# Efficacy and Safety of Roflumilast Foam 0.3% in Patients with Seborrheic Dermatitis in a Randomized, Double-blind, Vehicle-controlled Phase 2 Study

Matthew Zirwas[1], Zoe D. Draelos[2], Janet DuBois[3], Leon Kircik[4], Angela Moore[5], Linda Stein Gold[6], Robert C. Higham[7], Lynn Navale[7], Patrick Burnett[7], David R. Berk[7]

[1]Dermatologists of the Central States, Probity Medical Research, and Ohio University, Bexley, OH, USA; [2]Dermatology Consulting Services, High Point, NC, USA; [3]DermResearch, Inc., Austin, TX, USA; [4]Icahn School of Medicine at Mount Sinai, NY, Indiana Medical Center, Indianapolis, IN, Physicians Skin Care, PLLC, Louisville, KY, and Skin Sciences, PLLC, Louisville, KY, USA; [5]Arlington Center for Dermatology, Arlington, TX, USA; [6]Henry Ford Medical Center, Detroit, MI, USA; [7]Arcutis Biotherapeutics, Inc., Westlake Village, CA, USA

Disclosures: Matthew Zirwas, Janet DuBois, Leon Kircik, and Angela Moore are investigators and/or consultants for Arcutis Biotherapeutics, Inc. and received grants/research funding and/or honoraria; Robert C. Higham, Lynn Navale, Patrick Burnett, and David R. Berk are employees of Arcutis Biotherapeutics, Inc. Additional disclosures provided on request.

**This work was supported by Arcutis Biotherapeutics, Inc.**

Writing support was provided by Christina McManus, PhD, Alligent Biopharm Consulting LLC, and funded by Arcutis Biotherapeutics, Inc.

# Introduction and Study Design

Seborrheic dermatitis (SD) is a chronic inflammatory skin condition that may cause physical discomfort and emotional burden for patients[1,2]

- SD is characterized by erythematous, scaly plaques, with a yellowish, oily, moist, and/or greasy appearance and affects areas with abundant sebaceous glands [3,4]

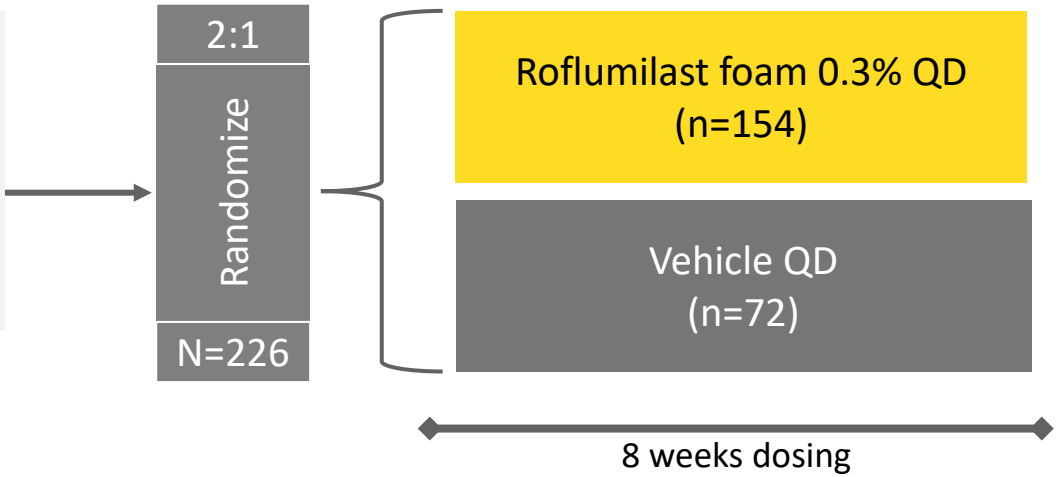
Topical treatments include antifungals, steroids, immunomodulators, and dandruff shampoos,[3,4] but efficacious and safe options are needed, especially for long-term use

Roflumilast is a potent, nonsteroidal, PDE-4 inhibitor being investigated for once-daily treatment of several dermatologic conditions,[5] including SD

A phase 2, 8-week study investigated using roflumilast foam 0.3% once-daily for the treatment of SD.

**Eligibility**

- Diagnosis of at least moderate seborrheic dermatitis (IGA ≥3)
- Age 18+
- ≤20% BSA




**Endpoints**

- Primary: IGA Success at week 8
- Secondary:
  - Overall Assessment of Erythema (0-3)
  - Overall Assessment of Scaling (0-3)
  - WI-NRS (itch)
- Safety & tolerability

IGA Success = Clear or Almost Clear with at least a 2-grade improvement from baseline

BSA: Body Surface Area; IGA: Investigator's Global Assessment; QD: once daily; WI-NRS: Worst Itch-Numeric Rating Scale

1. Araya M et al. Indian J Dermatol 2015;60:519; 2. Pärna, E., et al. Acta Derm Venereol 2015; 95:312-6; 3. Clark GW et al. Am Fam Physician 2015;91:185-90; 4. Kastarinen H et al. Cochrane Database Syst Rev 2014:Cd009446; 5. Lebwohl MG et al. NEJM 2020;383:229-39.



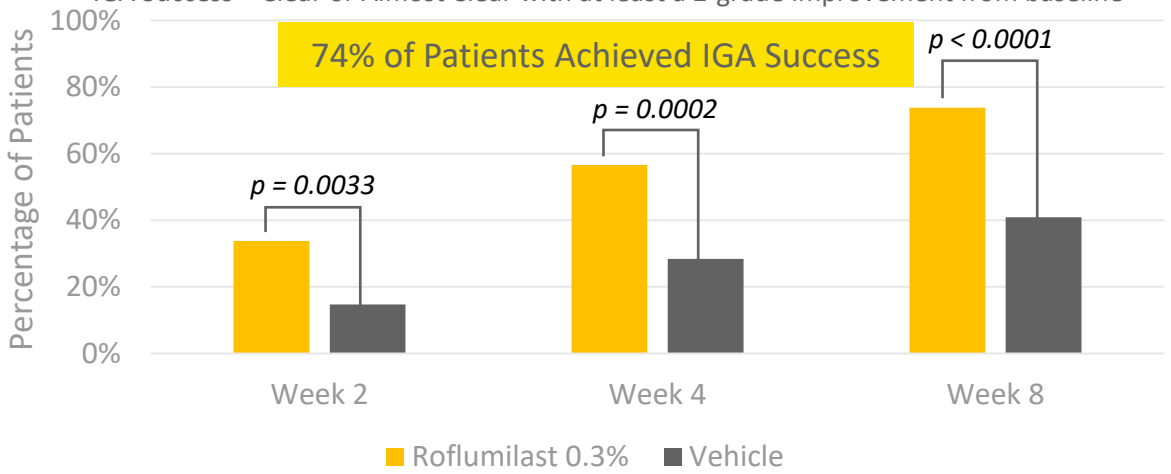
Presented at the American Academy of Dermatology Virtual Annual Meeting, April 23-25, 2021

# Roflumilast Foam 0.3% Demonstrated Significant and Rapid Improvement in SD, Redness, Scaling, and Itch

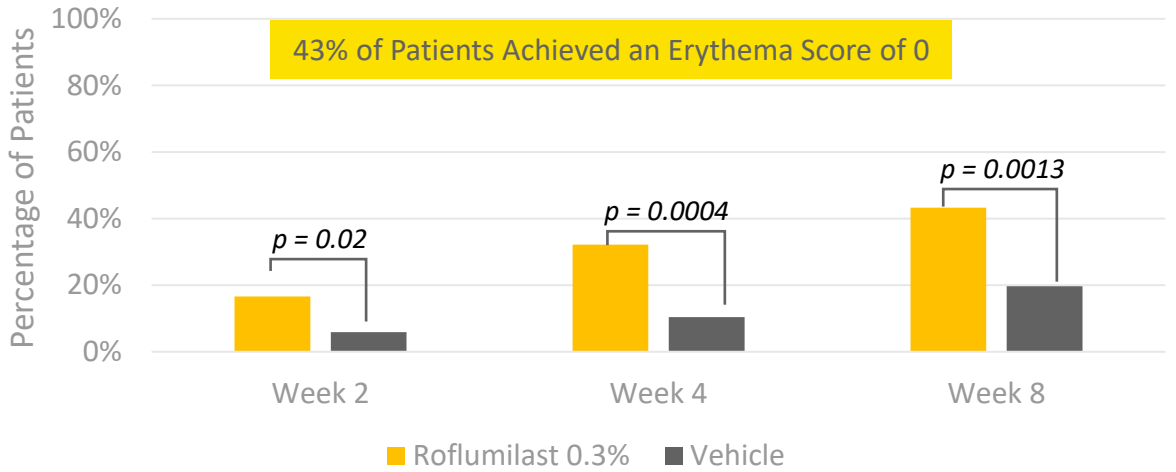
## Primary Endpoint

Patients Achieving IGA Success at Each Visit (mITT)

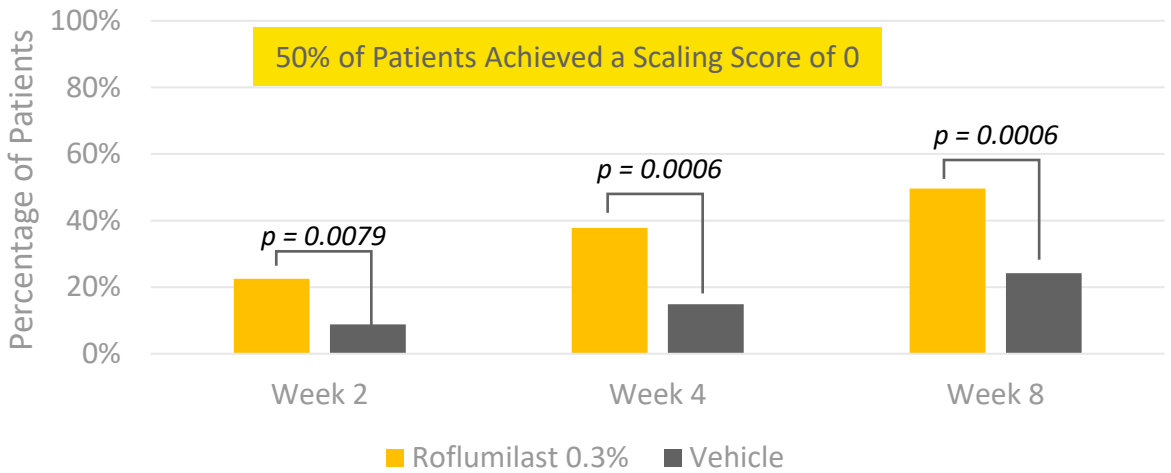
IGA Success = Clear or Almost Clear with at least a 2-grade improvement from baseline




Patients Achieving Erythema Score of 0 ("None") at Each Visit (mITT)

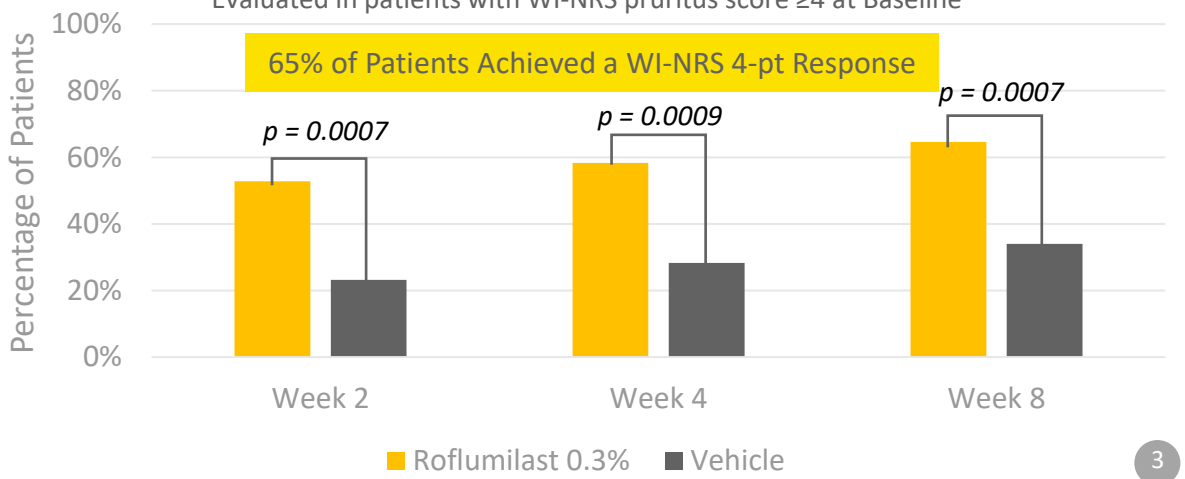



Patients Achieving Scaling Score of 0 ("None") at Each Visit (mITT)




Patients Achieving WI-NRS 4-pt Response at Each Visit

Evaluated in patients with WI-NRS pruritus score ≥4 at Baseline




mITT: all randomized patients except those who missed the week 8 IGA assessment specifically due to COVID-19 disruption



Presented at the American Academy of Dermatology Virtual Annual Meeting, April 23-25, 2021

# Results: Safety

- Rates of AEs were low
- Few treatment-related AEs were reported
- Very few AEs lead to study discontinuation
  - Rates of discontinuation were similar between roflumilast and vehicle groups
- No patients had a SAE
- ≥99% of roflumilast-treated and ≥98% of vehicle-treated patients had no evidence of irritation on the investigator-rating of local tolerability

| N (%) | Roflumilast 0.3% foam (n=154) | Vehicle foam (n=72) |
|---|---|---|
| **Patients with any TEAE** | 37 (24.0) | 13 (18.1) |
| **Patients with any treatment-related TEAE** | 3 (1.9) | 3 (4.2) |
| **Patients with any SAE** | 0 (0.0) | 0 (0.0) |
| **Patients who discontinued study due to AE[a]** | 2 (1.3) | 1 (1.4) |
| **Most common TEAE (>2% in any group), preferred term** | | |
| Contact Dermatitis[b] | 3 (1.9) | 2 (2.8) |
| Insomnia | 3 (1.9) | 1 (1.4) |
| Nasopharyngitis | 3 (1.9) | 0 (0.0) |

[a]AEs leading to discontinuation for roflumilast were application site pain, migraine, dyspnea. In the vehicle group: application site dysesthesia
[b]Contact dermatitis was reported to be unrelated to treatment in all cases; 2 cases were reported as poison ivy rash

Data are presented for safety population. AE: adverse event; SAE: serious adverse event; TEAE: treatment-emergent adverse event.



Presented at the American Academy of Dermatology Virtual Annual Meeting, April 23-25, 2021

# Summary and Conclusions

- Roflumilast foam 0.3% demonstrated significant improvement in IGA Success, erythema, scaling, and itch
  - The improvements in IGA Success were statistically significant at the first post-baseline visit (Week 2) and continued through Week 8
  - Roflumilast foam resulted in significant improvements in itch by Week 2
    - ~80% of patients reported notable itch at baseline (WI-NRS $\geq$ 4)
- Rates of treatment-related adverse events, discontinuations due to adverse events, and application-site pain were low and similar to vehicle
- Once-daily roflumilast foam 0.3% provided safe, well-tolerated, and effective treatment of erythema, scaling, and itch caused by seborrheic dermatitis, and represents a promising novel treatment with early onset of action



Presented at the American Academy of Dermatology Virtual Annual Meeting, April 23-25, 2021