Efficacy and Safety of Crisaborole Ointment, 2%, for Treatment of Mild to Moderate Atopic Dermatitis Across Racial and Ethnic Groups

Supplemental Tables 1-6.

Journal name: *American Journal of Clinical Dermatology*

Valerie D. Callender[1,2] • Andrew F. Alexis[3,4] • Linda F. Stein Gold[5] • Mark G. Lebwohl[4] • Amy S. Paller[6] • Seemal R. Desai[7,8] • Huaming Tan[9] • William C. Ports[9] • Michael A. Zielinski[10] • Anna M. Tallman[11*]

[1]Howard University College of Medicine, Washington, DC, USA; [2]Callender Dermatology & Cosmetic Center, Glenn Dale, Maryland, USA; [3] Mount Sinai St. Luke's and Mount Sinai West, New York, NY, USA; [4]Icahn School of Medicine at Mount Sinai, New York, NY, USA; [5]Henry Ford Health System, Detroit, MI, USA; [6]Northwestern University Feinberg School of Medicine, Chicago, IL, USA; [7]University of Texas Southwestern Medical Center, Dallas, TX, USA; [8]Innovative Dermatology, Plano, TX, USA; [9]Pfizer Inc., Groton, CT, USA; [10]Pfizer Inc., Collegeville, PA, USA; [11]Pfizer Inc., New York, NY, USA

*****Former Pfizer employee

Corresponding Author:

Valerie D. Callender, MD

Callender Dermatology & Cosmetic Center

12200 Annapolis Road, Suite 315

Glenn Dale, MD 20769

Email: drcallender@CallenderSkin.com

Supplementary Table 1. Baseline demographics and disease characteristics of nonwhite racial subgroups (AD-301 and AD-302 ITT population)

	Asian/Native Hawaiian/Other Pacific Islander		Black/African American		Other/American Indian/Alaskan Native	
	Crisaborole *N* = 59	Vehicle *N* = 35	Crisaborole *N* = 285	Vehicle *N* = 139	Crisaborole *N* = 55	Vehicle *N* = 26
Age, mean (range), y	12.7 (2–53)	18.1 (2–66)	12.5 (2–64)	13.0 (2–72)	10.6 (2–55)	9.2 (2–45)
Age group, %						
2–11 years	59.3	45.7	60.0	61.2	67.3	73.1
12–17 years	23.7	31.4	24.9	21.6	18.2	19.2
≥18 years	16.9	22.9	15.1	17.3	14.5	7.7
Sex, %						
Female	62.7	51.4	64.6	63.3	47.3	65.4
ISGA, %						
Mild: 2	25.4	34.3	42.8	39.6	41.8	42.3
Moderate: 3	74.6	65.7	57.2	60.4	58.2	57.7
Average SPS score, %						
None: 0 to <0.5	0.00	0.00	1.75	1.44	0.00	0.00
Mild: 0.5 to <1.5	15.25	22.86	19.30	23.02	14.55	23.08
Moderate: 1.5 to <2.5	35.59	28.57	28.42	29.50	43.64	42.31
Severe: 2.5 to ≤3	20.34	14.29	22.46	20.14	20.00	19.23

CDLQI						
N	44	24	221	106	43	24
Mean (SD)	8.2 (4.9)	8.7 (6.6)	10.9 (6.6)	9.8 (6.2)	10.0 (6.2)	8.2 (6.3)
DLQI						
N	14	10	60	31	11	2
Mean (SD)	11.9 (6.6)	10.3 (6.3)	8.2 (5.6)	10.0 (8.0)	10.3 (6.0)	17.0 (14.1)
DFI						
N	49	26	241	111	46	24
Mean (SD)	8.1 (6.2)	7.2 (6.0	9.5 (7.4)	8.7 (6.7)	7.7 (7.0)	6.3 (5.7)

ISGA Investigator's Static Global Assessment, *ITT* intention to treat, *CDLQI* Children's Dermatology Life Quality Index, *DFI* Dermatology Family Impact questionnaire, *DLQI* Dermatology Life Quality Index, *SPS* Severity of Pruritus; the ITT population was defined as all subjects who were randomly assigned and dispensed study drug.

Supplementary Table 2. Proportion of patients with success in lichenification at days 8, 15, 22, and 29 by race and ethnicity (pooled data, AD-301 and AD-302, ITT population with baseline score >0, observed cases)

Lichenification	Treatment (*N*)	*n* (%)	Nominal *P* Value	Lichenification	Treatment (*N*)	*n* (%)	Nominal *P* Value
White				**Nonwhite**			
Day 8	Crisaborole (558)	258 (46.2)	0.0005	Day 8	Crisaborole (376)	143 (38.0)	0.0429
	Vehicle (266)	90 (33.8)			Vehicle (186)	55 (29.6)	
Day 15	Crisaborole (549)	280 (51.0)	0.0041	Day 15	Crisaborole (360)	168 (46.7)	0.0008
	Vehicle (258)	104 (40.3)			Vehicle (178)	57 (32.0)	
Day 22	Crisaborole (539)	283 (52.5)	0.0420	Day 22	Crisaborole (357)	190 (53.2)	0.0579
	Vehicle (246)	110 (44.7)			Vehicle (171)	76 (44.4)	
Day 29	Crisaborole (535)	308 (57.6)	0.0066	Day 29	Crisaborole (360)	189 (52.5)	0.0169
	Vehicle (242)	114 (47.1)			Vehicle (171)	71 (41.5)	

Hispanic/Latino				**Not Hispanic/Latino**			
Day 8	Crisaborole (186)	94 (50.5)	0.0021	Day 8	Crisaborole (748)	307 (41.0)	0.0035
	Vehicle (94)	30 (31.9)			Vehicle (358)	115 (32.1)	
Day 15	Crisaborole (181)	97 (53.6)	0.0013	Day 15	Crisaborole (728)	351 (48.2)	0.0011
	Vehicle (92)	31 (33.7)			Vehicle (344)	130 (37.8)	
Day 22	Crisaborole (179)	93 (52.0)	0.0325	Day 22	Crisaborole (717)	380 (53.0)	0.0412
	Vehicle (84)	32 (38.1)			Vehicle (333)	154 (46.2)	
Day 29	Crisaborole (180)	101 (56.1)	0.0215	Day 29	Crisaborole (715)	396 (55.4)	0.0036
	Vehicle (85)	35 (41.2)			Vehicle (328)	150 (45.7)	

ITT intention to treat; the ITT population was defined as all subjects who were randomly assigned and dispensed study drug.

Supplementary Table 3. Proportion of patients with success in lichenification at days 8, 15, 22, and 29 in nonwhite racial subgroups (pooled data, AD-301 and AD-302, ITT population with baseline score >0, observed cases)

Lichenification	Treatment (*N*)	*n* (%)	Nominal *P* Value
Asian/native Hawaiian/other Pacific Islander			
Day 8	Crisaborole (57)	24 (42.1)	0.0240
	Vehicle (34)	7 (20.6)	
Day 15	Crisaborole (56)	27 (48.2)	0.0530
	Vehicle (32)	9 (28.1)	
Day 22	Crisaborole (55)	30 (54.5)	0.0382
	Vehicle (31)	10 (32.3)	
Day 29	Crisaborole (55)	30 (54.5)	0.0520
	Vehicle (30)	10 (33.3)	

Black/African American			
Day 8	Crisaborole (266)	95 (35.7)	0.1906
	Vehicle (130)	38 (29.2)	
Day 15	Crisaborole (252)	117 (46.4)	0.0041
	Vehicle (124)	39 (31.5)	
Day 22	Crisaborole (250)	129 (51.6)	0.4142
	Vehicle (119)	56 (47.1)	
Day 29	Crisaborole (252)	131 (52.0)	0.1787
	Vehicle (119)	53 (44.5)	
Other/American Indian/Alaskan native			
Day 8	Crisaborole (53)	24 (45.3)	0.9892
	Vehicle (22)	10 (45.5)	
Day 15	Crisaborole (52)	24 (46.2)	0.6762
	Vehicle (22)	9 (40.9)	
Day 22	Crisaborole (52)	31 (59.6)	

	Vehicle (21)	10 (47.6)	0.3505
Day 29	Crisaborole (53)	28 (52.8)	
	Vehicle (22)	8 (36.4)	0.1820

ITT intention to treat; the ITT population was defined as all subjects who were randomly assigned and dispensed study drug.

Supplementary Table 4. Change from baseline in CDLQI, DLQI, and DFI of patients and parents/caregivers in nonwhite racial subgroups at day 29 (pooled data, AD-301 and AD-302, ITT population). Data shown are least squares mean change from baseline.

	Asian/Native Hawaiian/Other Pacific Islander			Black/African American			Other/American Indian/Alaskan Native		
	Crisaborole	Vehicle	Nominal *P* Value	Crisaborole	Vehicle	Nominal *P* Value	Crisaborole	Vehicle	Nominal *P* Value
CDLQI									
N	44	21		201	93		43	22	
Change	-2.7	-2.7	0.9742	-5.4	-3.7	0.0026	-4.5	-2.5	0.1039
DLQI									
N	13	9		56	28		11	2	
Change	-3.0	-2.6	0.8258	-5.2	-2.9	0.0051	-6.7	-0.89	0.2514
DFI									
N	49	22		221	98		46	22	
Change	-2.0	-2.2	0.8843	-4.8	-3.3	0.0096	-3.1	-2.0	0.3834

CDLQI, Children's Dermatology Life Quality Index; DFI, Dermatitis Family Impact Questionnaire; DLQI, Dermatology Life Quality Index.

Supplementary Table 5. Treatment-emergent adverse events in nonwhite racial subgroups (pooled data, AD-301 and AD-302, safety population)

Frequency of TEAEs, n (%)	Asian/Native Hawaiian/Other Pacific Islander		Black/African American		Other/American Indian/Alaskan Native	
	Crisaborole *N* = 59	Vehicle *N* = 35	Crisaborole *N* = 283	Vehicle *N* = 136	Crisaborole *N* = 55	Vehicle *N* = 25
≥1 TEAEs	19 (32.2)	10 (28.6)	69 (24.4)	30 (22.1)	21 (38.2)	9 (36.0)
≥1 serious TEAEs	1 (1.7)	0	2 (0.7)	0	1 (1.8)	0
Any treatment-related TEAE	3 (5.1)	2 (5.7)	19 (6.7)	3 (2.2)	9 (16.4)	1 (4.0)
Treatment-related TEAEs						
Mild	2 (3.4)	1 (2.9)	5 (1.8)	1 (0.7)	6 (10.9)	1 (4.0)
Moderate	1 (1.7)	1 (2.9)	11 (3.9)	2 (1.5)	2 (3.6)	0
Severe	0	0	3 (1.1)	0	1 (1.8)	0
TEAEs that led to discontinuation of drug	0	0	7 (2.5)	1 (0.7)	0	0

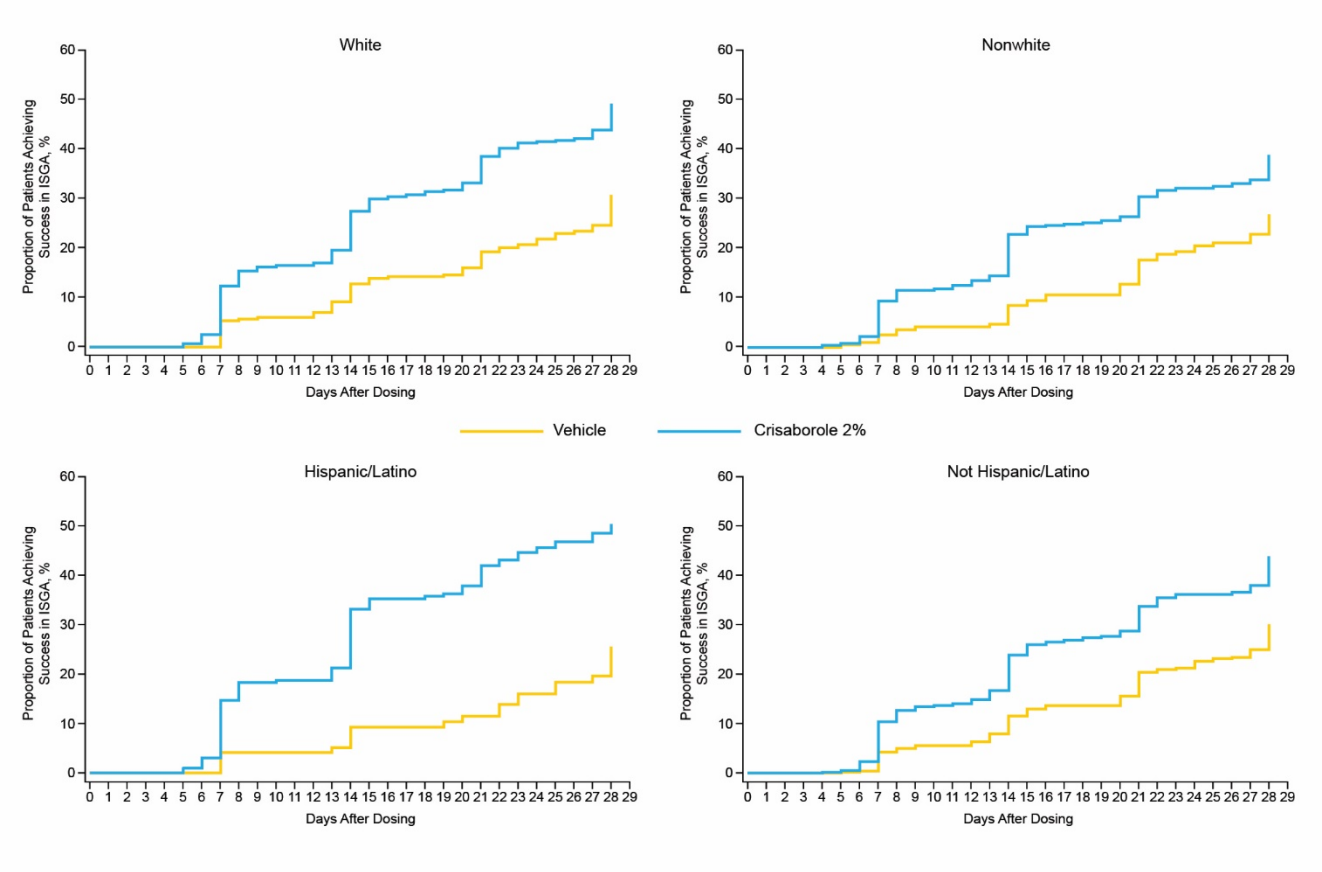
TEAE treatment-emergent adverse event; the safety population was defined as all subjects who were randomized, received ≥1 confirmed dose of study drug, and had ≥1 postbaseline assessment.

Supplementary Table 6. Treatment-emergent adverse events in nonwhite racial subgroups (AD-303, safety population)

Frequency of TEAEs, *n* (%)	Asian/Native Hawaiian/Other Pacific Islander	Black/African American	Other/American Indian/Alaskan Native
	N = 29	*N* = 152	*N* = 21
≥1 TEAEs	15 (51.7)	76 (50.0)	18 (85.7)
≥1 serious TEAEs	0 (0)	5 (3.3)	1 (4.8)
Any treatment-related TEAE	3 (10.3)	12 (7.9)	5 (23.8)
TEAEs that led to discontinuation of drug	0 (0)	3 (2.0)	1 (4.8)

TEAE treatment-emergent adverse event; Treatment-emergent adverse events were those with an onset on or after the day of the first study drug (crisaborole ointment, 2%, or vehicle) application in AD-301 or AD-302; includes all TEAEs with an onset on or after the day of the first study drug application (crisaborole or vehicle) in AD-301 or AD-302; the safety population was defined as all subjects who were randomized, received ≥1 confirmed dose of study drug, and had ≥1 postbaseline assessment.

Supplementary Figure 1. Kaplan-Meier plots of time to success in ISGA by race and ethnicity (pooled data, AD-301 and AD-302, ITT population, observed cases)



Supplementary Figure 2. Kaplan-Meier plots of time to success in ISGA by nonwhite racial subgroup (pooled data, AD-301 and AD-302, ITT population, observed cases)