Efficacy and Safety Trends With Continuous Long-Term Use of Crisaborole Ointment, 2%, in Patients With Mild-to-Moderate Atopic Dermatitis

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Disclosures

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Introduction, Methods, and Baseline Characteristics

Introduction

- AD is a chronic inflammatory skin disease that often requires long-term treatment
- Crisaborole is a nonsteroidal PDE4 inhibitor for the treatment of mild-to-moderate AD

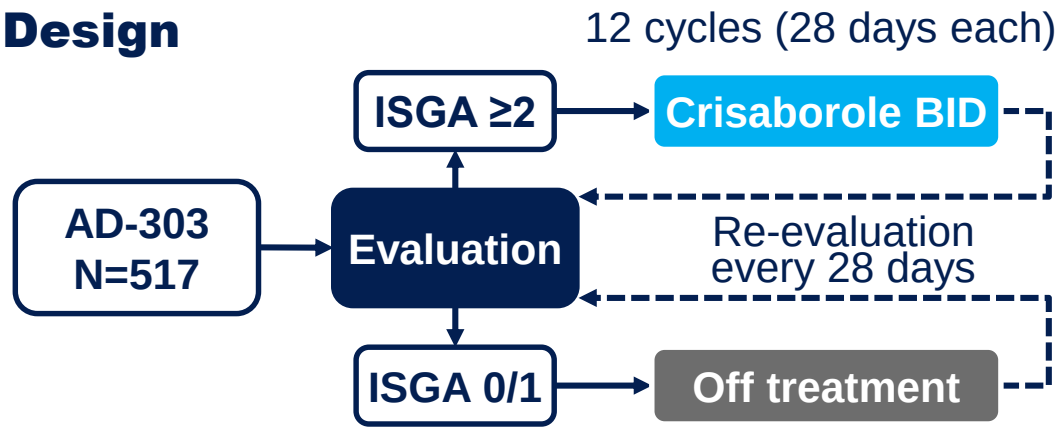
Objective

- Assess efficacy and safety of crisaborole for long-term use in patients aged ≥2 years with mild-to-moderate AD

Methods

- Patients who completed AD-301 (NCT02118766) or AD-302 (NCT02118792) (28-day, double-blind, vehicle-controlled phase 3 studies) without safety concerns were eligible to enroll in AD-303 (48-week, open-label, phase 3 extension study)
- Post hoc analysis of AD-303
  - Patients were stratified by number of initial consecutive on-treatment cycles (1, 2, 3, or 4 cycles) into cohorts 1 through 4, respectively

Study Design

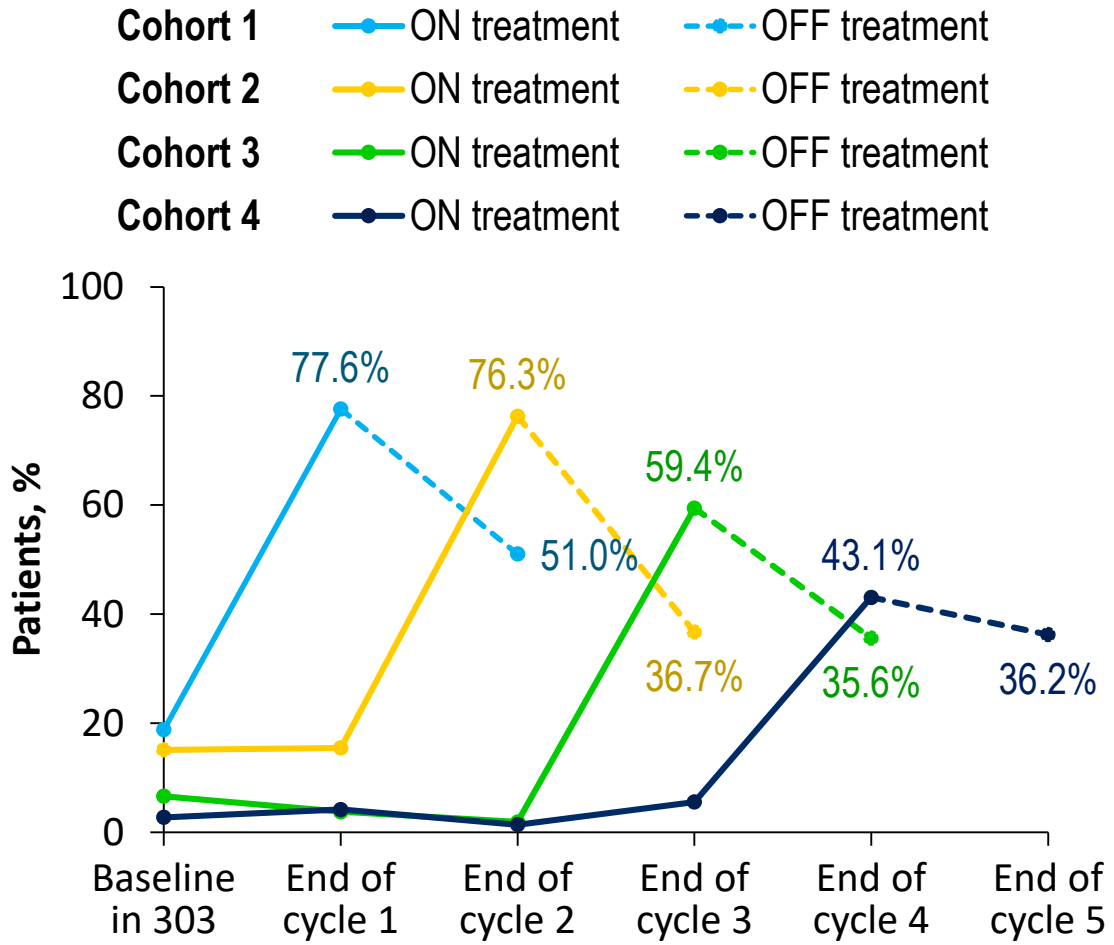


Baseline in AD-303	Cohort 1 N=133	Cohort 2 N=106	Cohort 3 N=106	Cohort 4 N=73
Age, mean (SD), years	11.4 (10.1)	13.7 (12.2)	10.9 (9.9)	11.0 (9.8)
White race, n (%)	85 (63.9)	67 (63.2)	66 (62.3)	40 (54.8)
%BSA, mean (SD)	18.3 (18.8)	18.4 (16.4)	20.6 (19.6)	19.6 (17.3)
ISGA, n (%)				
Clear (0)	7 (5.3)	6 (5.7)	3 (2.8)	1 (1.4)
Almost clear (1)	18 (13.5)	10 (9.4)	4 (3.8)	1 (1.4)
Mild (2)	61 (45.9)	47 (44.3)	46 (43.4)	21 (28.8)
Moderate (3)	44 (33.1)	42 (39.6)	50 (47.2)	46 (63.0)
Severe (4)	3 (2.3)	1 (0.9)	3 (2.8)	4 (5.5)

%BSA, percentage of treatable body surface area; AD, atopic dermatitis; BID, twice daily; ISGA, Investigator's Static Global Assessment; PDE4, phosphodiesterase 4.

Efficacy Results

Patients Achieving ISGA 0/1 at the End of Each On-Treatment Cycle and After 28 Days Off Treatment



	Cohort 1	Cohort 2	Cohort 3	Cohort 4
Restarted treatment				
n/N (%)	80/133 (60.2)	68/106 (64.2)	79/106 (74.5)	60/73 (82.2)
Consecutive cycles off treatment				
Mean (SD)	2.2 (2.7)	1.7 (2.4)	1.6 (1.8)	2.1 (1.9)
Median (range)	1.0 (0-11)	1.0 (0-10)	1.0 (0-9)	1.0 (0-8)
Achieved ISGA 0/1 at end of first retreatment cycle				
n/N (%)	42/80 (52.5)	26/68 (38.2)	29/79 (36.7)	14/60 (23.3)

ISGA, Investigator's Static Global Assessment.

Safety Results and Conclusions

All-Cause and Treatment-Related Adverse Events (AEs) by Cohort

	Cohort 1 N=133	Cohort 2 N=106	Cohort 3 N=106	Cohort 4 N=73
Treatment-Emergent AEs (TEAEs)				
Any TEAE, n (%)	25 (18.8)	33 (31.1)	35 (33.0)	31 (42.5)
Most frequently reported (≥5% in any group), n (%)				
Dermatitis atopic	5 (3.8)	5 (4.7)	8 (7.5)	5 (6.8)
Cough	3 (2.3)	1 (0.9)	2 (1.9)	5 (6.8)
Upper respiratory tract infection	4 (3.0)	2 (1.9)	4 (3.8)	5 (6.8)
Viral upper respiratory tract infection	1 (0.8)	3 (2.8)	6 (5.7)	1 (1.4)
Treatment-Related AEs (TRAEs)				
Any TRAE, n (%)	6 (4.5)	5 (4.7)	4 (3.8)	1 (1.4)
Most frequently reported (≥2% in any group), n (%)				
Dermatitis atopic	2 (1.5)	4 (3.8)	1 (0.9)	1 (1.4)
Treatment-related application site reactions, n (%)				
Application site dermatitis	0	0	0	0
Application site pain	1 (0.8)	1 (0.9)	2 (1.9)	0
Application site paraesthesia	1 (0.8)	0	0	0
Application site pruritus	0	0	2 (1.9)	0

Conclusions

- Some patients, particularly those with greater disease severity, may require longer periods of treatment to achieve ISGA clear/almost clear (ie, twice daily for up to 4 cycles)
- Upon discontinuing therapy, some patients maintain ISGA clear/almost clear for ~1-2 months (ie, had 1 or 2 off-treatment cycles before restarting); ISGA clear/almost clear was re-achieved upon restarting therapy
- No new safety signals were observed with crisaborole being used for multiple consecutive cycles

ISGA, Investigator's Static Global Assessment.