EUCRISA® (crisaborole) BRIEF PRODUCT SUMMARY **April 2021**

The purpose of this document is to provide the clinical and/or pharmacoeconomic information regarding EUCRISA that was requested; it is not intended to be used for any other purpose. This document contains relevant information for EUCRISA, which may or may not be included in the U.S. Prescribing Information (USPI). Pfizer does not suggest or recommend the use of EUCRISA in any manner other than as described in the USPI. Approved Prescribing Information on EUCRISA can be accessed via the following link: https://www.pfizermedicalinformation.com/en-us/eucrisa. In the event this link does not work, please access the product's Approved Prescribing Information at www.pfizer.com. Please refer to the EUCRISA Prescribing information for additional information including important safety information.

Eucrisa® (crisaborole) ointment, 2% is indicated for topical treatment of mild to moderate atopic dermatitis in adult and pediatric patients 3 months of age and older.[1] Crisaborole is a phosphodiesterase 4 (PDE-4) inhibitor. PDE-4 inhibition results in increased intracellular cyclic adenosine monophosphate (cAMP) levels. The specific mechanism(s) by which crisaborole exerts its therapeutic action for the treatment of atopic dermatitis is not well defined.[1]

The safety and effectiveness of EUCRISA have been established in pediatric patients ages 3 months and older for topical treatment of mild to moderate atopic dermatitis. Use of EUCRISA in this age group is supported by data from two 28-day adequate, vehicle controlled safety and efficacy trials which included 1,313 pediatric subjects ages 2 years to 17 years of whom 874 received EUCRISA. The most commonly reported adverse reaction in subjects 2 years and older was application site pain. Additionally, use of EUCRISA in pediatric patients ages 3 months to less than 2 years was supported by data from a 28 day open label, safety and pharmacokinetics (PK) trial in 137 subjects. No new safety signals were identified in subjects 3 months to less than 2 years of age.[1]

Clinical Data in Infants 3 months to < 24 months old

- **3 to <24 Month Infant Safety Data: i**n a multicenter, open-label, single-arm, phase 4 study of crisaborole in patients aged 3 to <24 months with mild-to-moderate AD (n=137), all-cause treatment-emergent adverse events (TEAEs) were reported for 88 patients (64.2%); treatment-related AEs were reported for 22 patients (16.1%) 4 patients (2.9%) discontinued study drug because of a TEAE; all remained in the study, including 1 patient with a serious AE of febrile seizure (not related to treatment), 1 patient with dermatitis infected (not related to treatment), 1 patient with application site pain (treatment-related), and 1 patient with application site discomfort (treatment-related) The most frequently reported (≥5%) all-cause TEAEs were pyrexia (9.5%), upper respiratory, tract infection (7.3%), diarrhea (7.3%), dermatitis atopic (6.6%), dermatitis diaper (6.6%), and cough (5.1%). The most frequently reported treatment-related treatment area AEs (≥2.5%) were application site pain (n=5; 3.6%), application site discomfort (n=4; 2.9%), and erythema (n=4; 2.9%). No safety signals were identified by clinical laboratory findings, ECG, height, weight, or vital signs.[2]
- **3 to <24 Month Infant Effectiveness Assessment Exploratory Endpoint:** results from a multicenter, open-label, single-arm, phase 4 study of crisaborole in patients aged 3 to <24 months with mild-to-moderate AD (n=137) showed 20% of patients achieved success in Investigator Static Global Assessment (ISGA) at day 8, 21.6% at day 15 and 30.2% at day 29. Success was defined as an ISGA score of clear or almost clear with a ≥2-grade improvement from baseline. Patients who achieved an ISGA response of clear or almost clear were 40.7% on day 8, 40.3% on day 15 and 47.3% on day 29. The mean percent change from baseline in the Eczema Area and Severity Index (EASI) was 49.5% at day 15 and 57.5% at day 29. The mean change from baseline in the Patient Oriented Eczema Measure (POEM) was 6.9 at day 8, 8.2 at day 15, and 8.5 at day 29.[2]
- Limitations of this study include its open-label nature and lack of a comparator group, as well as the exploratory nature of the efficacy analyses. In addition, as with any study in patients of this age range, the study relied on parents/observers/caregivers to report sensory AEs, such as 'application site pain. Additionally, because propylene glycol is found in numerous products, it was not possible to capture all potential sources of propylene glycol exposure, nor the frequency or quantity of exposure (particularly food/diet sources).

References

.EUCRISA® (crisaborole). Full Prescribing Information. March 2020. 2. Schlessinger J et al. Safety, effectiveness, and pharmacokinetics of crisaborole in infants aged 3 to <24 onths with mild-to-moderate atopic dermatitis: A phase IV, open-label study (CrisADe CARE 1). Am J Clin Dermatol. 2020;21(2):275-284.