Abrocitinib Reduces Skin Pain in Adolescent and Adult Patients With Moderate-to-Severe Atopic Dermatitis

Jacob P. Thyssen,[1] Anthony Bewley,[2] Sonja Ständer,[3] Carla Castro,[4] Laurent Misery,[5] Brian S. Kim,[6] Pinaki Biswas,[7] Gary Chan,[8] Daniela E. Myers,[9] Melissa Watkins,[7] Justine Alderfer,[9] Erman Guler,[10] Jonathan I. Silverberg[11]

[1]Bispebjerg Hospital, University of Copenhagen, Copenhagen, Denmark; [2]Barts Health NHS Trust, London, United Kingdom; [3]Center for Chronic Pruritus, Münster University Hospital, Munster, Germany; [4]Hospital Universitario Austral, Pilar, Argentina; [5]University Hospital of Brest, Brest, France; [6]Washington University School of Medicine, St. Louis, MO, USA; [7]Pfizer Inc., New York, NY, USA; [8]Pfizer Inc., Groton, CT, USA; [9]Pfizer Inc., Collegeville, PA, USA; [10]Pfizer Inc., Istanbul, Turkey; [11]The George Washington University School of Medicine and Health Sciences, Washington DC, USA

BACKGROUND

- Skin pain is a commonly reported and burdensome symptom in patients with atopic dermatitis (AD)[1]
- Abrocitinib is an oral once-daily, Janus kinase 1–selective inhibitor approved for the treatment of patients with moderate-to-severe AD[2,3]

OBJECTIVE

- To assess the efficacy of abrocitinib on skin pain in adult and adolescent patients with moderate-to-severe AD

METHODS

- Data were analyzed from trials with abrocitinib as monotherapy (pooled phase 2b trial [age 18-75 years] and phase 3 trials JADE MONO-1 [NCT03349060] and MONO-2 [NCT03575871; both age ≥12 years]) or in combination with topical therapy (phase 3 trials JADE COMPARE [NCT03720470; age ≥18 years] and JADE TEEN [NCT03796676; age 12-17 years])
- Patients received oral abrocitinib 200 mg or 100 mg or placebo once daily
  - JADE COMPARE also included an active-control arm (dupilumab 300 mg administered subcutaneously every other week)
- Patients rated their skin pain score from 0 (not painful) to 10 (extremely painful) over a 24-hour period using the Pruritus and Symptoms Assessment for Atopic Dermatitis (PSAAD) instrument[4]
- Least squares mean change from baseline in PSAAD item # 2 ("How painful was your skin over the past 24 hours?") was assessed in:
  - Adult and adolescent patients from the pooled monotherapy trials
    - Results from JADE COMPARE and JADE TEEN have been presented previously[5]
  - A subset of patients across the trials who were classified as nonresponders per Investigator's Global Assessment (IGA)
    - IGA response was defined as achieving an IGA score of 0/1 and a ≥2-point improvement from baseline

RESULTS

Patients

- Baseline demographics for patients in the pooled monotherapy, JADE COMPARE, and JADE TEEN trials are shown in **Table 1**

Table 1. Baseline Characteristics (full analysis set)

	Pooled monotherapy[a] N=942	JADE COMPARE N=837	JADE TEEN N=285
Age, y mean ± SD median (IQR)	35.0 ± 15.9 NA	37.7 ± 14.7 NA	NA 15.0 (13.0-17.0)
Age <18 years of age, n (%)	124 (13.2)	0 (0.0)	284 (99.6)[b]
Duration of disease, y, mean ± SD	23.0 ± 15.5	22.7 ± 15.4	10.0 ± 5.2
EASI score, mean ± SD	28.8 ± 12.7	30.9 ± 12.8	29.9 ± 12.5
PP-NRS total score, mean ± SD	7.0 ± 1.9	7.3 ± 1.7	7.0 ± 1.8
DLQI total score, mean ± SD	14.6 ± 6.9	15.7 ± 6.6	NA
CDLQI total score, mean ± SD	12.7 ± 6.0	NA	14.0 ± 6.6
HADS Anxiety score, mean ± SD	6.1 ± 4.1	5.3 ± 3.8	5.5 ± 4.0
HADS Depression score, mean ± SD	4.3 ± 3.8	3.9 ± 3.5	3.6 ± 3.2
PSAAD item # 2 score, mean ± SD	5.6 ± 2.5[f]	5.6 ± 2.6[g]	5.0 ± 2.6[h]

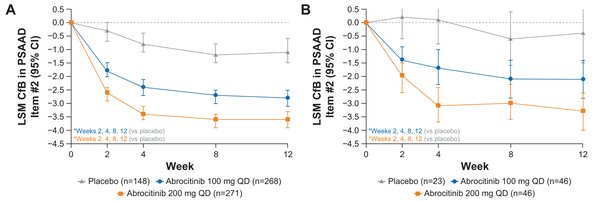
CDLQI, Children's Dermatology Life Quality Index; DLQI, Dermatology Life Quality Index; EASI, Eczema Area and Severity Index; HADS, Hospital Anxiety and Depression Scale; IQR, interquartile range; NA, not applicable; PP-NRS, Peak Pruritus Numerical Rating Scale (used with permission from Regeneron Pharmaceuticals, Inc., and Sanofi); PSAAD, Pruritus and Symptoms Assessment for Atopic Dermatitis.

[a]Pooled monotherapy population includes patients from the phase 2b and the phase 3 JADE MONO-1 and JADE MONO-2 trials.
[b-f]1 patient in the placebo group was enrolled at age 18 years, which was a protocol deviation.
[f]N=802.
[g]N=780.
[h]N=254.

Efficacy of Abrocitinib in the Pooled Monotherapy Population

- Abrocitinib monotherapy improved skin pain in both adult and adolescent patients as early as week 2, and improvements were maintained through week 12 (**Figure 1**)
  - Improvements with abrocitinib were greater than placebo at all evaluated time points and were dose dependent

Figure 1. Change From Baseline to Week 12 in Skin Pain in (A) Adult and (B) Adolescent Patients in the Pooled Monotherapy Population



CfB, change from baseline; LSM, least squares mean; PSAAD, Pruritus and Symptoms Assessment for Atopic Dermatitis; QD, once daily.

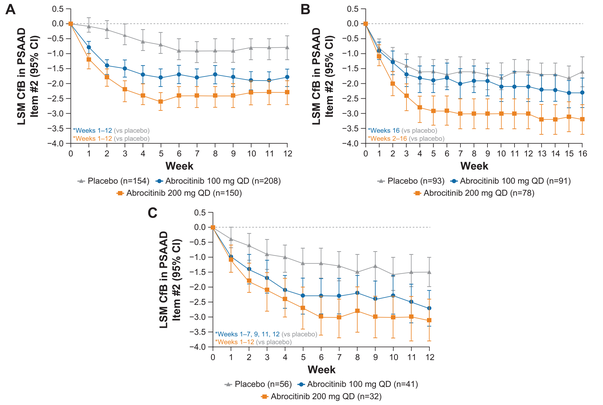
*Nominal $P<0.05$ for abrocitinib versus placebo.

Pooled monotherapy population includes patients from the phase 2b, and phase 3 JADE MONO-1 and JADE MONO-2 trials. Results from JADE COMPARE and JADE TEEN have been presented previously.[5]

Efficacy of Abrocitinib Treatment in Nonresponders per IGA

- Improvements in skin pain were observed among patients classified as nonresponders per IGA after treatment with abrocitinib as monotherapy (**Figure 2A**) or in combination with topical treatment in JADE COMPARE (**Figure 2B**) and JADE TEEN (**Figure 2C**)
  - Skin pain improvement was seen as early as week 1 in a dose-dependent manner across all studies
  - Improvements were maintained through week 12 or week 16 of treatment

Figure 2. Change From Baseline to Week 12/16 in Skin Pain Among Nonresponders per IGA[a] in (A) the Monotherapy Pool,[b] (B) JADE COMPARE, and (C) JADE TEEN



CfB, change from baseline; LSM, least squares mean; PSAAD, Pruritus and Symptoms Assessment for Atopic Dermatitis; QD, once daily.

*Nominal $P<0.05$ for abrocitinib vs placebo.

[a]IGA response was defined as achieving an IGA score of 0/1 and a ≥2-point improvement from baseline.
[b]Pooled monotherapy population includes patients from the phase 2b and the phase 3 JADE MONO-1 and JADE MONO-2 trials.

CONCLUSIONS

- Abrocitinib as monotherapy or in combination with topical therapy rapidly and consistently reduced skin pain in adult and adolescent patients with moderate-to-severe AD, including those who did not achieve IGA response

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DISCLOSURES

JPT is an advisor for Pfizer Inc., AbbVie, Almirall, Arena Pharmaceuticals, Aslan Pharmaceuticals, Coloplast, Eli Lilly and Company, OM Pharma, LEO Pharma, Regeneron, Sanofi Genzyme, and Union Therapeutics and a speaker for Pfizer Inc., AbbVie, Almirall, Eli Lilly and Company, LEO Pharma, Regeneron, and Sanofi Genzyme and has received research grants from Pfizer Inc., Regeneron, and Sanofi Genzyme. **AB** reports consultancy for and travel grants from AbbVie, Almirall, Eli Lilly and Company, Galderma, Janssen, LEO Pharma, Novartis, Sanofi, and UCB. **SST** is an investigator for Dermasence, Galderma, Kiniksa, Menlo Therapeutics, Novartis, Sanofi, Trevi Therapeutics, and Vanda; roles as a member of scientific advisory boards, consultant, and/or speaker for Pfizer Inc., AbbVie, Almirall, Beiersdorf, Bellus Health, Benevolent, Bionorica, Cara, Clexio, Escient, Galderma, Grünenthal, Kiniksa, LEO Pharma, Eli Lilly and Company, Menlo Therapeutics, P.G. Unna Academy, Sanofi, Trevi Therapeutics, and Vifor. **CC** is a principal or sub-investigator for Pfizer Inc., AbbVie, Boehringer Ingelheim, Eli Lilly and Company, Novartis, and Sanofi and a speaker and/or advisor for Pfizer Inc., AbbVie, Andromaco, Cerave, Galderma, Isdin, La Roche-Posay, Novartis, and Sanofi. **LM** is an investigator for Pfizer Inc., AbbVie, Galderma, Kiniksa, Eli Lilly and Company, Menlo Therapeutics, Novartis, Sanofi, and Trevi Therapeutics and a consultant for AbbVie, Beiersdorf, Clexio, Galderma, Eli Lilly and Company, Menlo Therapeutics, Novartis, Sanofi, Sienna Biopharmaceuticals, and Trevi Therapeutics. **BSK** is a consultant and advisor for Pfizer Inc., AbbVie, Boehringer Ingelheim, Cara Therapeutics, Kiniksa, Menlo Therapeutics, and Sanofi-Regeneron; has received research grants from Cara Therapeutics, Celgene, and LEO Pharma; and is founder and stockholder in Nuogen Pharma. **PB**, **GC**, **DEM**, **MW**, **JA**, and **EG** are employees and shareholders of Pfizer Inc. JIS served as an investigator for Celgene, Eli Lilly and Company, F. Hoffmann-La Roche, Menlo Therapeutics, Realm Therapeutics, Regeneron, and Sanofi; as a consultant for Pfizer Inc., AbbVie, Anacor, AnaptysBio, Arena Pharmaceuticals, Dermavant, Dermira, Eli Lilly and Company, Galderma, GlaxoSmithKline, Glenmark, Incyte, Kiniksa Pharmaceuticals, LEO Pharma, Menlo Therapeutics, Novartis, Realm Therapeutics, Regeneron, and Sanofi; and as a speaker for Regeneron and Sanofi.

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