

# 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%

Jacob P. Thyssen,<sup>1</sup> Chuanbo Zang,<sup>2</sup> Maureen P. Neary,<sup>2</sup> Andrew G. Bushmakin,<sup>3</sup> Joseph C. Cappelleri,<sup>3</sup> Amy Cha,<sup>4</sup> Christopher Russo,<sup>4</sup> Thomas Luger<sup>5</sup>

<sup>1</sup>Herlev-Gentofte Hospital, University of Copenhagen, Hellerup, Denmark; <sup>2</sup>Pfizer Inc., Collegeville, PA, USA; <sup>3</sup>Pfizer Inc, Groton, CT, USA; <sup>4</sup>Pfizer Inc., New York, NY, USA <sup>5</sup>Westphalian Wilhelms University of Münster, Münster, Germany

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## BACKGROUND

The severity of atopic dermatitis (AD) was measured in two phase 3 US studies in patients aged  $\geq 2$  years using the Investigator's Static Global Assessment (ISGA), a 5-point US Food and Drug Administration–recommended scale from 0 (clear) to 4 (severe). The Eczema Area and Severity Index (EASI), a validated scale ranging from 0–72, is used globally to assess AD severity in clinical trials.

## OBJECTIVES

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  $\geq 2$  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) ( $P<0.0001$ ), and using Chopra et al. severity strata was  $-26.3\%$  (17) vs  $45.2\%$  (35) ( $P=0.0671$ ). For proportions of patients with improvement, results for Leshem were EASI-50,  $68.8\%$  (crisaborole) versus  $54.0\%$  (vehicle); EASI-75,  $54.8\%$  versus  $40.5\%$ ; EASI-90,  $38.9\%$  versus  $27.2\%$ ;  $P<0.0001$  for each difference. Results for Chopra were EASI-50,  $72.1\%$  (crisaborole) versus  $57.6\%$  (vehicle); EASI-75,  $63.0\%$  versus  $47.8\%$ ; EASI-90,  $55.0\%$  versus  $40.1\%$ ;  $P<0.0001$  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.