Roflumilast Foam 0.3% in Patients With Seborrheic Dermatitis: Subgroup Analysis of Patients With Involvement of the Face and/or Scalp in the STRATUM Trial

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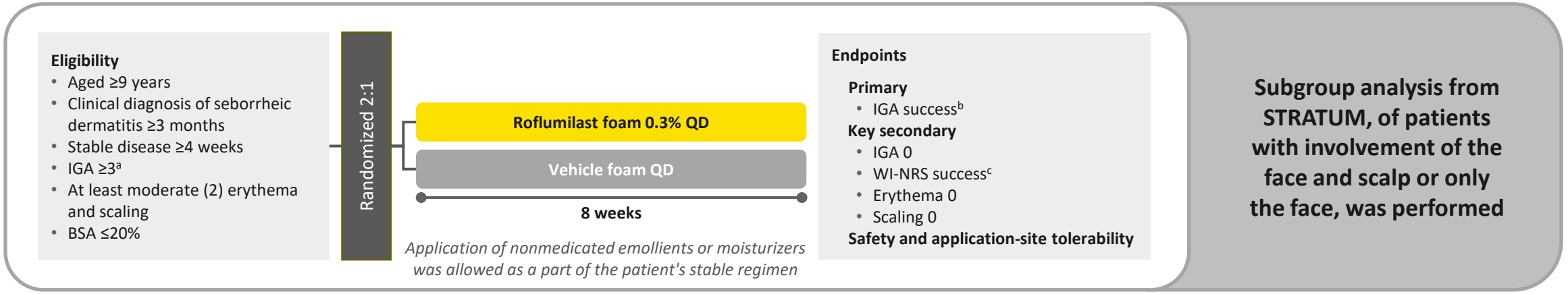
- Seborrheic dermatitis is a chronic, inflammatory skin disease causing flaking scales and persistent itching on the scalp[1] and can be distressing to the patient, especially in cases with more visible facial involvement[2]
- There is a higher risk for adverse reactions to allergenic/irritating excipients of topical treatments in thin-skinned areas, such as the face[3]; roflumilast foam 0.3% is a PDE4 inhibitor–based advanced targeted topical therapy that does not contain potentially skin-irritating excipients[4]
- Efficacy and tolerability of roflumilast foam 0.3% were demonstrated for the treatment of moderate-to-severe seborrheic dermatitis in patients aged ≥9 years in the phase 3 STRATUM trial[5]



[a]IGA is a global assessment based on a 5-point scale. [b]Defined as clear/almost clear (0/1) plus ≥2-grade improvement from baseline. [c]Defined as ≥4-point improvement from baseline in patients with WI-NRS ≥4 at baseline. BSA, body surface area affected; IGA, Investigator Global Assessment; PDE4, phosphodiesterase 4; QD, once daily; WI-NRS, Worst Itch-Numeric Rating Scale.

1. Dall'Oglio F, et al. *Clin Cosmet Investig Dermatol*. 2022;15:1537–1548. 2. Galizia G, et al. *Cosmetics.* 2024; 11(6):208. 3. Burshtein J, et al. *Dermatol Online J*. 2025;31(1). doi: 10.5070/D331164978.
4. Draelos ZD, et al. *J Drugs Dermatol*. 2024;23(10):834–840. 5. Blauvelt A, et al. *J Am Acad Dermatol*. 2024;90(5):986–993.

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Patient Baseline Characteristics and Safety Summary

- 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%)
- Of 457 patients, 254 (55.6%) had seborrheic dermatitis with both face and scalp involvement at baseline and 30 (6.6%) had face (without scalp) involvement

		Roflumilast foam 0.3% (n=304)	Vehicle foam (n=153)
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	Mild (1)	0	1 (0.7)
	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)
Involvement	Face and scalp	173 (56.9)	81 (52.9)
	Face only	13 (4.3)	17 (11.1)

ITT population.

Roflumilast foam 0.3% was well tolerated, with few AEs at the application site and no irritation in most patients

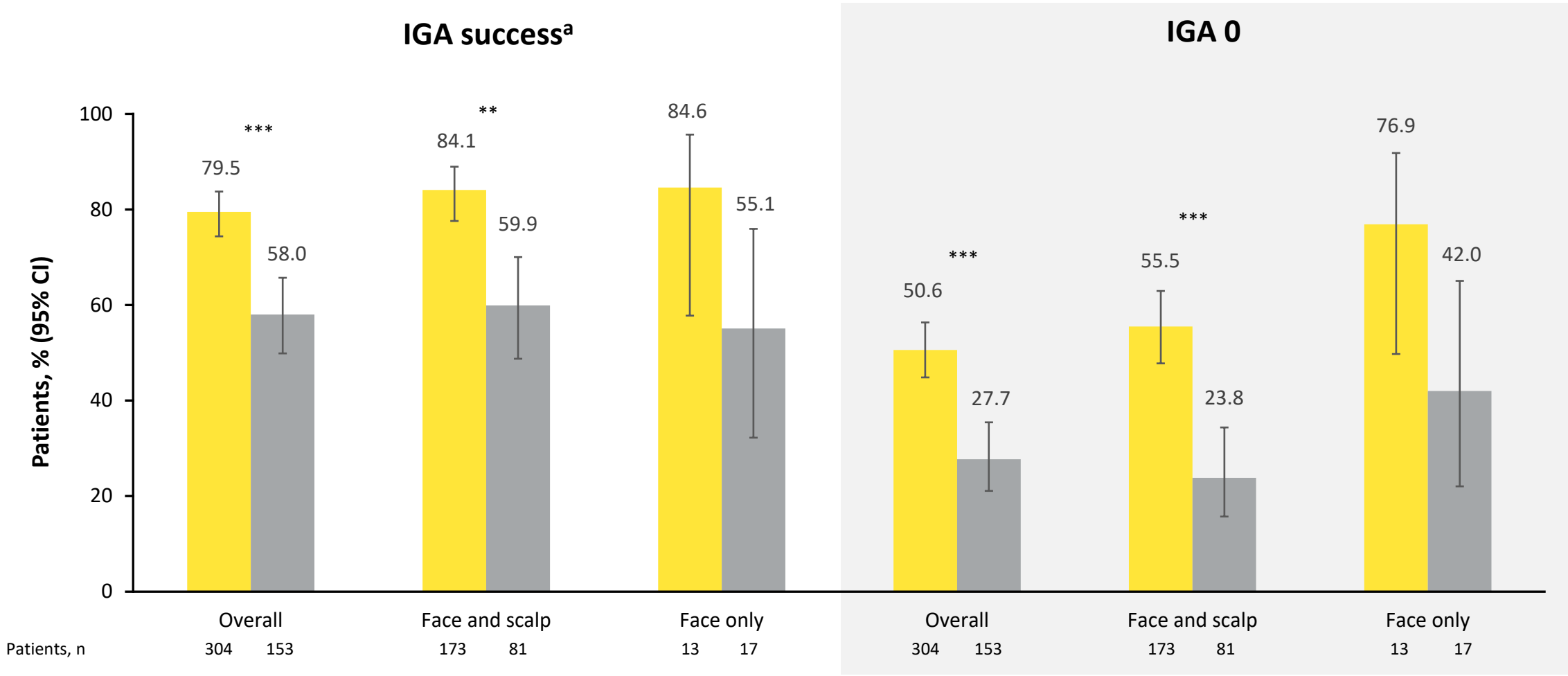
- No evidence of irritation with roflumilast was reported by the investigator for ≥98.9% of patients at all assessments
- A hot, tingling/stinging sensation was reported by 4 (1.3%) patients after the first application of roflumilast in patient-rated tolerability assessments

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)[b]	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.

[a]Daily value, indicating worst itch in the previous 24 hours. [b]Keratoacanthoma, not at the application site, and considered unrelated to treatment.
AE, adverse event; BSA, body surface area affected; IGA, Investigator Global Assessment; ITT, intention to treat; SAE, serious AE; TEAE, treatment-emergent adverse event; WI-NRS, Worst Itch-Numeric Rating Scale.

Improvements in Seborrheic Dermatitis Disease Severity at Week 8

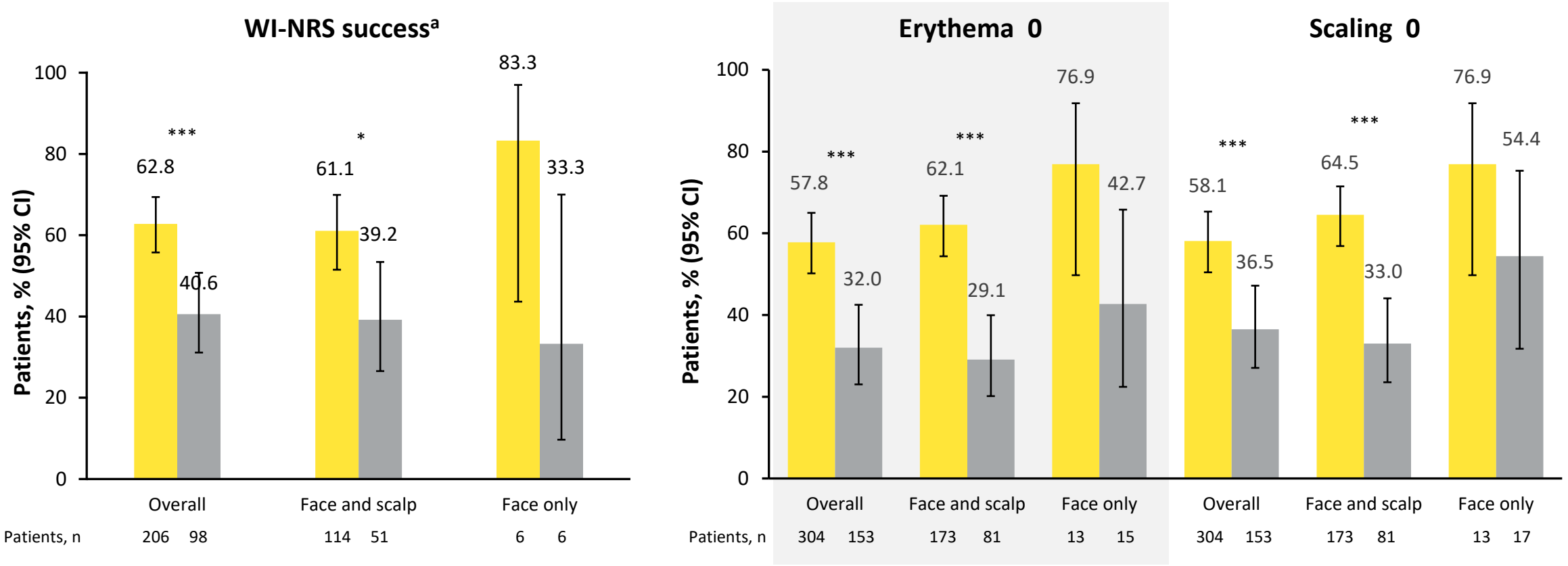


ITT population; multiple imputation. **P<0.001; ***P≤0.0001; P values are nominal for face and scalp and face only subgroups.
[a]Defined as clear/almost clear (0/1) plus ≥2-grade improvement from baseline.
IGA, Investigator Global Assessment; ITT, intention to treat.

Improvements in Signs and Symptoms of Seborrheic Dermatitis at Week 8

Roflumilast foam 0.3%
Vehicle foam

Roflumilast foam 0.3% significantly improved itch symptoms and signs of seborrheic dermatitis compared with vehicle foam overall, and for patients with facial involvement



ITT population; multiple imputation. *P<0.01; **P<0.001; ***P≤0.0001; P values are nominal for face and scalp and face only subgroups. P value was not evaluable for WI-NRS success in the face only subgroup.
[a]Defined as ≥4-point improvement from baseline in patients with WI-NRS ≥4 at baseline.
ITT, intention to treat; WI-NRS, Worst Itch-Numeric Rating Scale.

Improvement of Seborrheic Dermatitis

Conclusions

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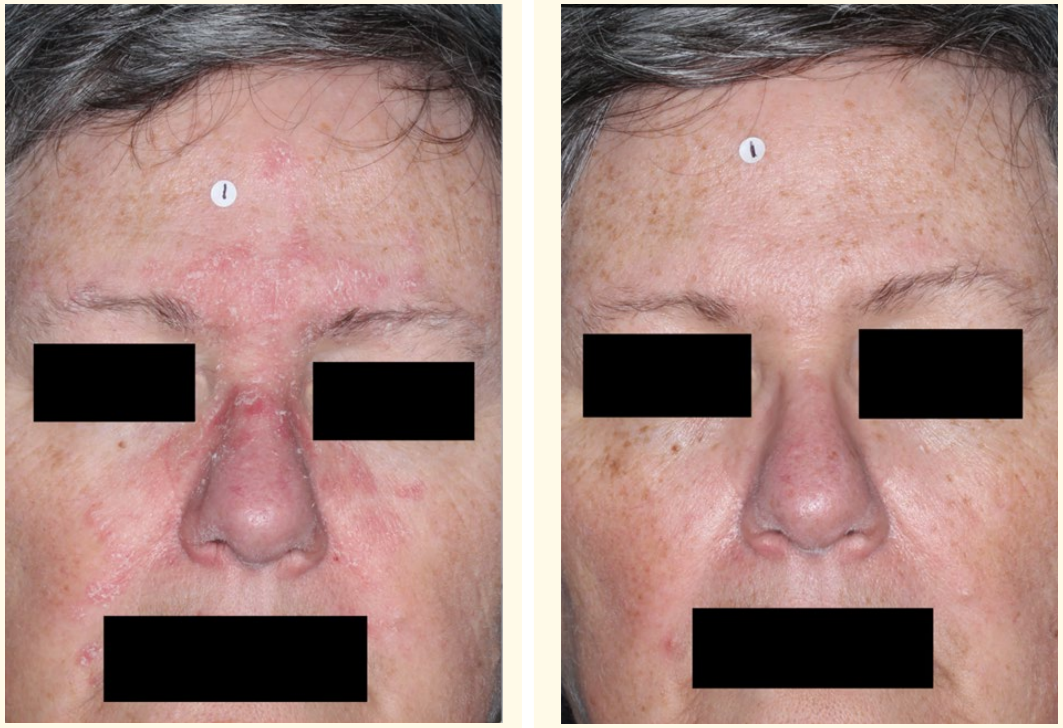
63-year-old White, not Hispanic/Latina female with a 2-year history of seborrheic dermatitis and a history of inadequate response, intolerance, or contraindication to TCS

Baseline	Week 8
IGA 3	IGA 1



Roflumilast foam 0.3% improved signs and symptoms of seborrheic dermatitis through 8 weeks, overall and in patients with face and/or scalp involvement

- Significant improvements in IGA were observed in the overall population and in patients with face and scalp involvement
- Higher proportions of roflumilast- versus vehicle-treated patients achieved erythema/scaling 0 overall and within subgroups

Roflumilast foam 0.3% was well tolerated

- Investigators reported no evidence of irritation at the application site for ~99% of patients throughout study assessments

Roflumilast foam 0.3% was well tolerated and is suitable for the treatment of anatomical areas where TCS use is limited by safety considerations, such as the face

IGA, Investigator Global Assessment; TCS, topical corticosteroids.

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