., AbbVie, Amgen, Dexcel Pharma, Eli Lilly, Janssen, Neopharm, Novartis, Rafa, Sanofi, and Taro; and on advisory boards for Amgen, Eli Lilly/ICOS, and Samsung.

SS is an investigator for Dermasence, Galderma, Menlo Therapeutics, Novartis, and Trevi Therapeutics; a member of scientific advisory boards for Beiersdorf, Celgene, Galderma, Kiniksa, Menlo Therapeutics, Sienna Biopharmaceuticals, and Trevi Therapeutics; and a consultant for Bellus Health, Galderma, and Novartis.

CF, HV, PB, MCC, MD, RG are employees and shareholders of Pfizer Inc.

JADE MONO-1: Introduction, Objective, Methods, and Baseline Characteristics

Introduction

- AD imparts substantial patient burden[1]
- 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 adolescents and adults with moderate-to-severe AD[2]

Objectives

- To assess changes in PROs of global assessment of symptoms (PP-NRS, PtGA, and POEM) and QoL (DLQI, CDLQI) in JADE MONO-1

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 requirement for systemic therapy to control AD

Baseline Characteristics

		Total N=387	Placebo N=77	100 mg N=156	200 mg N=154
Age, mean (SD), years		32.5 (16.0)	31.5 (14.4)	32.6 (15.4)	33.0 (17.4)
Age group, n (%)	<18 years	84 (21.7)	17 (22.1)	34 (21.8)	33 (21.4)
Disease duration, median (range), years		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)
PtGA, n (%)	Moderate (3)	183 (47.3)	39 (50.6)	72 (46.2)	72 (46.8)
	Severe (4)	176 (45.5)	35 (45.5)	71 (45.5)	70 (45.5)
POEM, mean (SD)		19.7 (6.1)	19.9 (6.1)	19.5 (6.5)	19.6 (5.9)
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)

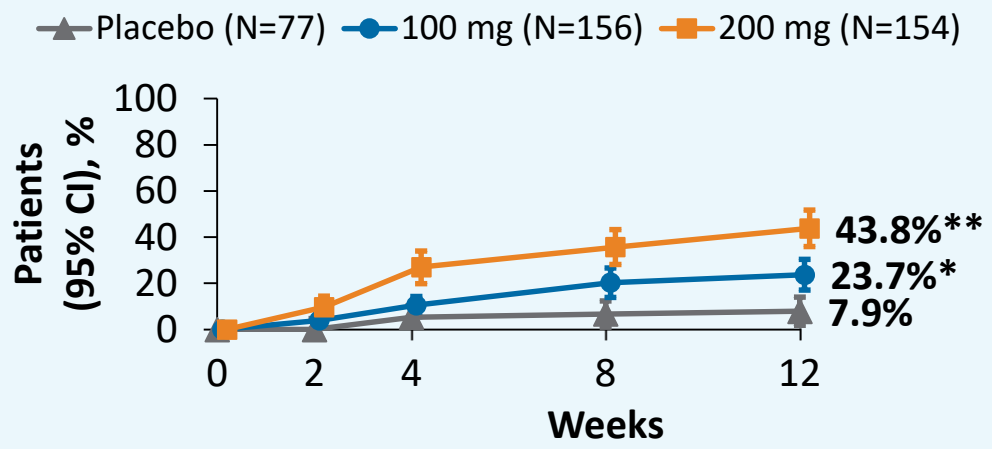
%BSA, percentage of body surface area; AD, atopic dermatitis; CDLQI, Children's Dermatology Life Quality Index; DLQI, Dermatology Life Quality Index; EASI, Eczema Area and Severity Index; IGA, Investigator's Global Assessment; JAK1, Janus kinase 1; POEM, Patient-Oriented Eczema Measure; PP-NRS, Peak Pruritus Numerical Rating Scale (used with permission of Regeneron Pharmaceuticals, Inc. and Sanofi); PRO, patient-reported outcome; PtGA, Patient Global Assessment; QoL, quality of life. [a]For patients ≥18 years. [b]For patients <18 years.

1. Silverberg JI et al. *Ann Allergy Asthma Immunol.* 2018;121:340-347. 2. Simpson E et al. Presented at: European Academy of Dermatology and Venereology - 28th Congress; October 9-13, 2019; Madrid, Spain.

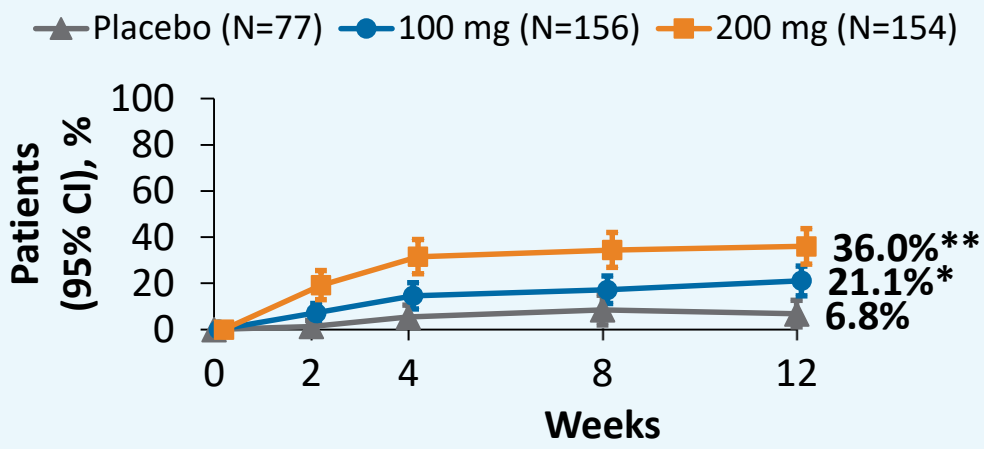
JADE MONO-1: Clinical and PRO Assessments of Symptoms Results

Clinical

IGA Response

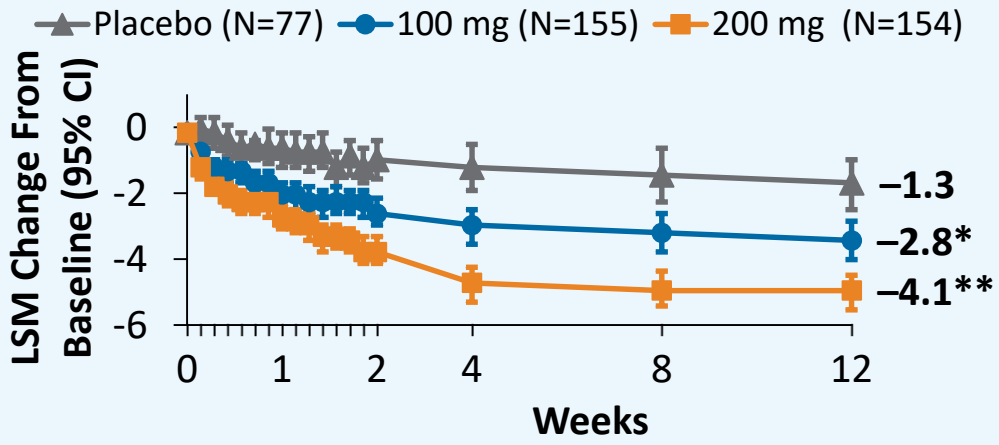


PtGA "Clear" or "Almost Clear"[a]

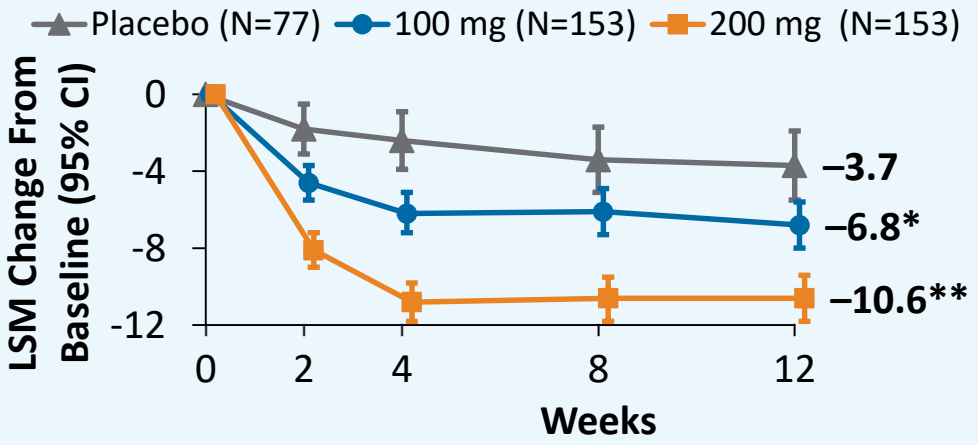


PROs

Change From Baseline in PP-NRS



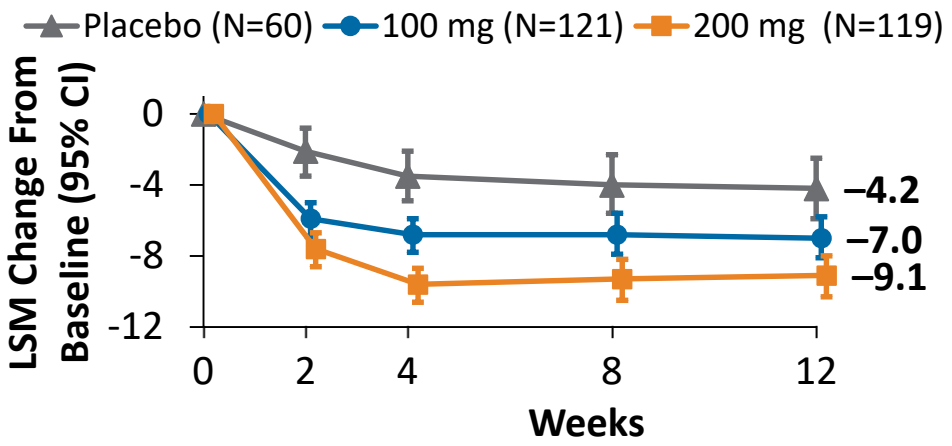
Change From Baseline in POEM



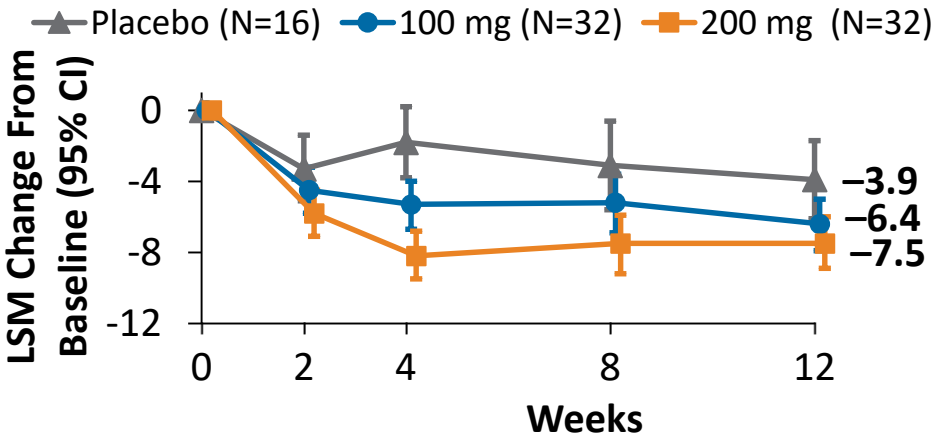
IGA, Investigator's Global Assessment; LSM, least-squares mean; POEM, Patient-Oriented Eczema Measure; PRO, patient-reported outcome; PP-NRS, Peak Pruritus Numerical Rating Scale; PtGA, Patient Global Assessment.
IGA response defined as clear (0) or almost clear (1) with ≥2-grade improvement.
[a]With ≥2-grade improvement from baseline. *$P<0.05$, **$P<0.0001$ vs placebo.

JADE MONO-1: QoL Results, Safety, and Conclusions

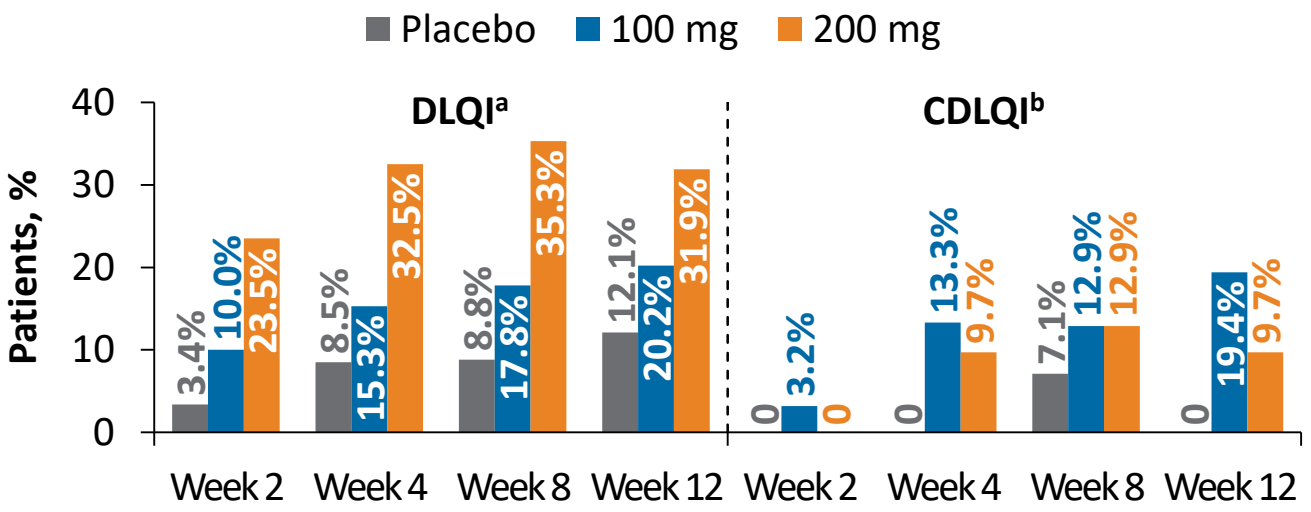
Change From Baseline in DLQI[a]



Change From Baseline in CDLQI[b]



Patients With "No Effect on QoL"[c]



Conclusions

- Adolescents and adults with moderate-to-severe AD treated with abrocitinib reported greater improvements in PROs of symptoms (PP-NRS, PtGA, and POEM) and QoL (DLQI, CDLQI) compared with placebo
- Abrocitinib was well tolerated with incidence of serious AEs similar to placebo[1]
- These PRO results reflect the clinical efficacy observed in JADE MONO-1[1]

AD, atopic dermatitis; AE, adverse event; CDLQI, Children's Dermatology Life Quality Index; DLQI, Dermatology Life Quality Index; LSM, least-squares mean; POEM, Patient-Oriented Eczema Measure; PRO, patient-reported outcome; PtGA, Patient Global Assessment; QoL, quality of life.
"No effect on QoL" defined as DLQI/CDLQI score <2.
[a]For patients ≥18 years. [b]For patients <18 years. [c]Includes only patients with DLQI/CDLQI score ≥2 at baseline.

1. Simpson E et al. Presented at: European Academy of Dermatology and Venereology - 28th Congress; October 9-13, 2019; Madrid, Spain.