AAD annual MEETING
MARCH 17–21, 2023
NEW ORLEANS, LA

S042 - Late-Breaking Research: Session 2

A Randomized, Double-blind, Vehicle-controlled, Sample Size Adaptive Design Study To Evaluate The Safety And Efficacy Of Topically Applied EB01 Cream In Adult Subjects With Moderate To Severe Chronic Allergic Contact Dermatitis

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DISCLOSURE OF RELATIONSHIPS WITH INDUSTRY

Blair Gordon, PhD;

S042 - Late-Breaking Research: Session 2

"A Randomized, Double-blind, Vehicle-controlled, Sample Size Adaptive Design Study to Evaluate the Safety and Efficacy of Topically Applied EB01 Cream in Adult Subjects with Moderate to Severe Chronic Allergic Contact Dermatitis"

DISCLOSURES

Edesa Biotech, Employee, Salary and Stock Options

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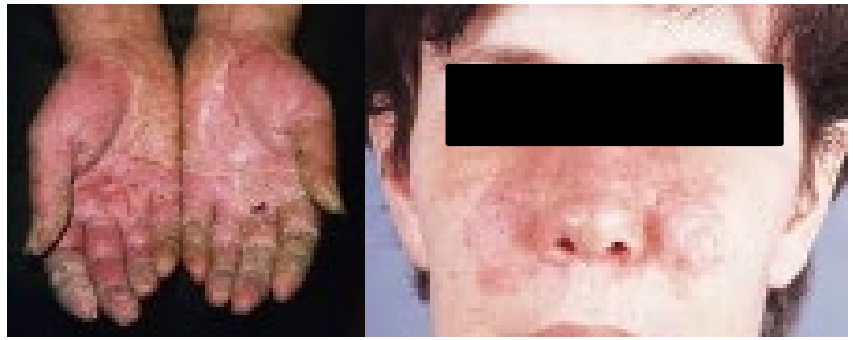
Background: Disease and Current treatment

Allergic Contact Dermatitis (ACD)

- A type IV hypersensitivity reaction, induced upon contact with an allergen
- **Causative allergen can be difficult to identify, and many patients are unable to fully avoid contact leading to Chronic ACD**

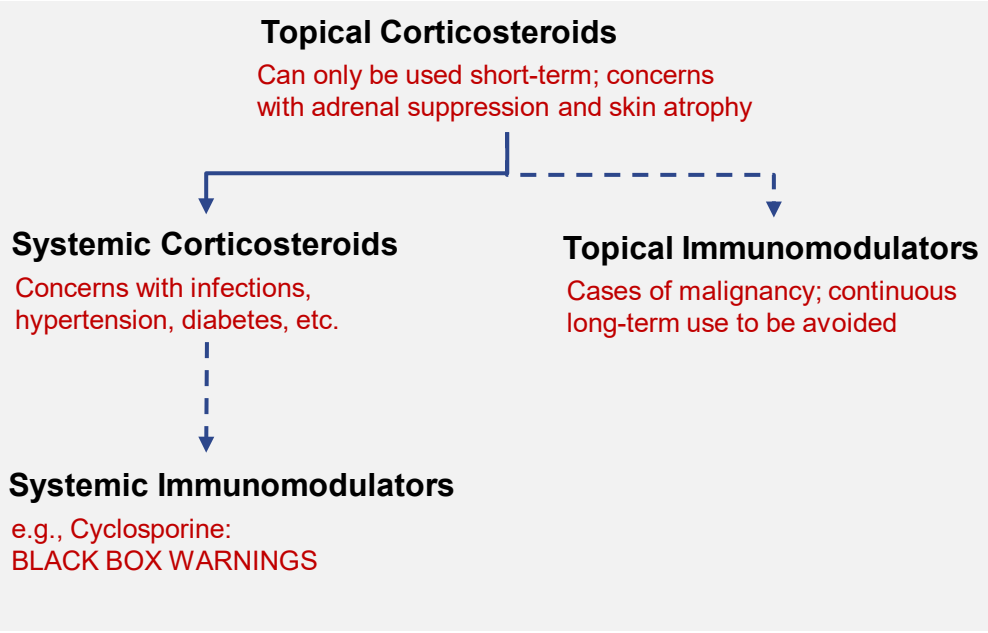
Current Treatment

- **No approved treatments for ACD** with patients relying on non-specific corticosteroids and immunomodulators
- Limitations of treatments: safety concerns, low efficacy leading to short-term benefits for a chronic disease



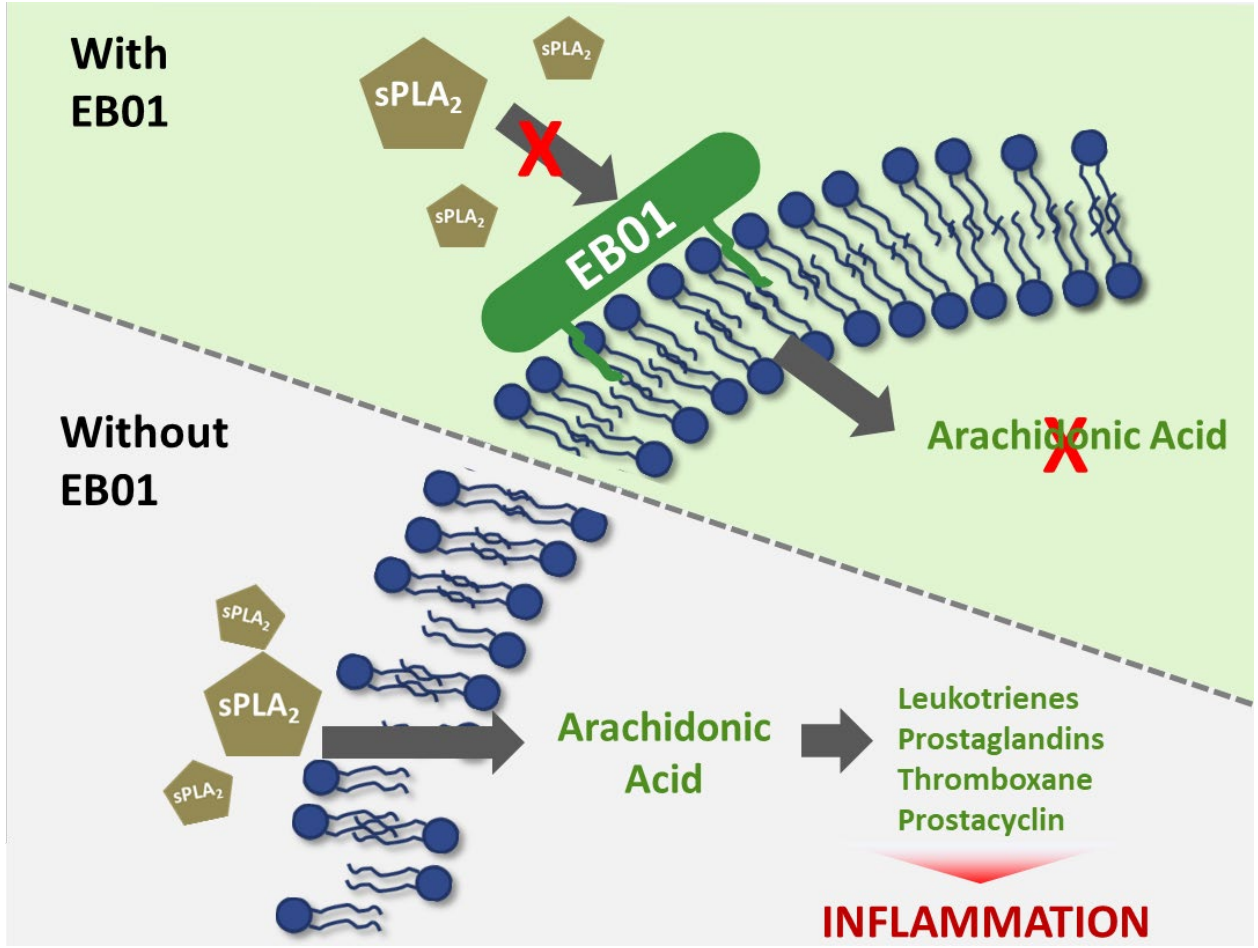
Current Limited Treatment Approaches for ACD

Safety Issues Often Result in Discontinuation of Treatment



EB01: A Secreted Phospholipase A_2 Inhibitor

Inflammatory/Allergic Process



- **EB01 is composed of a secreted phospholipase A_2 (sPLA2) inhibitor, conjugated to a Glycosaminoglycan molecule**
- **EB01 inhibits the inflammatory/allergic process at its inception**
  - Upstream of NSAIDs
  - Non-steroidal
- **Positive efficacy and safety data from two exploratory clinical studies[1]**

[1]Ingber A., et al. 2007 A novel treatment of contact dermatitis by topical application of phospholipase A2 inhibitor: a double-blind placebo-controlled pilot study. Int J Immunopathol Pharmacol;20(1):191-5.

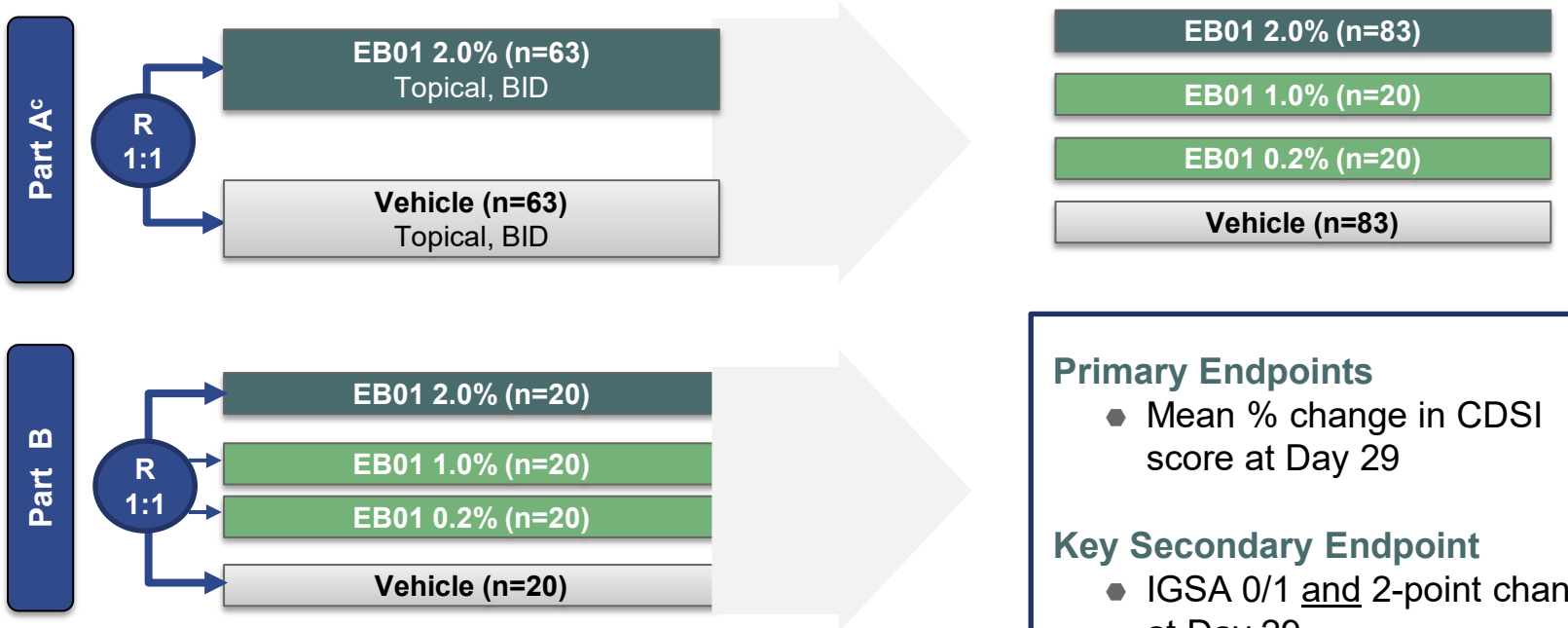
Phase 2B Study: EB01 Versus Vehicle in Patients with Chronic Moderate to Severe ACD

Phase 2b Design: Multi-center, randomized, double-blind, vehicle-controlled, dose-ranging study

Chronic moderate to severe ACD[a]
12 sites

Key Eligibility:

- Age ≥ 18 y
- 0.5-10% of total BSA
- CDSI ≥ 7, ISGA ≥ 3
- Positive patch test to suspected allergen
- No concomitant treatment and with adequate wash-out of previous therapy[b]



Primary Endpoints

- Mean % change in CDSI score at Day 29

Key Secondary Endpoint

- IGSA 0/1 and 2-point change at Day 29

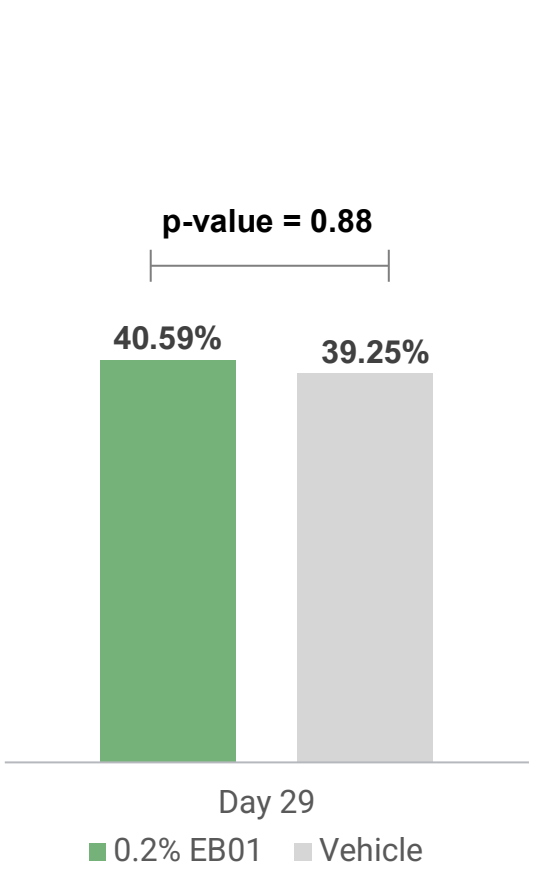
[a] Moderate to severe chronic allergic contact dermatitis at Day 1, defined by either one of the following: CDSI score ≥ 7,CDSI score of severe (3) in ≥ 2 of the 5 assessed symptoms (Fissures, Scaling Redness, Pruritus, Dryness). [b] Wash-outs for systemic treatments (other than biologics) less than 2 weeks prior to Day 1; biological agent within 12 weeks or 5 half-lives (whichever is longer) prior to Day 1; topical medicated treatment within 1 week prior to Day 1. [c] Blinded interim analysis for possible sample size adjustment up to 126 Subjects or terminate early for futility

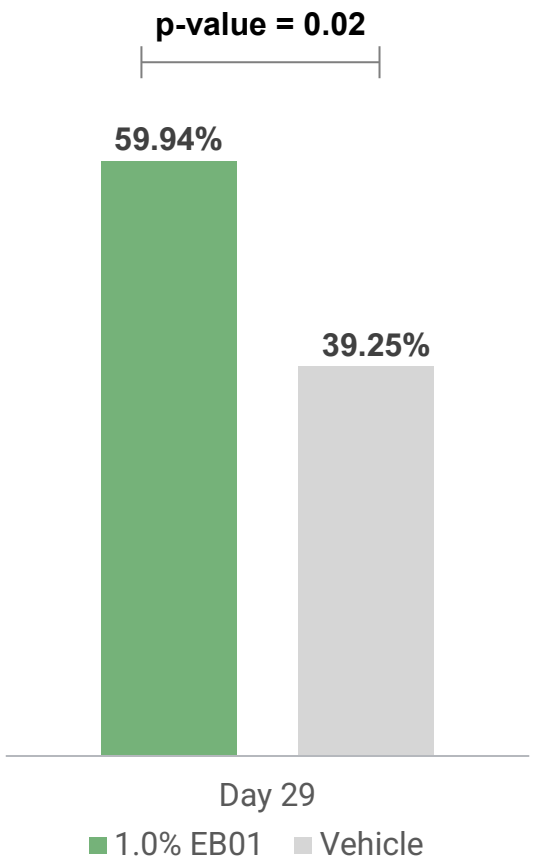
Baseline Patient and Disease Characteristics

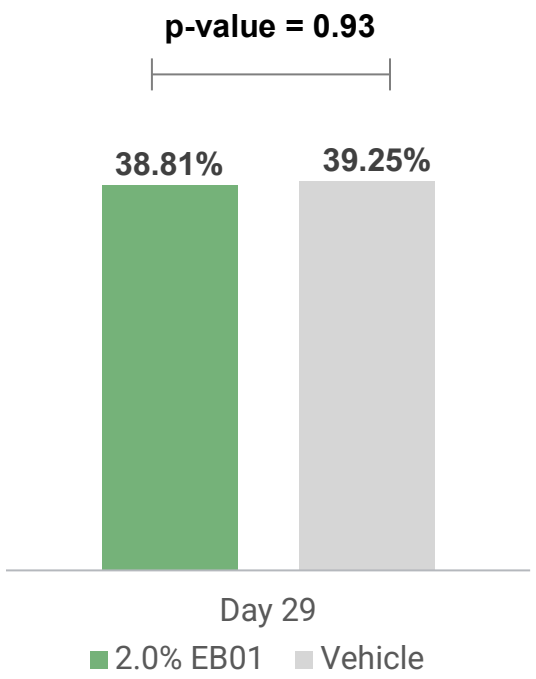
		EB01 0.2%	EB01 1.0%	EB01 2.0%	Vehicle
Randomized (n)		19	19	81	84
Age (y)	Mean	51.1	49.5	46.4	46.2
	Range	23 - 72	18 -70	19 - 83	18 - 80
Sex (%)	Male	21.1%	36.8%	35.8%	28.6%
	Female	78.9%	63.2%	64.2%	71.4%
Race (%)	Black or African American	26.3%	26.3%	8.6%	7.1%
	American Indian or Alaska Native	0.0%	0.0%	0.0%	0.0%
	Native Hawaiian or other Pacific Islander	0.0%	0.0%	1.2%	0.0%
	Asian	0.0%	0.0%	8.6%	8.3%
	White	73.7%	73.7%	81.5%	82.1%
	Other	0.0%	0.0%	0.0%	2.4%
Baseline CDSI Score	Mean	10.0	9.3	10.0	10.1
	SD	1.5	2.3	1.8	2.1
Baseline ISGA (%)	Moderate (3)	100.0%	89.5%	85.2%	81.0%
	Severe (4)	0.0%	10.5%	14.8%	19.0%
Baseline BSA (%)	Mean	3.7	3.0	3.7	3.4
	SD	2.7	2.2	2.7	2.3

Primary Endpoint

Mean % improvement from baseline of the CDSI at Day 29

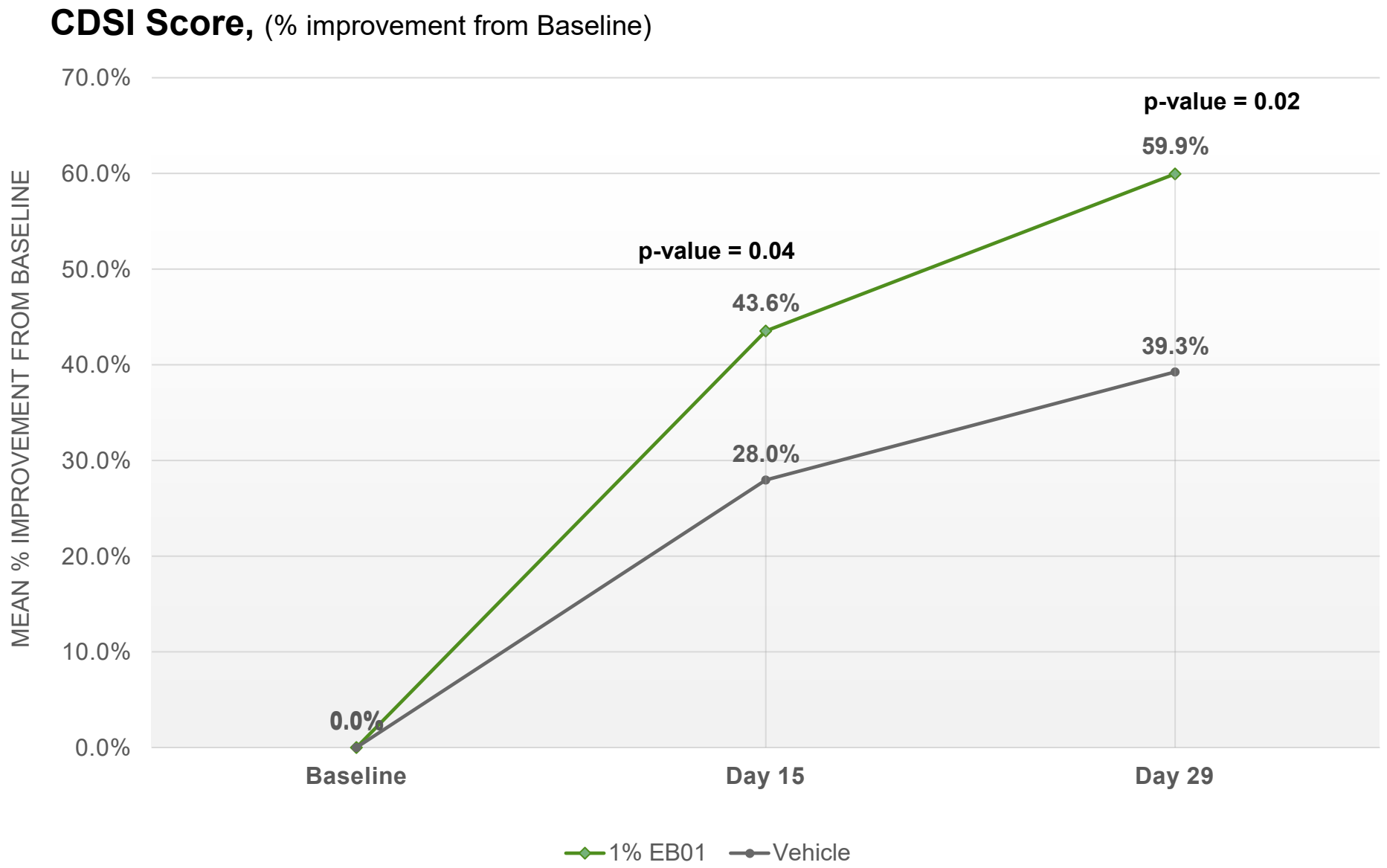






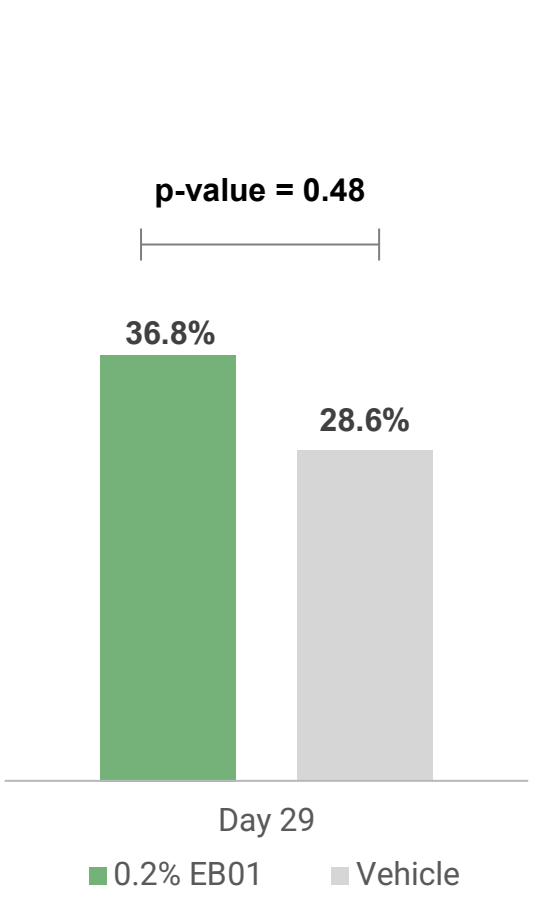
Onset of Action

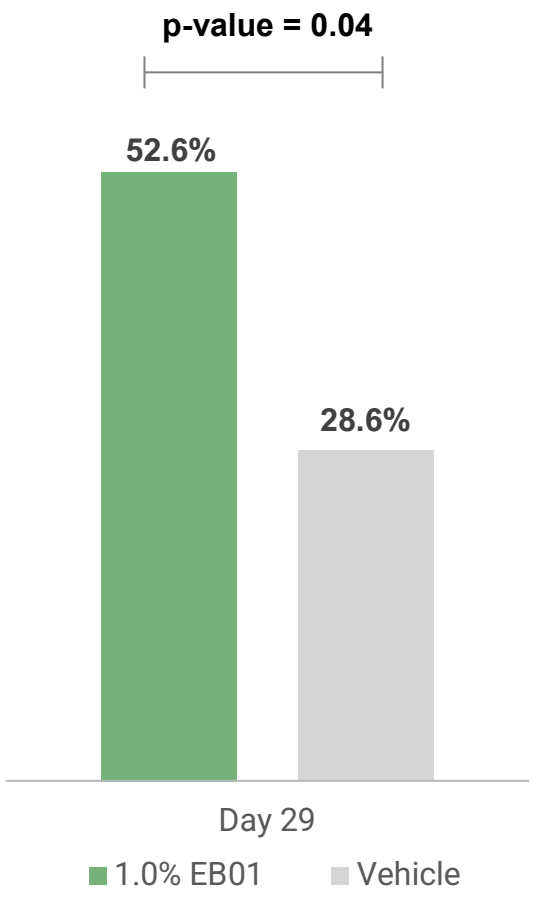
Mean % improvement from baseline of the CDSI over time for EB01 1.0%

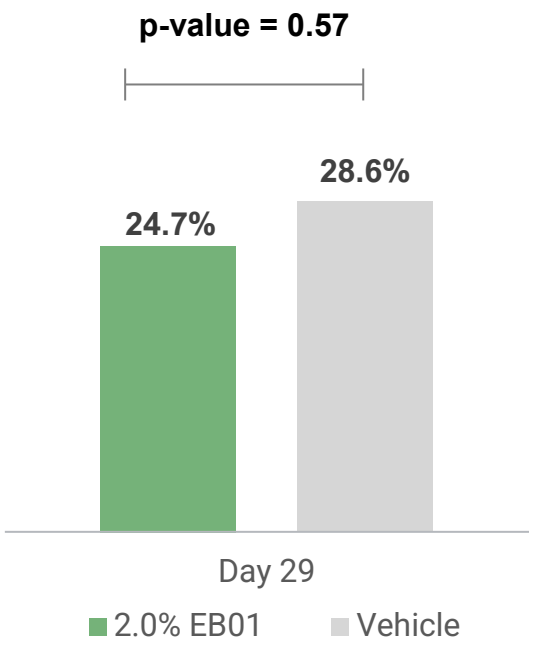


Secondary Endpoint

% of patients achieving success on the ISGA* at Day 29







*IGSA 0/1 and 2-point change at Day 29

Safety

Summary of Incidence of Treatment Emergent Adverse Events

Parameter	Treatment Group							
	Placebo/Vehicle (n=84)		EB01 2.0% Cream (n=81)		EB01 1.0% Cream (n=19)		EB01 0.2% Cream (n=19)	
	Number of Events	Subjects (%)	Number of Events	Subjects (%)	Number of Events	Subjects (%)	Number of Events	Subjects (%)
Overall	35	21(25%)	53	30(37%)	0	0(0%)	1	1(5%)
Severity, n (%)								
Mild	23	15(18%)	35	21(26%)	0	0(0%)	1	1(5%)
Moderate	7	6(7%)	15	5(19%)	0	0(0%)	0	0(0%)
Severe	5	2(2%)	3	3(4%)	0	0(0%)	0	0(0%)
Seriousness, n (%)								
No	34	21(25%)	53	30(37%)	0	0(0%)	1	1(5%)
Yes	1	1(1%)	0	0(0%)	0	0(0%)	0	0(0%)

Conclusions

- **The study identified the EB01 1.0% cream as the lowest efficacious dose.**
- **The EB01 1.0% cream demonstrated a meaningful clinical benefit over Vehicle:**
  - 60% average improvement in symptoms from baseline on the CDSI versus 39% for the vehicle-treated patients
  - 53% of the patients achieved a ISGA 0/1 and 2-point improvement versus 29% for the vehicle
- **Favorable safety profile was observed in the EB01 1.0% cream**
  - No adverse events were reported for the 1.0% cream
- **If these results are confirmed in Phase 3 studies, EB01 may offer Chronic ACD patients a targeted, novel treatment option**

Acknowledgements

- The patients, families and caregivers

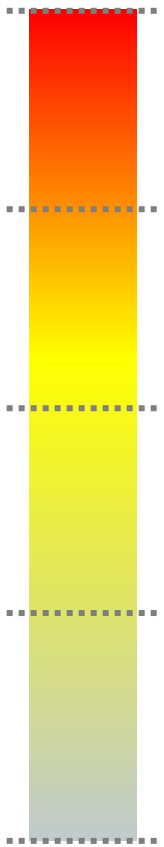
- The entire Phase 2b EB01 study team of investigators (Dr. Belsito, Dr. Christofer N. Buatti, Dr. Vincette Chavarria, Dr. Alison Ehrlich, Dr. Joseph Fowler, Dr. Jorge Garcia-Zuazaga, Dr. Rola Gharib-Rucker, Dr. Scott Guenthner, Dr. Nicole Mathis Harrell, Dr. Bruce Katz, Dr. Kenneth Kim, Dr. Steve Kempers, Dr. Alda Lugo-Somolinos, Dr. Charles Lynde, Dr. Danielle Manolakos, and Dr. Matthew Zirwas) coordinators, and healthcare staff at each study site

CDSI Scale

Fissures	Scaling	Redness	Pruritus	Dryess
3	3	3	3	3
Marked, deep or Extensive fissures	Severe Scaling	Deep, marked, Extensive redness	Bothersome itching, Disturbs sleep/activity	Extensive dryness
2	2	2	2	2
Definite fissures	Moderate Scaling	Dull red, clearly distinguishable	Consent/intermittent, Does not disturb sleep	Definite dryness
1	1	1	1	1
Mild fissures	Minor Scaling	Mildly detectable Erythema, pink	Ocasional, slight itching	Minor or faint Signs of dryness
0	0	0	0	0
No evidence of fissure	No visible flakes	No Redness	No itching	No dryness

CDSI Composite Score

ISGA Scale



4	Severe	Deep or bright red erythema with severe induration/papulation with oozing/crusting.
3	Moderate	Pink-red erythema with moderate induration/papulation with or without oozing/crusting.
2	Mild	Faint pink erythema with mild induration/papulation no oozing/crusting
1	Almost Clear	Trace faint pink erythema, no induration/papulation and no oozing/crusting.
0	Clear	Minor, residual hypopigmentation/hyperpigmentation; no erythema or induration/papulation; no oozing/crusting.