9-1-2022

Impact of crisaborole in patients with mild-to-moderate atopic dermatitis who received prior treatment

Linda F. Stein Gold

Vivian Shi

Bonnie Vlahos

Paul Sanders

Chuanbo Zang

See next page for additional authors

Authors

Linda F. Stein Gold, Vivian Shi, Bonnie Vlahos, Paul Sanders, Chuanbo Zang, and Amy Cha

Eczema Area and Severity Index (EASI) score at week 16. Secondary efficacy endpoints to be examined at week 16 include proportion of patients exhibiting a validated Investigator Global Assessment for Atopic Dermatitis score of 0 (cleared) or 1 (almost cleared) and a ≥ 2-point reduction from baseline; proportion of patients exhibiting a ≥ 50% reduction from baseline in EASI score; proportion of patients exhibiting a ≥ 4-point improvement from baseline in pruritus numerical rating scale (NRS); mean percentage change from baseline in pruritus NRS; mean change from baseline in percentage of affected body surface area; and incidence and severity of serious adverse events.

235

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 Kim,[6] Pinaki Biswas,[7] Gary Chan,[8] Daniela E. Myers,[9] Melissa Watkins,[7] Justine Alderfer,[9] Erman Guler[10] and Jonathan I. Silverberg[11]

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

Skin pain is a commonly reported and burdensome symptom in patients with atopic dermatitis (AD). Abrocitinib, an oral once-daily Janus kinase 1 selective inhibitor, has been approved for the treatment of patients with moderate-to-severe AD. The objective was to assess the efficacy of abrocitinib on skin pain in adult and adolescent patients with moderate-to-severe AD. Data were analysed from clinical trials with abrocitinib as monotherapy [pooled phase IIb (NCT02780167), patients aged 18–75 years; and phase III JADE MONO-1 (NCT03349060) and MONO-2 (NCT03575871), patients ≥12 years of age], or in combination with topical therapy [phase III JADE COMPARE (NCT03720470), patients aged ≥18 years; and JADE TEEN (NCT03796676), patients aged 12–17 years]. Patients received once-daily oral abrocitinib (200 mg or 100 mg) or placebo. The JADE COMPARE study 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-h period using the Pruritus and Symptom Assessment for Atopic Dermatitis (PSAAD) instrument. This post hoc analysis includes least squares mean (LSM) change from baseline in PSAAD item 2 ('How painful was your skin over the past 24 hours?'). Overall mean (SD) score for PSAAD item 2 at baseline was 5·6 (2·5) in the pooled monotherapy population, 5·6 (2·6) in JADE COMPARE and 5·0 (2·6) in JADE TEEN; baseline scores were similar between treatment arms across the studies. In pooled monotherapy trials, LSM change from baseline in PSAAD item 2 was greater in both adult and adolescent patients receiving abrocitinib 200 mg and 100 mg vs. placebo at week 2 {adults −2·6 [95% confidence interval (CI) −2·8 to −2·3] and − 1·8 [95% CI −2·1 to −1·6] vs. −0·3 [95% CI −0·7 to 0·0]; adolescents: −2·0 [95% CI −2·5 to −1·4] and − 1·4 [95% CI −1·9 to −0·8] vs. 0·2 [95% CI −0·6 to 1·1]}, which was sustained through week 12 [adults: −3·6 (95% CI −3·9 to −3·3) and − 2·8 (95% CI −3·1 to −2·5) vs. −1·1 (95% CI −1·5 to −0·6); adolescents: −3·3 (95% CI −4·0 to −2·6) and − 2·1 (95% CI −2·8 to −1·4) vs. −0·4 (95% CI −1·5 to 0·6)] supporting similar results in both adolescent and adult patients. Additionally, LSM change in PSAAD item 2 was greater with abrocitinib 200 mg and 100 mg vs. placebo among patients who were classified as nonresponders on the Investigator's Global Assessment (IGA) scale (IGA 0/1 with ≥2-point improvement from baseline) across all studies at week 2 [pooled monotherapy: −1·8 (95% CI −2·1 to −1·5) and −1·4 (95% CI −1·6 to −1·1) vs. −0·2 (95% CI −0·5 to 0·1); COMPARE: −2·0 (95% CI −2·4 to −1·6] and −1·3 (95% CI −1·7 to −0·9) vs. −1·2 (95% CI −1·6 to −0·8); TEEN: −1·8 (95% CI −2·4 to −1·2) and −1·4 (95% CI −1·9 to −0·9) vs. −0·6 (95% CI −1·1 to −0·2)], which was sustained through week 12/16 [pooled monotherapy: −2·3 (95% CI −2·7 to −1·9) and −1·8 (95% CI −2·1 to −1·5) vs. −0·8 (95% CI −1·2 to −0·4); COMPARE: −3·2 (95% CI −3·7 to −2·7) and −2·3 (95% CI −2·8 to −1·8) vs. −1·6 (95% CI −2·1 to −1·1); TEEN: −3·1 (95% CI −3·8 to −2·4) and −2·7 (95% CI −3·3 to −2·1) vs. −1·5 (−2·0 to −1·0)]. 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 an IGA response.

Acknowledgments: This study was sponsored by Pfizer. Editorial/medical writing support under the guidance of the authors was provided by Jaya Kolipaka and Renata Cunha, PharmD, at ApotheCom, San Francisco, CA, USA, and was funded by Pfizer Inc., New York, NY, USA, in accordance with Good Publication Practice (GPP3) guidelines.

236

Impact of crisaborole in patients with mild-to-moderate atopic dermatitis who received prior treatment

Linda Stein Gold,[1] Vivian Shi,[2] Bonnie Vlahos,[3] Paul Sanders,[4] Chuanbo Zang[3] and Amy Cha[5]

[1]*Henry Ford Hospital, Detroit, MI, USA;* [2]*Department of Dermatology, University of Arkansas for Medical Sciences, Little Rock, AR, USA;* [3]*Pfizer, Collegeville, PA, USA;* [4]*Pfizer R&D UK, Surrey, UK; and* [5]*Pfizer, New York, NY, USA*

Topical treatments can provide relief with minimal adverse events (AEs) in patients with atopic dermatitis (AD). Crisaborole ointment 2% is a nonsteroidal phosphodiesterase inhibitor for the treatment of mild-to-moderate AD. The objective was to assess the efficacy and safety of crisaborole ointment in

patients with AD who had received prior treatments of corticosteroids [topical corticosteroids (TCS) or systemic corticosteroids)], topical calcineurin inhibitors (TCI) or no prior treatments (treatment-naïve). This was a post-hoc analysis of two identically designed, vehicle-controlled, randomized, double-blind, phase III studies of patients aged ≥2 years (ClinicalTrials.gov NCT02118766 and NCT02118792). Patients were assigned crisaborole or vehicle (2: 1) twice daily for 28 days and had a baseline Investigator's Static Global Assessment (ISGA) score of mild (2) or moderate (3). Patients were divided into three subgroups: treatment-experienced patients who had received prior treatments of corticosteroids (systemic or dermatologic) or TCI; treatment-experienced patients who had received prior treatment with TCS or TCI; and treatment-naïve patients who received no prior treatments within 90 days to screening. The primary endpoint was success in ISGA, defined as an ISGA score at day 29 of clear (0) or almost clear (1) with a ≥ 2-grade improvement from baseline. Additional endpoints included a Severity of Pruritus Scale (SPS) at week 4 (weekly average) of none (0) or mild (1) with a ≥ 1-grade improvement from baseline; changes in the Atopic Dermatitis Severity Index (ADSI), Dermatology Life Quality Index (DLQI), Children's Dermatology Life Quality Index (CDLQI) and Dermatitis Family Impact Questionnaire (DFI) results were also assessed at day 29. AEs, including treatment-emergent AEs and serious AEs, were analysed. A significantly higher proportion of crisaborole-treated patients than vehicle-treated patients achieved success in ISGA in all subgroups [corticosteroids or TCI: 27·9% vs. 15·9% ($P = 0·001$); TCS or TCI: 27·4% vs. 14·7% ($P = 0·001$); treatment-naïve: 35·0% vs. 26·8% ($P = 0·017$)]. SPS score 0/1 with a ≥ 1-grade improvement was also achieved by a significantly higher proportion of crisaborole-treated patients than vehicle-treated patients in all subgroups [corticosteroids or TCI: 35·1% vs. 14·9% ($P < 0·001$); TCS or TCI: 34·5% vs. 13·5% ($P < 0·001$); treatment-naïve: 36·3% vs. 26·0% ($P = 0·01$)]. Changes in the least squares mean for ADSI, DLQI, CDLQI and DFI results were also significant for crisaborole- vs. vehicle-treated patients in all subgroups except for DLQI, DFI and ADSI (not examined) results for the treatment-naïve subgroup. Treatment-related AEs were infrequent and mild to moderate in severity. Crisaborole demonstrated a favourable efficacy and safety profile in both treatment-naïve and treatment-experienced patients with AD.

237

History of atopic dermatitis is associated with different characteristics and aetiologies in patients with hand eczema referred for patch testing in North America

Nisha Patel,[1] Jonathan I. Silverberg,[1,2] Erin M. Warshaw,[3–5] Joel G. DeKoven,[6] Amber R. Atwater,[7] Howard I. Maibach,[8] Kathryn A. Zug,[9] Margo J. Reeder,[10] Denis Sasseville,[11] James S. Taylor,[12] Joseph F. Fowler, Jr,[13] Melanie D. Pratt,[14] Donald V. Belsito,[15] Vincent A. DeLeo,[16] Cory A Dunnick[17,18] and Marie-Claude Houle[19]

[1]*Department of Dermatology, The George Washington University School of Medicine and Health Sciences, Washington, DC, USA;* [2]*Department of Dermatology, The Northwestern University Feinberg School of Medicine, Chicago, IL, USA;* [3]*Department of Dermatology, Park Nicollet Health Services, Minneapolis, MN, USA;* [4]*Department of Dermatology, University of Minnesota, Minneapolis, MN, USA;* [5]*Department of Dermatology, Minneapolis Veterans Affairs Medical Center, Minneapolis, MN, USA;* [6]*Division of Dermatology, Sunnybrook Health Sciences Centre, University of Toronto, ON, Canada;* [7]*Department of Dermatology, Duke University Medical Center, Durham, NC, USA;* [8]*Department of Dermatology, University of California San Francisco, San Francisco, CA, USA;* [9]*Department of Dermatology, Dartmouth-Hitchcock Medical Center, Lebanon, NH, USA;* [10]*Department of Dermatology, University of Wisconsin School of Medicine and Public Health, Madison, WI, USA;* [11]*Division of Dermatology, Montreal General Hospital, McGill University, Montreal, QC, Canada;* [12]*Department of Dermatology, Cleveland Clinic, OH, USA;* [13]*Division of Dermatology University of Louisville, Louisville, KY, USA;* [14]*Division of Dermatology, University of Ottawa, ON, Canada;* [15]*Department of Dermatology, Columbia University, New York, NY, USA;* [16]*Department of Dermatology, Keck School of Medicine, Los Angeles, CA, USA;* [17]*Department of Dermatology, University of Colorado Anschutz Medical Campus, Aurora, CO, USA;* [18]*Department of Dermatology, Rocky Mountain Regional Veterans Affairs Medical Center, Aurora, CO, USA; and* [19]*Division of Dermatology, CHU de Quebec, Laval University, QC, Canada*

Hand eczema (HE) is a heterogeneous disorder with multiple underlying aetiologies, including atopic dermatitis (AD), irritant contact dermatitis (ICD) and allergic contact dermatitis (ACD). History of AD is a strong risk factor for developing HE. However, many patients with HE report no prior history of AD. Little is known about differences in the patient characteristics and aetiology of HE in patients with vs. without a history of AD. The objective was to characterize differences of demographics, aetiology and patch testing results in patients with HE who were referred for patch testing with or without a history of AD. This was a retrospective analysis of patients who were patch tested by the North American Contact Dermatitis Group between 2001 and 2018. Of 43 677 patients who underwent patch testing, 11 591 (26·5%) had hands listed as a site of dermatitis. Patients with HE were more likely to be male, white, aged <40 years, employed, and have a history of eczema, asthma or hay fever. Among patients with HE, those with history of AD were less likely to have one or more allergic patch test reaction (80·9% vs. 85·2%; $P < 0·001$), currently relevant reaction (73·3% vs. 79·9%; $P < 0·001$) or