

Roflumilast Foam 0.3% in Patients With Seborrheic Dermatitis and Prior Inadequate Response, Intolerance, or Contraindication to Topical Antifungals and/or Topical Corticosteroids

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INTRODUCTION

- Seborrheic dermatitis is a chronic, inflammatory skin disease associated with flaking scales and persistent itch, most commonly on the scalp, face, and upper torso¹
- Common treatments for seborrheic dermatitis include topical antifungal (TAF) and anti-inflammatory (eg, TCS) products; however, antifungal resistance and corticosteroid side effects are important treatment considerations²
 - Prolonged use of TAF may result in irritant contact dermatitis and promote microbial resistance,² and prolonged or potent TCS use poses a risk of skin atrophy, striae, and hypopigmentation³
 - Additional limitations of TCS include recommendations against long-term use and use of potent agents in thin-skinned areas where there is greater systemic absorption⁴
- Roflumilast foam 0.3% is a PDE4 inhibitor–based advanced targeted topical therapy that does not contain excipients such as propylene glycol, formaldehyde, or fragrances that may irritate skin or damage hair and is suitable for all hair types^{5,6}
- The efficacy and safety of roflumilast foam 0.3% versus vehicle foam for the treatment of seborrheic dermatitis were demonstrated in the 8-week, phase 3 STRATUM trial⁷
- Subgroup analysis of patients from STRATUM with prior inadequate response or intolerance (referred to as failure) or contraindication to TAF and/or TCS

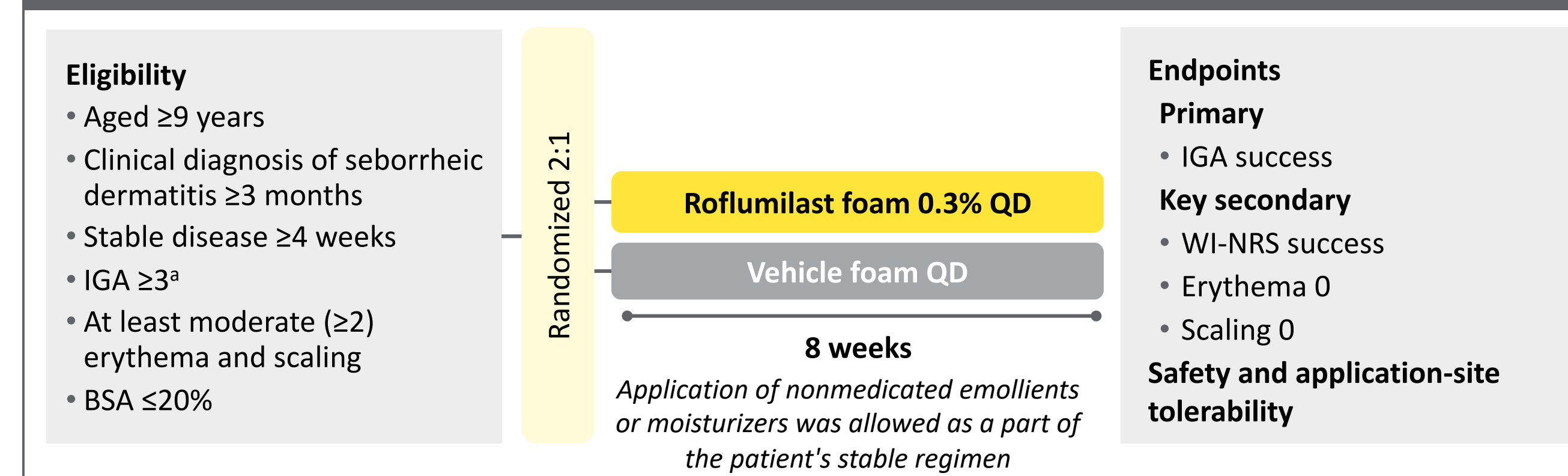
METHODS

- Patients aged ≥9 years with moderate-to-severe seborrheic dermatitis (IGA ≥3) for ≥3 months that was stable for ≥4 weeks with moderate-to-severe erythema and scaling were enrolled

Endpoints

- IGA success, defined as clear/almost clear (0/1) plus ≥2-point improvement from baseline
- WI-NRS success, defined as ≥4-point improvement in patients with baseline WI-NRS ≥4
- Erythema and scaling scores of 0, each measured on a 4-point scale from 0 (none) to 3 (severe)
- Safety and application-site tolerability

Study Design



RESULTS

- Baseline demographics were comparable among the 457 patients randomized to the roflumilast foam 0.3% and vehicle foam groups
 - Half of the patients were female, mean age was 42.7 years, and most patients were White (77.9%) and not Hispanic or Latino (78.8%)
- 30.6% and 41.4% of patients had prior failure/contraindication to TAF and TCS, respectively
- Significantly higher proportions of patients achieved IGA success with roflumilast foam 0.3% versus vehicle foam at week 8 overall (79.5% vs 58.0%), and in prior failure/contraindication to TAF (80.5% vs 27.6%) and TCS (78.8% vs 48.3%) subgroups (each $P < 0.001$)
- At week 8, roflumilast foam 0.3% improved itch symptoms (WI-NRS success) overall (62.8% vs 40.6%; $P \leq 0.0001$) and in prior failure/contraindication to TAF (66.3% vs 34.9%; $P < 0.05$) and TCS (58.4% vs 37.6%) subgroups
- Significantly higher proportions of patients reported no erythema ($P < 0.0001$) or scaling ($P < 0.05$) with roflumilast versus vehicle at week 8, overall and across subgroups
- No treatment-related SAEs were reported; there was 1 patient with an application-site pain AE in the roflumilast foam 0.3% group
 - No evidence of application-site irritation with roflumilast (investigator-reported) for ≥98.9% of patients at all assessments

Patient Demographics and Baseline Clinical Characteristics

	Roflumilast foam 0.3% (n=304)	Vehicle foam (n=153)
Age, years, mean (median) [range]	43.2 (42.0) [9–87]	41.8 (40.0) [9–83]
Female sex at birth, n (%)	151 (49.7)	78 (51.0)
Not Hispanic or Latino	235 (77.3)	125 (81.7)
Race		
White	234 (77.0)	122 (79.7)
Black or African American	36 (11.8)	15 (9.8)
Asian	18 (5.9)	10 (6.5)
Other	15 (4.9)	5 (3.3)
Multiple	1 (0.3)	1 (0.7)
BSA, %, mean (median) [range]	2.9 (2.5) [0.3–15.0]	3.0 (2.0) [0.2–20.0]
IGA, n (%)		
Moderate (3)	287 (94.4)	141 (92.2)
Severe (4)	17 (5.6)	12 (7.8)
WI-NRS, mean (median) [range] ^a	5.1 (5.0) [0–10]	4.9 (5.0) [0–10]
Erythema ^b		
Moderate (2)	282 (92.8)	141 (92.2)
Severe (3)	22 (7.2)	11 (7.2)
Scaling		
Moderate (2)	256 (84.2)	130 (85.0)
Severe (3)	48 (15.8)	23 (15.0)
Prior failure/contraindication to:		
TAF	100 (32.9)	40 (26.1)
TCS	129 (42.4)	60 (39.2)

ITT population. ^aDaily value indicating worst itch in the previous 24 hours. ^bOne patient in the vehicle group had baseline erythema of 1 which was considered a protocol deviation.

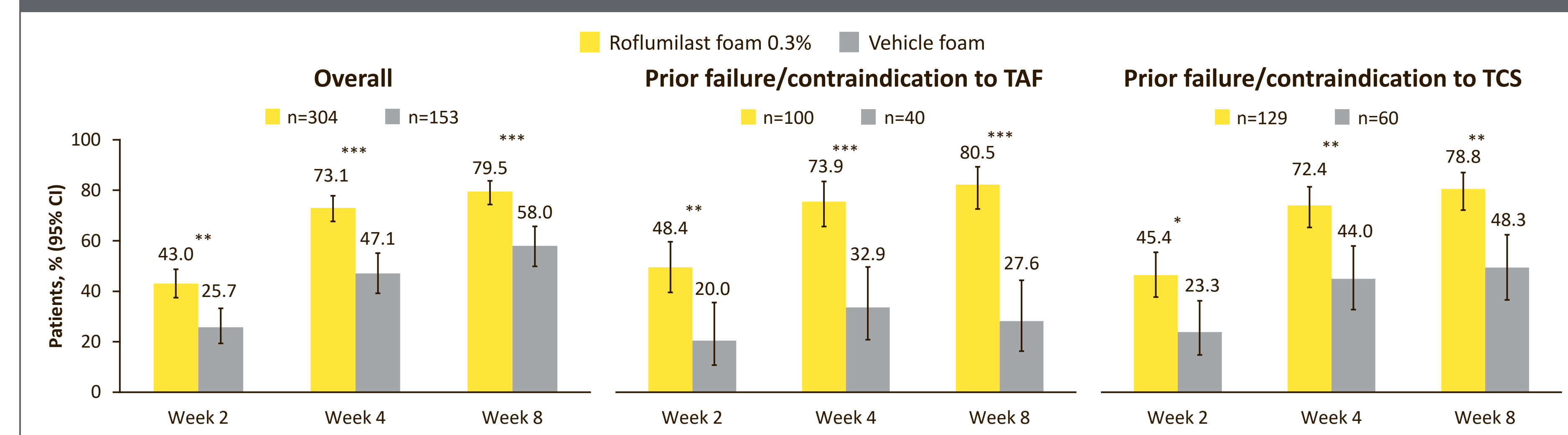
ABBREVIATIONS

AE, adverse event; BSA, body surface area affected; IGA, Investigator Global Assessment; ITT, intention-to-treat; PDE4, phosphodiesterase 4; QD, once daily; SAE, serious AE; TAF, topical antifungal; TCS, topical corticosteroids; TEAE, treatment-emergent AE; WI-NRS, Worst Itch-Numeric Rating Scale.

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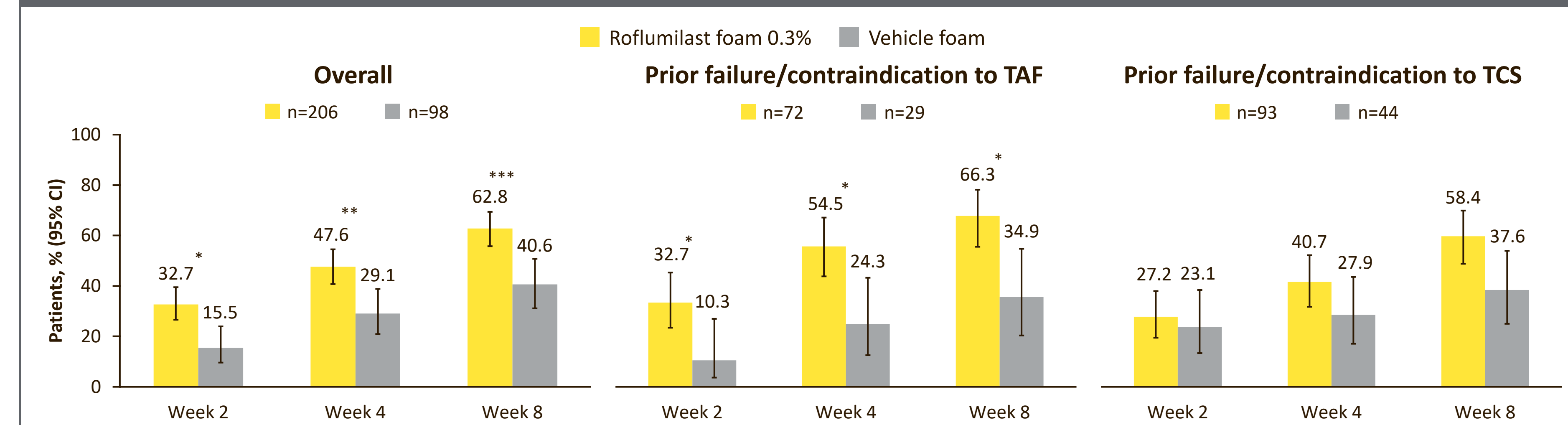
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IGA Success With Roflumilast Foam 0.3%



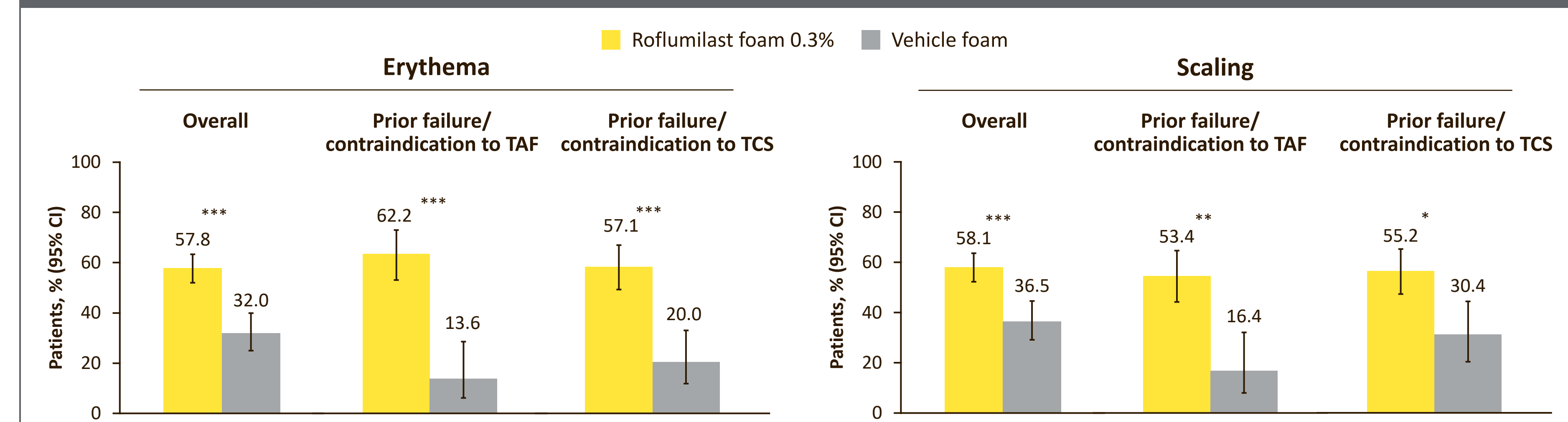
ITT population; multiple imputation. * $P < 0.05$; ** $P < 0.001$; *** $P \leq 0.0001$; P values for prior failure/contraindication to TAF and TCS subgroups are not adjusted for multiplicity and do not account for any differences in baseline characteristics between treatments within the subgroups.

WI-NRS Success With Roflumilast Foam 0.3%



ITT population of patients with baseline WI-NRS ≥4; multiple imputation. * $P < 0.05$; ** $P < 0.001$; *** $P \leq 0.0001$; P values for prior failure/contraindication to TAF and TCS subgroups are not adjusted for multiplicity and do not account for any differences in baseline characteristics between treatments within the subgroups.

Erythema 0 or Scaling 0 With Roflumilast Foam 0.3% at Week 8



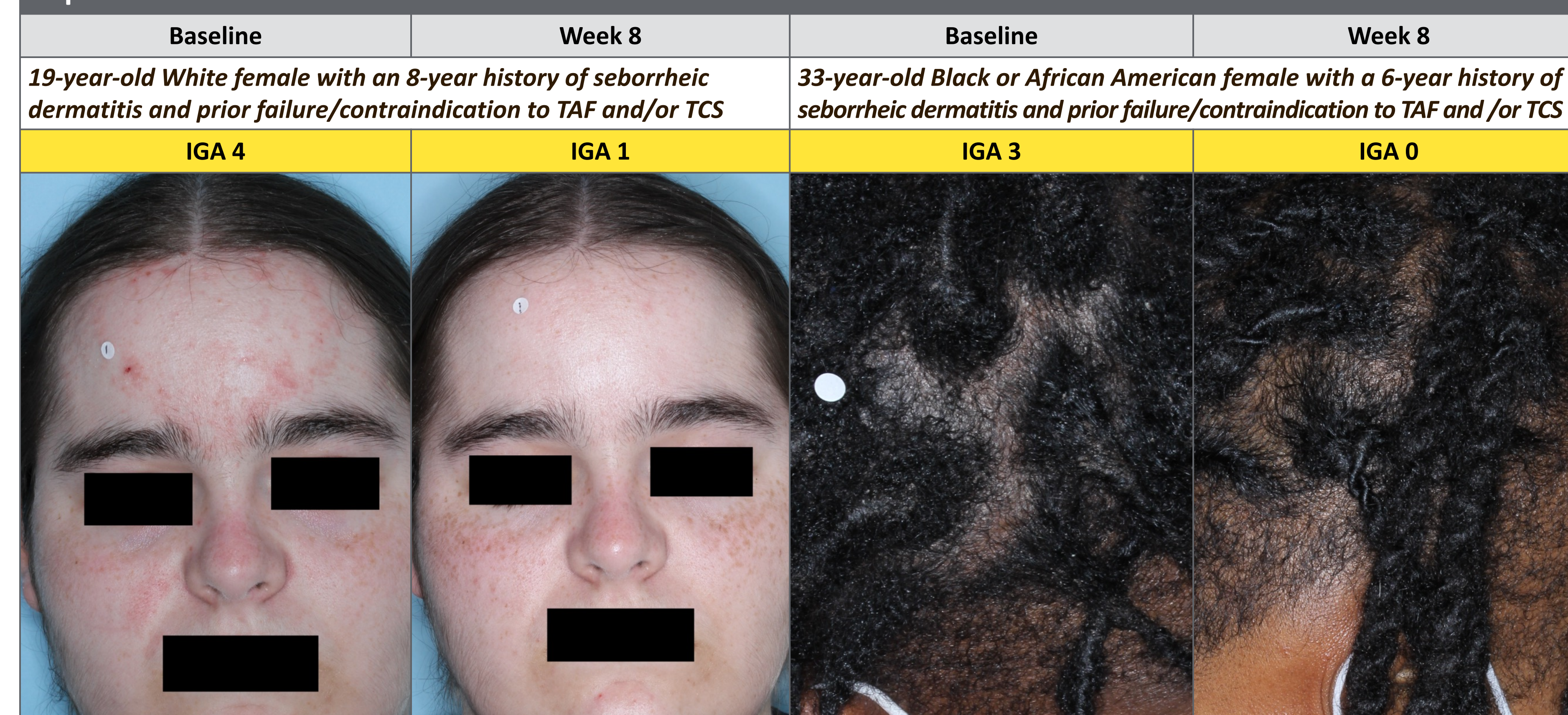
ITT population; multiple imputation. * $P < 0.05$; ** $P < 0.001$; *** $P \leq 0.0001$; P values for prior failure/contraindication to TAF and TCS subgroups are not adjusted for multiplicity and do not account for any differences in baseline characteristics between treatments within the subgroups. Patients in roflumilast and vehicle groups: overall, 304 and 153; prior failure/contraindication to TAF, 100 and 40; prior failure/contraindication to TCS, 129 and 60.

Safety Summary

Patients, n (%)	Roflumilast foam 0.3% (n=304)	Vehicle foam (n=153)
≥1 TEAE	70 (23.0)	33 (21.6)
≥1 Treatment-related AE	8 (2.6)	5 (3.3)
≥1 SAE	1 (0.3) ^a	0
≥1 Treatment-related SAE	0	0
≥1 TEAE leading to discontinuation of study/study drug	2 (0.7)/2 (0.7)	3 (2.0)/3 (2.0)
Most common TEAEs by preferred term, ≥2.0% in either group		
COVID-19	11 (3.6)	5 (3.3)
Urinary tract infection	4 (1.3)	3 (2.0)
Application-site pain	1 (0.3)	3 (2.0)

Safety population. ^aKeratoacanthoma, not at the application site and considered unrelated to treatment.

Improvements With Roflumilast Foam 0.3% Over Time



Note: The white sticker is placed by investigator for reference.

CONCLUSIONS

- Roflumilast foam 0.3% improved signs and symptoms of seborrheic dermatitis throughout 8 weeks of treatment
 - Significantly higher proportions of patients achieved IGA success with roflumilast compared with vehicle across prior failure/contraindication to TAF and TCS subgroups
 - Itch symptoms improved with roflumilast and >53% of patients, overall and across subgroups, reported no erythema or scaling at week 8
- Roflumilast foam 0.3% was well tolerated and seborrheic dermatitis signs and symptoms improved in patients with prior failure/contraindication to TAF and/or TCS



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ACKNOWLEDGMENTS

Thank you to the investigators and their staff for their participation in the trial. We are grateful to the study participants and their families for their time and commitment. Writing support was provided by Kelly M. Fahrbach, PhD, CMPP, and Andrea M. Michels, of Ashfield MedComms, an Inizio company, and was funded by Arcutis Biotherapeutics, Inc.

DISCLOSURES

This study was funded by Arcutis Biotherapeutics, Inc. RC, ED, EL, HCH, TS, and HW-L are investigators and/or consultants for and have received grants/research funding and/or honoraria from Arcutis Biotherapeutics, Inc. DK, JCI, MSS, DH, PB, and BS are employees of Arcutis Biotherapeutics, Inc. Additional disclosures provided on request.

Presented at the 83rd Society for Investigative Dermatology Annual Meeting, May 13–16, 2026; Chicago, IL.