Long-Term Efficacy of Abrocitinib in Adolescents and Adults With Moderate-to-Severe Atopic Dermatitis: A Post Hoc Analysis of JADE EXTEND

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INTRODUCTION

- Abrocitinib is an oral, once-daily, Janus kinase 1–selective inhibitor approved for the treatment of moderate-to-severe atopic dermatitis (AD) in adolescents and adults in several countries, including Great Britain and the United States[1,2]
- Pivotal phase 3 trials have demonstrated short-term efficacy of abrocitinib over 12 or 16 weeks in adolescent and adult patients with moderate-to-severe AD[3-6]

OBJECTIVE

- To assess abrocitinib treatment efficacy up to 96 weeks in adolescents and adults with moderate-to-severe AD who enrolled in the ongoing phase 3 extension trial JADE EXTEND (NCT03422822)

METHODS

- This interim analysis included adolescent (aged 12 to <18 years) and adult (aged ≥18 years) patients from qualifying parent phase 3 JADE trials who subsequently enrolled in JADE EXTEND (data cut-off date: September 25, 2021; **Supplementary Figure S1**; accessed via the QR code)
- Additional information on the study design, treatment, assessments and statistical analysis are described in the **Supplementary Information**

RESULTS

Patients

- This analysis included 357 adolescent and 1309 adult patients
- Baseline disease characteristics were largely comparable across both patient groups (**Supplementary Table S1**)
  - Adolescent patients tended to have more severe disease than adult patients (Investigator's Global Assessment [IGA] score of 4: 42.3% vs 36.7%) and greater median percentage body surface area affected by AD (48.0% [95% CI, 33.0-68.1] vs 43.0% [29.0-62.9]) at baseline

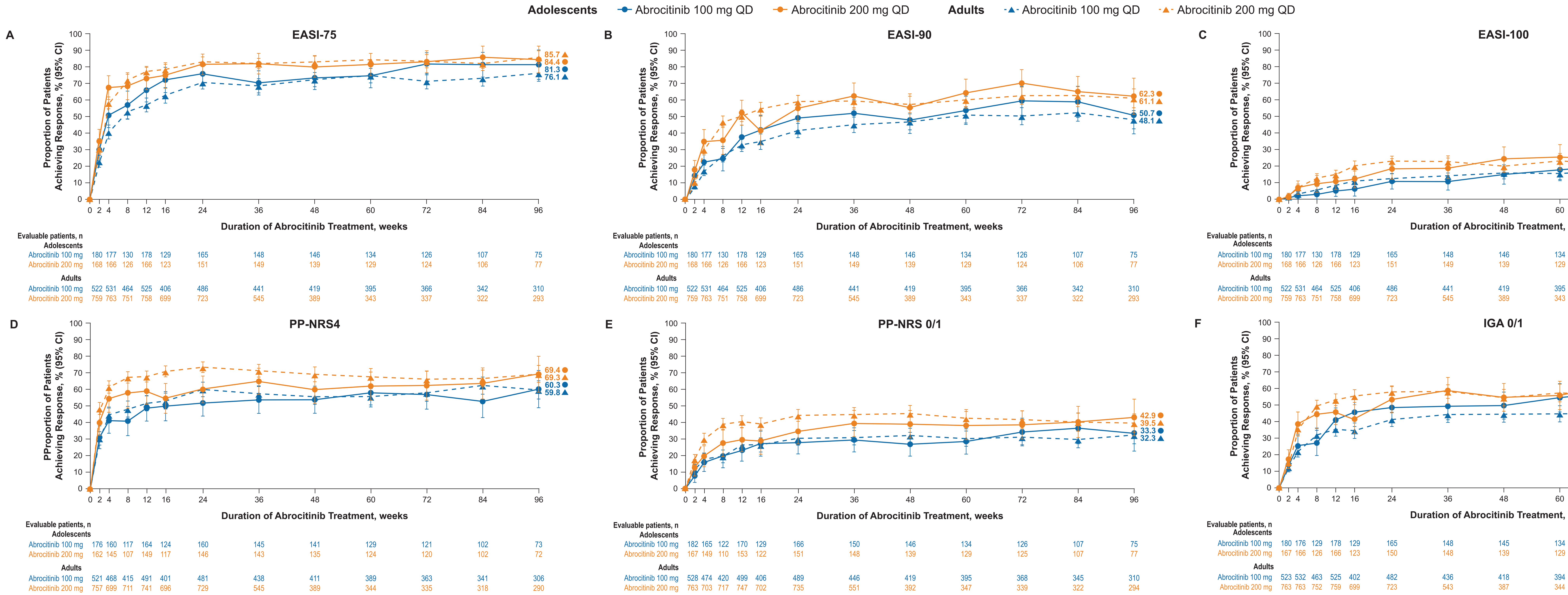
Efficacy Responses Up to Week 96 of Abrocitinib Treatment in Adolescent and Adult Patients

- In both adolescents and adults and regardless of abrocitinib dose, substantial proportions of patients achieved clinically meaningful responses and improvements in clinical and patient-reported efficacy measures, including high-threshold efficacy endpoints, up to week 96 of treatment (**Figure 1** and **Supplementary Figure S2**)
  - Dose-dependent efficacy was observed for both patient groups; treatment with abrocitinib 200 mg once daily (QD) resulted in numerically higher proportions of responders than abrocitinib 100 mg QD
- At week 96, the proportions of responders were largely comparable for both doses of abrocitinib in both adolescents and adults

CONCLUSIONS

- This analysis demonstrates the short-term and long-term efficacy of treatment with abrocitinib 100 mg and abrocitinib 200 mg up to 96 weeks for both adolescent and adult patients with moderate-to-severe AD
- Substantial proportions of adolescents and adults achieved high-threshold efficacy endpoints over the short-term and long-term with either dose of abrocitinib
- Dose-dependent efficacy was observed for both adolescents and adults over the short-term and long-term, including for high-threshold efficacy endpoints

Figure 1. Proportions of Adolescent and Adult Patients Who Achieved (A) EASI-75, (B) EASI-90, (C) EASI-100, (D) PP-NRS4, (E) PP-NRS 0/1, and (F) IGA 0/1 Responses Over 96 Weeks of Abrocitinib Treatment



EASI-75, ≥75% improvement from baseline in Eczema Area and Severity Index; EASI-90, ≥90% improvement from baseline in Eczema Area and Severity Index; EASI-100, 100% improvement from baseline in Eczema Area and Severity Index; IGA 0/1, Investigator's Global Assessment score of 0 (clear) or 1 (almost clear) with a ≥2-grade improvement from baseline; PP-NRS4, ≥4-point improvement from baseline in Peak Pruritus Numerical Rating Scale score; PP-NRS 0/1, Peak Pruritus Numerical Rating Scale score of 0 (no itch) or 1 (very little itch); QD, once daily.

Data are reported as observed. Data cut-off date: September 25, 2021 (JADE EXTEND is an ongoing trial, and not all patients reached week 96 visits at the clinical data cutoff). For all patients, the baseline value is always the last pre-dose observation, taken from the qualifying parent trial. Day 1 of treatment was defined as the first dose of abrocitinib received by the patient in either the qualifying parent trial or JADE EXTEND. PP-NRS used with permission from Regeneron Pharmaceuticals, Inc. ,and Sanofi

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DISCLOSURES

ASP is/has served as a study investigator for AbbVie, AnaptysBio, Eli Lilly, Incyte, Janssen, KrystalBio, Regeneron, and UCB; is/has received honoraria as a consultant for Pfizer Inc., Abbvie, Acrotech, Almirall, Amgen, Amryt, Arcutis, Arena, Azitra, BioCryst, BiomX, Bridgebio, Bristol Myers Squibb, Castle Biosciences, Catawba, Eli Lilly, Exicure, Gilead, Incyte, Janssen, Johnson & Johnson, Kamari, Leo, Novartis, OM Pharma, Pierre Fabre, RAPT, Regeneron, Sanofi/Genzyme, Seanergy, and UCB; and is/has served on the Data Safety Monitoring Board for AbbVie, Abeona, Bausch, Galderma, and Novan. **MJC** has been a clinical trial investigator for Pfizer Inc., 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 Inc., 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. **CF** is chief investigator of the UK National Institute for Health Research-funded TREAT (ISRCTN15837754) and SOFTER (Clinicaltrials.gov: NCT03270566) trials as well as the UK-Irish Atopic eczema Systemic Therapy Register (A-STAR; ISRCTN11210918) and a principal investigator in the European Union Horizon 2020-funded BIOMAP Consortium (http://www.biomap-imi.eu/). His department has also received funding from Sanofi-Genzyme. **CB** is/has been a clinical trial investigator for Abbvie, Eli Lilly, Galderma, Merck, Novartis, and Sanofi-Genzyme and an advisory board member, consultant and/or invited lecturer for Abbvie, ALK, Eli Lilly, LEO Pharma, Mylan, Merck, Novartis, Pfizer, and Sanofi-Genzyme. **SW** has received institutional research grants from Sanofi Deutschland GmbH, Leo Pharma, and La Roche Posay; has performed consultancies for Sanofi-Genzyme, Regeneron, LEO Pharma, AbbVie, Pfizer, Eli Lilly, Kymab, and Novartis; has lectured at educational events sponsored by Sanofi Genzyme, Regeneron, LEO Pharma, AbbVie, Novartis, and Galderma; and is involved in performing clinical trials with many pharmaceutical industries that manufacture drugs used for the treatment of psoriasis and atopic dermatitis. **JN**, **SAF**, **PB**, **MW** and **HK** are employees and shareholders of Pfizer Inc.

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