Evaluating the Severity of Atopic Dermatitis in Children and Adults: Mapping of Investigator's Static Global Assessment to Eczema Area and Severity Index in Phase 3 Studies of Crisaborole, 2%

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Introduction: The severity of atopic dermatitis (AD) was measured in two phase 3 US studies in patients aged ≥2 years using the Investigator's Static Global Assessment (ISGA), a 5-point scale from 0 (clear) to 4 (severe), recommended by the US Food and Drug Administration. The Eczema Area and Severity Index (EASI), a validated scale ranging from 0 to 72, is used globally to assess AD severity in clinical trials. The objective of this analysis was to translate ISGA scores from the CORE-1 (NCT02118766) and CORE-2 (NCT02118792) phase 3 studies into EASI scores, thereby aiding in the interpretability of the ISGA.

Methods: Mapping of ISGA scores to EASI scores was performed through 70,000 random simulations using published EASI severity strata for global severity states (Leshem Y et al. *Br J Dermatol*. 2015; Chopra R et al. *Br J Dermatol*. 2017). ISGA scores were mapped for pooled data from the CORE-1 and CORE-2 crisaborole, 2%, phase 3 trials, which evaluated patients aged ≥2 years with mild-to-moderate AD (crisaborole, n=1016; vehicle, n=506; 86% were children aged 2 to <18 years). Least-squares mean (LSM) percentage change from baseline (%CFB; where negative = improving and positive = worsening) in EASI and proportion of patients with 50%, 75%, and 90% improvement (EASI-50, EASI-75, and EASI-90) on day 29 were computed.

Results: At day 29, LSM (standard error) for %CFB in mapped EASI using Leshem et al. severity strata was −43.1% (4.6) (crisaborole) and −5.2% (8.4) (vehicle) (*P*<.0001), and using Chopra et al., severity strata was −26.3% (17) vs 45.2% (35) (*P*=.0671). For proportions of patients with improvement, results for Leshem et al. were EASI-50, 68.8% (crisaborole) vs 54.0% (vehicle); EASI-75, 54.8% vs 40.5%; EASI-90, 38.9% vs 27.2%; *P*<.0001 for each difference. Results for Chopra et al. were EASI-50, 72.1% (crisaborole) vs 57.6% (vehicle); EASI-75, 63.0% vs 47.8%; EASI-90, 55.0% vs 40.1%; *P*<.0001 for each difference. Mapped EASI results were consistent with ISGA findings from the clinical trials. A limitation of this study is that most patients in literature articles examining EASI strata were adults.

Conclusions: Mapping of ISGA to EASI scores was investigated using data from clinical trials to present results in terms of mapped EASI scores.

Abstract requirements: 349/700 words