Supplementary Materials

Long-Term Safety and Efficacy of Roflumilast Foam 0.3% in Patients with Seborrheic Dermatitis: A 52-Week, Phase II, Open-Label Trial

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Andrew F. Alexis[1] • Michael Bukhalo[2] • Fran E. Cook-Bolden[3] • James Q. Del Rosso[4] • Zoe D. Draelos[5] • Janet C. DuBois[6] • Laura K. Ferris[7] • Seth B. Forman[8] • Steven E. Kempers[9] • Leon H. Kircik[10,11,12] • Edward Lain[13] • Angela Y. Moore[14,15] • David M. Pariser[16] • Joseph Raoof[17] • Matthew J. Zirwas[18] • Melissa S. Seal[19] • Saori Kato[19] • David H. Chu[19] • David Krupa[19] • Scott Snyder[19] • Patrick Burnett[19] • David R. Berk, MD[19]

[1]Weill Cornell Medicine, New York, NY, USA

[2]Arlington Dermatology, Rolling Meadows, IL, USA

[3]Park South Medical, Bronx, NY, USA

[4]JDR Dermatology Research Center, LLC, Las Vegas, NV, USA

[5]Dermatology Consulting Services, High Point, NC, USA

[6]DermResearch, Inc., Austin, TX, USA

[7]University of North Carolina, Department of Dermatology, Chapel Hill, NC, USA

[8]ForCare Medical Center, Tampa, FL, USA

[9]Minnesota Clinical Study Center, Fridley, MN, USA

[10]Waldman Department of Dermatology, Icahn School of Medicine at Mount Sinai, New York, NY, USA

[11]Indiana Medical Center, Indianapolis, IN, USA

[12]Physicians Skin Care, PLLC and Skin Sciences, PLLC, Louisville, KY, USA

[13]Sanova Dermatology, Austin, TX, USA

[14]Arlington Research Center, Arlington, TX, USA

[15]Baylor University Medical Center, Dallas, TX, USA

[16]Eastern Virginia Medical School and Virginia Clinical Research, Inc., Norfolk, VA, USA

[17]Encino Research Center, Encino, CA, USA

[18]Dermatologists of the Central States, Probity Medical Research, and Ohio University, Bexley, OH, USA

[19]Arcutis Biotherapeutics, Inc., Westlake Village, CA, USA

Correspondence to: Andrew F. Alexis, MD, MPH. Email: alexisa@med.cornell.edu.

Table of Contents

Supplementary Table 1 Excluded medications and treatments

Excluded medications and treatments	Wash out period prior to day 1
Biologics	12 weeks or 5 half-lives, whichever was longer
Systemic treatment with antifungal agents, corticosteroids, immunosuppressive therapies, retinoids, roflumilast, or apremilast	4 weeks
Topical antifungals, corticosteroids, calcineurin inhibitors, sulfur-based treatments, medical devices, crisaborole, azelaic acid, or metronidazole	2 weeks
Medicated shampoos (e.g., coal tar, keratolytics including salicylic acid, antifungals, zinc pyrithione, selenium sulfide, corticosteroids, medical devices)	2 weeks
Topical medications used on the scalp for conditions besides seborrheic dermatitis, eg, use of topical minoxidil for androgenetic alopecia	4 weeks
Strong systemic P-450 cytochrome inhibitors (e.g., indinavir, nelfinavir, ritonavir, clarithromycin, itraconazole, ketoconazole, nefazodone, saquinavir, suboxone, and telithromycin)	2 weeks
Phototherapy, tanning beds, other light-emitting devices	4 weeks
Investigational drugs (other than roflumilast foam)	12 weeks (biologics) or 5 half-lives, whichever was longer; 5 half-lives (orals); 2 weeks (topicals)

Note: Eye drop and nasal corticosteroid preparations were allowed. Inhaled corticosteroid preparations were allowed if used for a stable condition and at a stable dose for > 28 days before screening and were continued at the same dose throughout the trial.
Non-medicated emollients, moisturizers and sunscreens were allowed once daily as normally used by patients and applied at least 3 hours after application of investigational product to untreated areas only

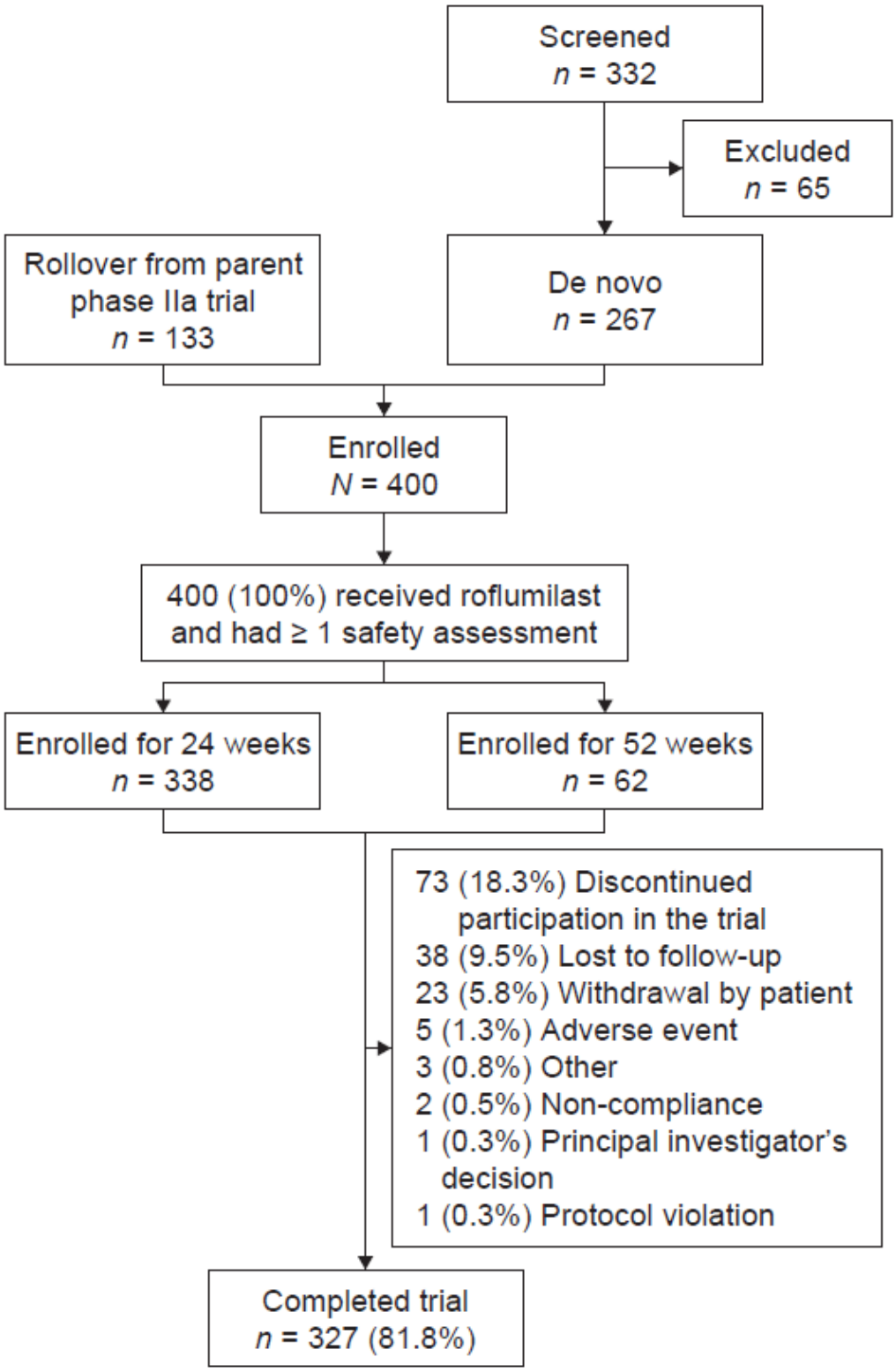
Supplementary Table 2 Secondary efficacy endpoints

	Roflumilast foam 0.3% (*n* = 400)				
	Week 4	Week 12	Week 24	Week 36	Week 52
IGA 0/1, % (95% CI)	*n* = 388	*n* = 365	*n* = 342	*n* = 50	*n* = 46
	56.4 (51.47, 61.29)	70.7 (65.82, 75.12)	76.0 (71.23, 80.24)	74.0 (60.45, 84.13)	80.4 (66.83, 89.35)
WI-NRS ≥ 4-point improvement from baseline, % (95% CI)[a]	*n* = 308	*n* = 286	*n* = 265	*n* = 35	*n* = 31
	56.2 (50.6, 61.6)	67.8 (62.2, 73.0)	71.3 (65.6, 76.4)	54.3 (38.2, 69.5)	58.1 (40.8, 73.6)
WI-NRS 0/1, % (95% CI)	*n* = 389	*n* = 366	*n* = 342	*n* = 50	*n* = 46
	40.9 (36.10, 45.83)	51.1 (45.99, 56.18)	55.8 (50.55, 61.02)	54.0 (40.40, 67.03)	52.2 (38.14, 65.88)
Erythema score 0, % (95% CI)	*n* = 388	*n* = 365	*n* = 342	*n* = 50	*n* = 46
	30.7 (26.29, 35.43)	46.6 (41.52, 51.70)	59.6 (54.37, 64.71)	64.0 (50.14, 75.86)	67.4 (52.97, 79.13)
Scaling score 0, % (95% CI)	*n* = 388	*n* = 365	*n* = 342	*n* = 50	*n* = 46
	31.4 (27.02, 36.23)	43.3 (38.30, 48.41)	50.6 (45.31, 55.85)	46.0 (32.97, 59.60)	58.7 (44.34, 71.71)
Scalpdex Total Score, mean (standard deviation)	*n* = 388	*n* = 365	*n* = 341	*n* = 50	*n* = 46
	23.0 (17.9)	19.9 (16.5)	18.0 (16.5)	18.1 (18.2)	15.4 (12.6)

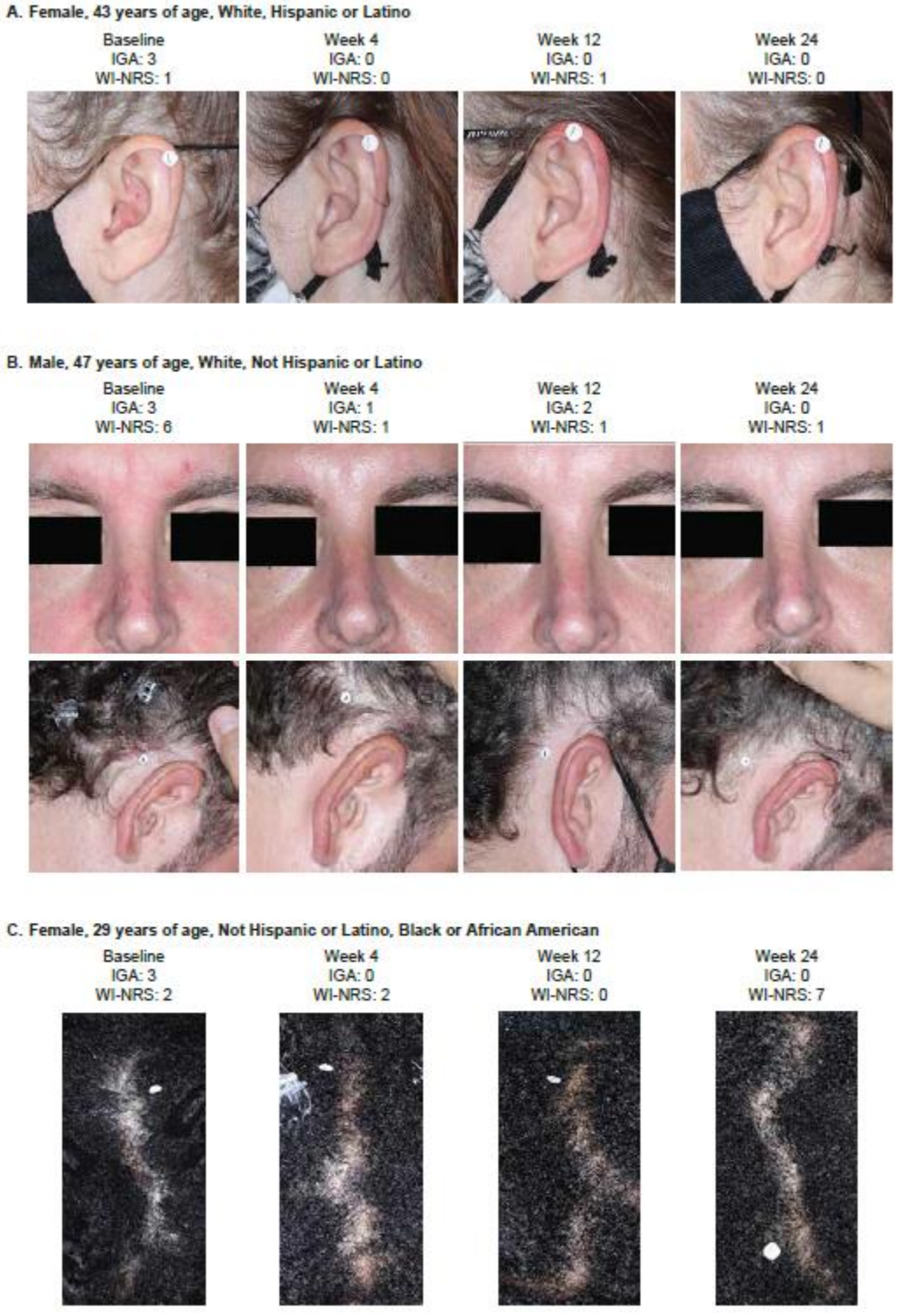
CI confidence interval, *IGA* Investigator Global Assessment, *WI-NRS* Worst Itch-Numeric Rating Scale

[a]Only evaluated in patients with baseline WI-NRS score ≥ 4. Baseline was defined as the last observation recorded before the first dose of roflumilast foam 0.3% in a prior trial or this trial (for patients who had not participated in a prior trial or who received vehicle in a prior trial)

Supplementary Fig. 1 Patient disposition. Percentages may not sum to 100% because of rounding.



Supplementary Fig. 2 Improvements in seborrheic dermatitis in patients treated with roflumilast foam 0.3%. IGA and WI-NRS are global assessments. *IGA* Investigator Global Assessment, *WI-NRS* Worst Itch-Numeric Rating Scale



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