# 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

Gil Yosipovitch,[1] Thomas Bieber,[2] Linda F. Stein Gold,[3] Shawn G. Kwatra,[4] Svitlana Tatulych,[5] Chudy Nduaka,[6] Michael C. Cameron,[7] David Williams,[8] Pinaki Biswas,[7] Hernan Valdez[7]

[1]Miami Itch Center, Miller School of Medicine, University of Miami, Miami, FL, USA; [2]University Hospital of Bonn, Bonn, Germany; [3]Henry Ford Health System, Detroit, MI, USA; Johns Hopkins University School of Medicine, Baltimore, MD, USA; [5]Pfizer Inc., Groton, CT, USA; [6]Pfizer Inc., Collegeville, PA, USA; [7]Pfizer Inc., New York, NY, USA; [8]Syneos Health, Indianapolis, IN, USA

**Presented at the American Academy of Dermatology 2020 Annual Meeting; March 20-24, 2020; Denver, Colorado**

Editorial/medical writing support under the guidance of the authors was provided by Renee Gordon, PhD, and Jennifer C. Jaworski, MS, at ApotheCom, San Francisco, CA, USA, and was funded by Pfizer Inc., New York, NY, USA, in accordance with Good Publication Practice (GPP3) guidelines (*Ann Intern Med*. 2015;163:461-464).
This study was funded by Pfizer Inc.

# Disclosures

**GY** is a consultant and advisor for Pfizer Inc., Bellus Health, Eli Lilly, Galderma, Kiniksa, Menlo Therapeutics, Sanofi-Regeneron, Sienna Biopharmaceuticals, and Trevi Therapeutics and a principal investigator for Pfizer Inc., Kiniksa, LEO Pharma, Menlo Therapeutics, Novartis, Sun Pharma, and Vanda Pharmaceuticals.

**TB** is a lecturer and/or consultant for Pfizer Inc., AbbVie, Almirall, AnaptysBio, Arena Pharmaceuticals, Asana Biosciences, BioVerSys, Boehringer Ingelheim, Daiichi-Sankyo, Dermavant/Roivant, Eli Lilly, Galapagos/MorphoSys, Galderma, Glenmark, GSK, Incyte, Kymab, LEO Pharma, L´Oréal/La Roche-Posay, Menlo Therapeutics, Novartis, RAPT Therapeutics (FLX Bio), Sanofi-Regeneron, UCB, and Vectans Pharma and an investigator for AFYX (DermTreat).

**LFSG** received grants from Pfizer Inc., Incyte, and LEO Pharma and has received payment for lectures from Pfizer Inc., and LEO Pharma.

**SGK** is an advisor for Pfizer Inc., Menlo Therapeutics, and Regeneron and has received grant funding from Pfizer Inc., and Kiniksa.

**ST, CN, MCC, PB, HV** are employees and shareholders of Pfizer Inc.

**DW** is an employee of Syneos Health, which received financial compensation from Pfizer Inc., to conduct this study.

# 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 AD[1]

## 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

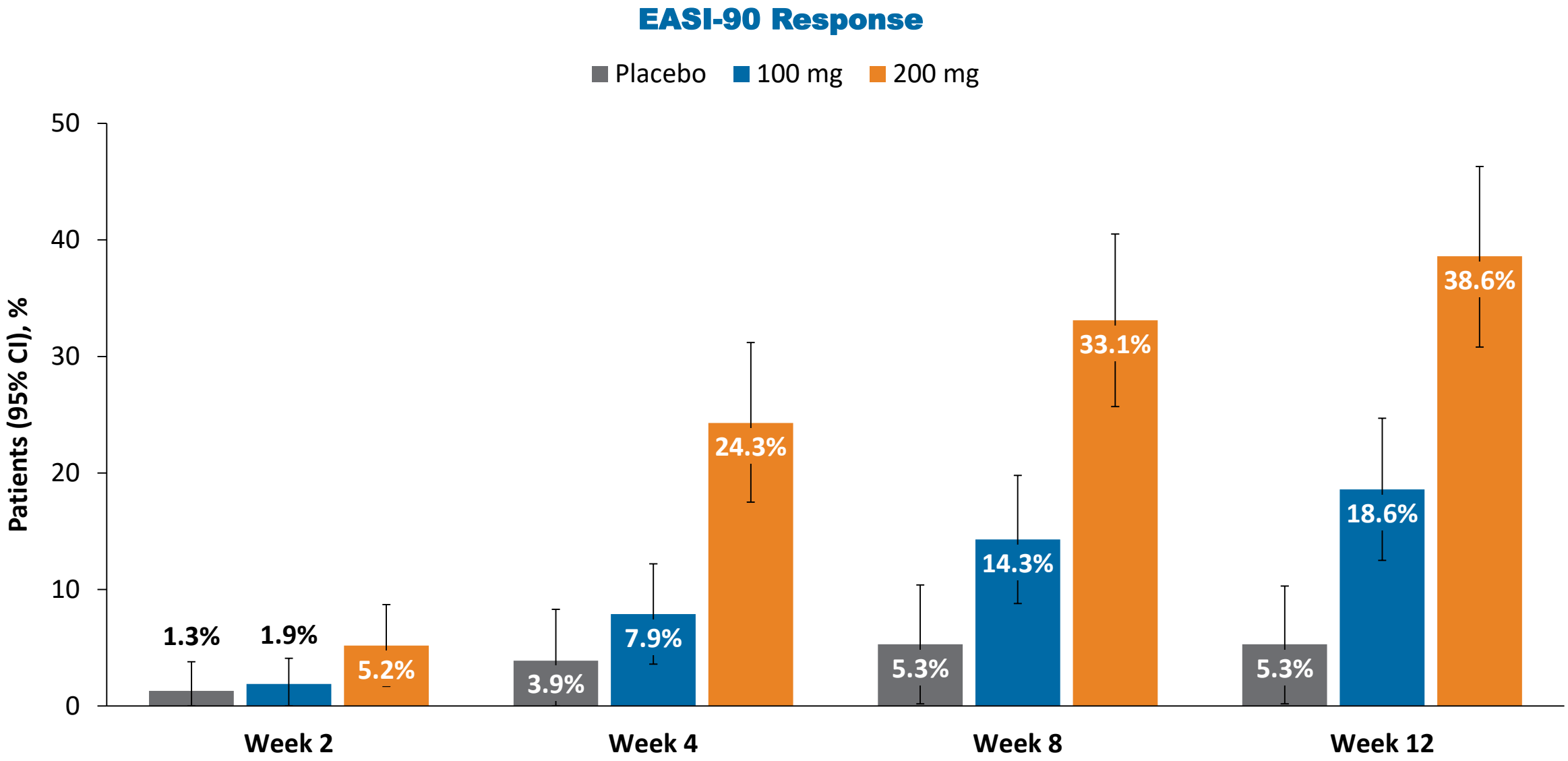
| | | Total N=387 | Placebo N=77 | 100 mg N=156 | 200 mg N=154 |
|---|---|---|---|---|---|
| Age, mean (SD), y | | 32.5 (16.0) | 31.5 (14.4) | 32.6 (15.4) | 33.0 (17.4) |
| Age group, n (%) | <18 y | 84 (21.7) | 17 (22.1) | 34 (21.8) | 33 (21.4) |
| %BSA, mean (SD) | | 49.8 (23.6) | 47.4 (22.7) | 50.8 (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.

[a]For patients ≥18 years. [b]For 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

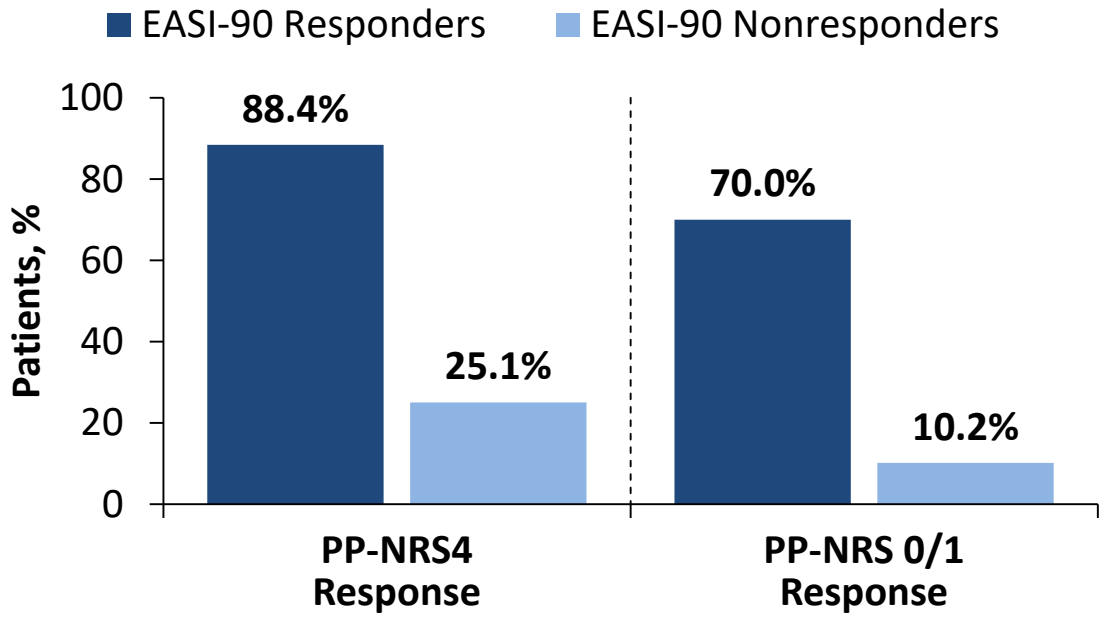



EASI-90, ≥90% improvement from baseline in Eczema Area and Severity Index.

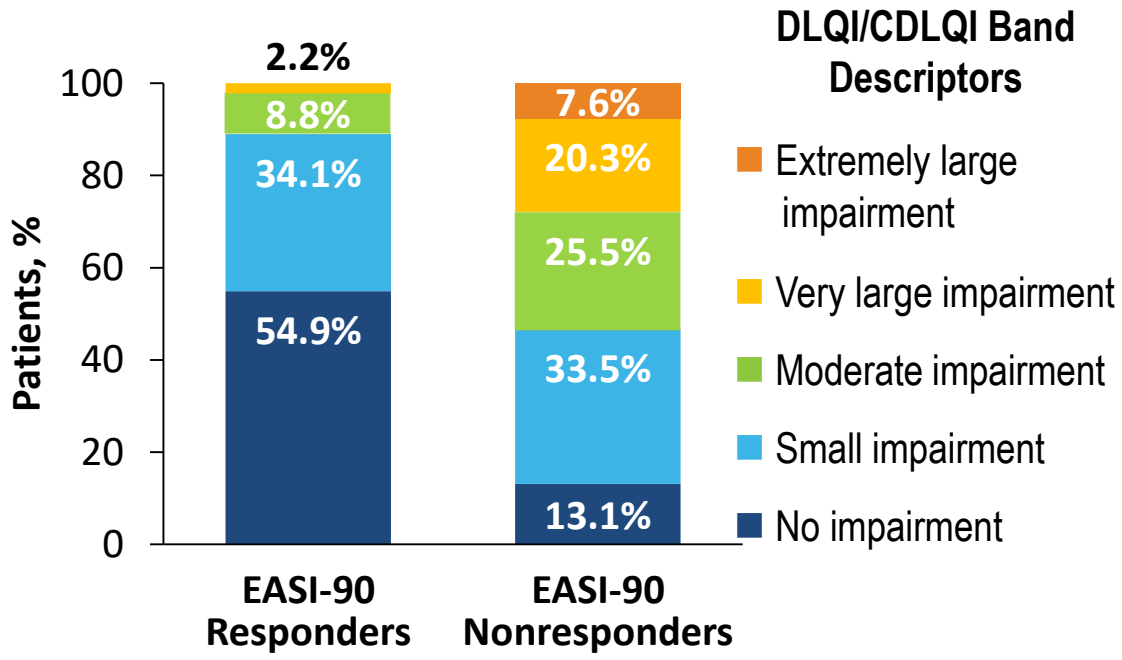
# JADE MONO-1: Patients Who Achieve EASI-90 Response Are More Likely to Achieve an Itch-Free State and Have Small or No Impairment in QoL



## 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 group[1]
- 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.

1. Simpson E et al. Presented at: 28th EADV Congress; October 9-13, 2019; Madrid, Spain.