Efficacy and Safety of Crisaborole in Patients With Mild-to-Moderate Atopic Dermatitis With and Without Comorbid Allergies or Asthma

Peter Lio,1,2 Michael J. Cork,3 Michael S. Blaiss,4 Aharon Kessel,5,6 Wendy C. Cantrell,7 John L. Werth,8 Michael O’Connell,8 Chuanbo Zang,8 Liza Takiya8

1Northwestern University Feinberg School of Medicine, Chicago, IL, USA; 2Chicago Integrative Eczema Center, Chicago, IL, USA; 3Sheffield Dermatology Research, Department of Infection, Immunity, and Cardiovascular Disease, University of Sheffield, Sheffield Children’s Hospital, Sheffield, United Kingdom; 4Medical College of Georgia at Augusta University, Augusta, GA, USA; 5Bnai Zion Medical Center, Haifa, Israel; 6Ruth and Bruce Rappaport Faculty of Medicine, Technion, Haifa, Israel; 7Village Dermatology, Birmingham, AL, USA; 8Pfizer Inc., Collegeville, PA, USA

Word count: 259 (limit: 700 words)

Background: Crisaborole ointment, 2%, is a nonsteroidal anti-inflammatory phosphodiesterase 4 inhibitor for treatment of mild-to-moderate atopic dermatitis (AD). This post hoc pooled analysis of the phase 3 studies CrisADe CORE 1 (Clinicaltrials.gov identifier: NCT02118766) and CORE 2 (NCT02118792) examined the efficacy and safety of crisaborole in patients with mild-to-moderate AD with or without comorbid asthma/allergies.

Methods: Patients aged ≥2 years with mild-to-moderate AD were randomly assigned 2:1 to receive twice-daily crisaborole or vehicle for 28 days. Outcomes were Investigator’s Static Global Assessment (ISGA) success (clear [0] or almost clear [1] with a ≥2-grade improvement from baseline) and ISGA clear/almost clear at day 29. Patients were stratified by history of asthma/allergies (which included but was not limited to allergic rhinitis, food, and other allergies).

Results: Crisaborole and vehicle were received by 585 vs 304 patients with asthma/allergies (mean age, 12.4 vs 12.1 years; moderate disease, 63.6% vs 66.1%) and by 431 vs 202 without asthma/allergies (mean age, 12.2 vs 12.1 years; moderate disease, 58.2% vs 55.5%). ISGA success rate (95% CI) at day 29 was 29.4% (25.5%-33.3%) vs 20.1% (15.3%-24.9%) in patients with asthma/allergies (difference, P=0.003) and 35.8% (31.1%-40.5%) vs 24.6% (18.1%-31.0%) in patients without asthma/allergies (difference, P=0.006). Rate of ISGA clear or almost clear at day 29 was 48.4% (44.1%-52.8%) vs 32.0% (26.5%-37.5%) with asthma/allergies (difference,
and 52.4% (47.6%-57.3%) vs 40.6% (32.4%-48.7%) without asthma/allergies (difference, \( P=0.014 \)). No new safety concerns were identified.

**Conclusion:** Crisaborole is efficacious and safe in treating patients with mild-to-moderate AD regardless of a history of asthma/allergies.

**Funding:** This study was sponsored by Pfizer Inc.