Safety, Effectiveness, and Pharmacokinetics of Crisaborole in Infants Aged 3 to <24 Months with Mild-to-Moderate Atopic Dermatitis: A Phase IV Open-Label Study (CrisADe CARE 1)

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[a]At the time of this study.

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Supplemental Table 1. Outcome measure descriptions

Measure	Description
ISGA [1]	A 5-point global static assessment that considers presence/amount of erythema, induration/papulation, and oozing/crusting scored on a 5-point scale (0 = clear; 1 = almost clear; 2 = mild; 3 = moderate; 4 = severe)
EASI [2, 3]	• A composite score of the degree of erythema, induration/papulation, excoriation, and lichenification (4-point scale: 0 = absent; 1 = mild; 2 = moderate; 3 = severe) for each of four body regions, with adjustment for the %BSA involved for each body region, excluding the scalp, and for the proportion of the body region to the whole body • In the current study, body regions were proportion-adjusted for subjects aged ≤7 years
%BSA	Percentage of a patient's total body surface area that is AD involved, excluding the scalp
POEM [4]	• 5-point scale measuring the frequency of each of seven AD symptoms (dryness, itching, flaking, cracking, sleep loss, bleeding, and weeping) over the past week scored as occurring "no days" (0), "1 to 2 days" (1), "3 to 4 days" (2), "5 to 6 days" (3) or "every day" (4) • Total score ranges from 0–28, with higher score indicating greater symptom impact

	• The proxy version of POEM used in this study was validated for completion by parents or caregivers of patients aged 12 months to 69 years

%BSA percentage of treatable body surface area; *AD* atopic dermatitis; *EASI* Eczema Area and Severity Index; *ISGA* Investigator's Static Global Assessment; *POEM* Patient-Oriented Eczema Measure.

Supplemental Table 2. Propylene glycol concentration (ng/mL)

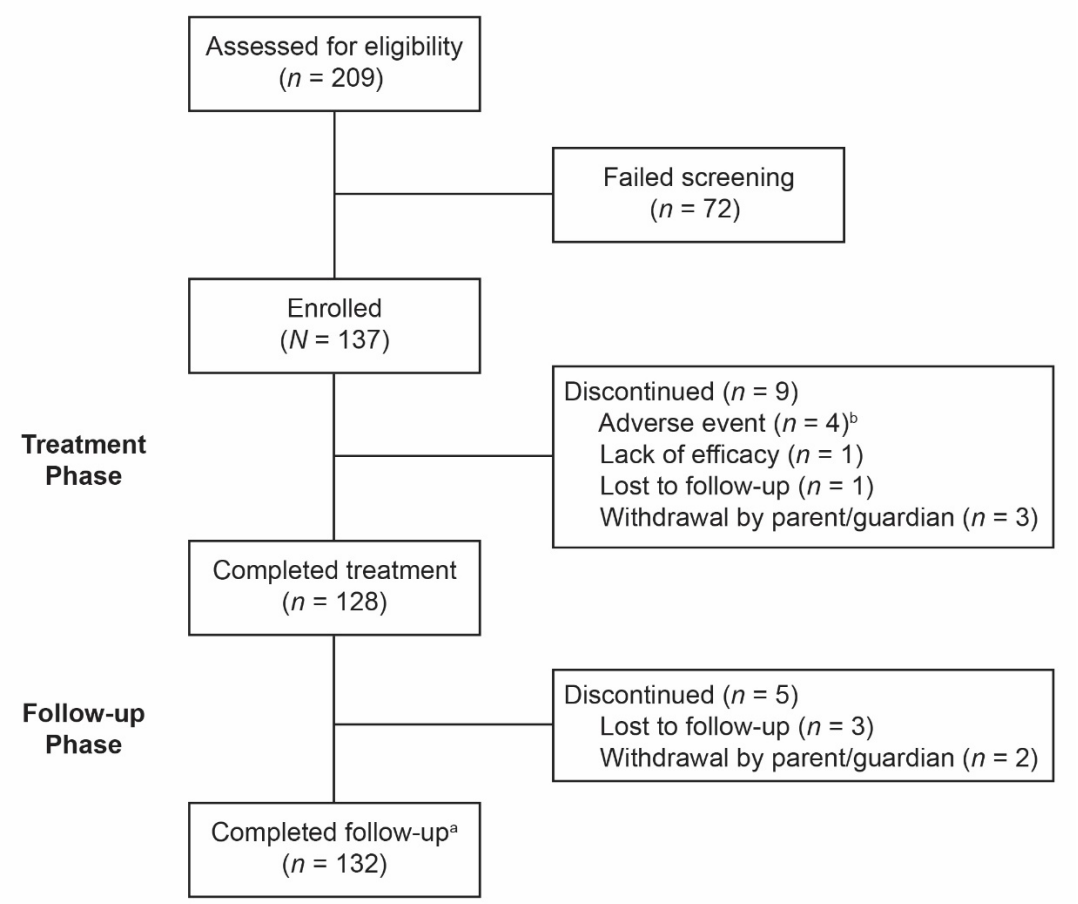
	Overall population	PK cohort	Overall population
Analysis visit	Screening *N* = 135	Day 8 *N* = 19	End of treatment *N* = 119
Mean (SD)	2838.84 (5099.61)	1380.26 (1737.1)	3906.54 (6828.21)
Median	1020 (0–30000)	916 (138–8130)	1190 (0–44000)

SD standard deviation.

Unplanned postbaseline visits were excluded.

The lower limit of quantification was 100 ng/mL. Summary statistics were calculated by setting concentration values below the lower limit of quantification to 0.

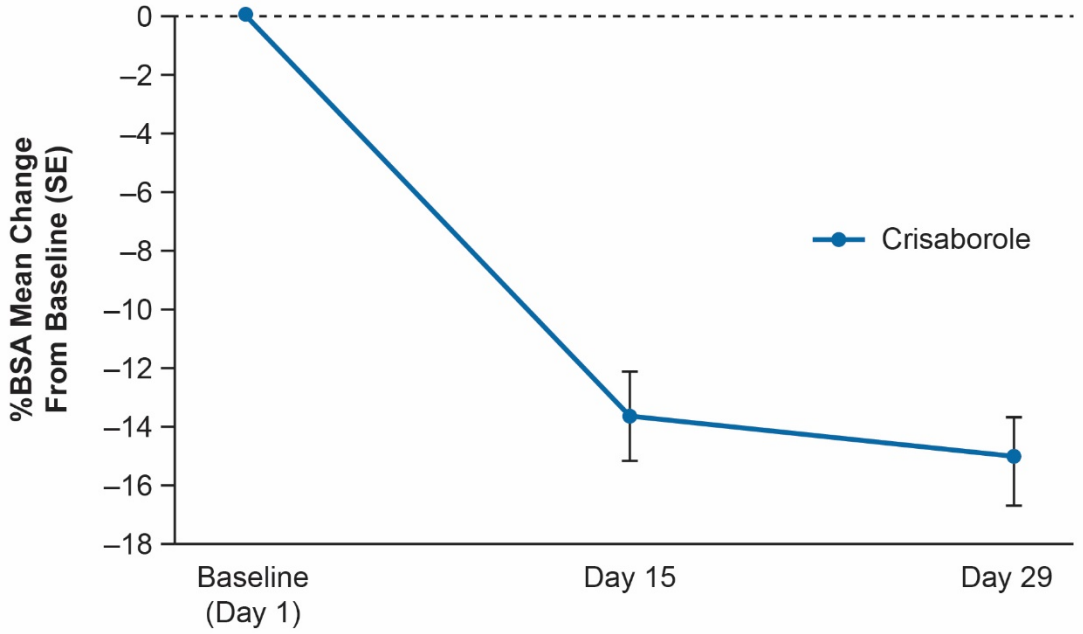
Supplemental Fig. 1 CONSORT diagram.



[a]Four patients who discontinued treatment during the treatment phase remained in the study and completed the follow-up phase.

[b]Adverse events leading to discontinuation of study drug were "febrile convulsion" (not related to treatment), "dermatitis infected" (not related to treatment), "application site pain" (treatment-related), and "application site discomfort" (treatment-related).

Supplemental Fig. 2 Mean change from baseline in %BSA with crisaborole.



Analysis Visit	n	Mean (SE)	Mean Change From Baseline (SE)
Baseline (Day 1)	137	28.12 (1.879)	—
Day 15	137	14.51 (1.149)	–13.61 (1.497)
Day 29	130	12.40 (1.181)	–15.24 (1.509)

%BSA percentage of treatable body surface area; *SE* standard error

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