# Reduction in Pruritus Across Indications in Phase 3 Trials of Topical Roflumilast in Patients as Young as 2 Years

Gil Yosipovitch,[1] Shawn G. Kwatra,[2] James Del Rosso,[3] Laura K. Ferris,[4] Melinda Gooderham,[5] Adelaide A. Hebert,[6] Edward Lain,[7] Mark Lebwohl,[8] Vimal H. Prajapati,[9] Todd Schlesinger,[10] Jennifer Soung,[11] Melissa Seal,[12] David Krupa,[12] Robert C. Higham,[12] David R. Berk,[12] Patrick Burnett[12]

[1]University of Miami, Miami, FL; [2]Johns Hopkins University School of Medicine and Bloomberg School of Public Health, Johns Hopkins University, Baltimore, MD; [3]JDR Dermatology Research, Las Vegas, NV; [4]University of North Carolina, Department of Dermatology, Chapel Hill, NC; [5]SKiN Centre for Dermatology, Probity Medical Research, and Queen's University, Peterborough, ON; [6]UTHealth McGovern Medical School, Houston, TX; [7]Sanova Dermatology, Austin, TX; [8]Icahn School of Medicine at Mount Sinai, New York, NY; [9]Dermatology Research Institute, Probity Medical Research, Skin Health & Wellness Centre, and University of Calgary, Calgary, AB; [10]Clinical Research Center of the Carolinas, Charleston, SC; [11]Southern California Dermatology, Inc., Santa Ana, CA; [12]Arcutis Biotherapeutics, Inc., Westlake Village, CA

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## DISCLOSURES

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## INTRODUCTION

- Pruritus is one of the most burdensome symptoms in patients with psoriasis, seborrheic dermatitis, and atopic dermatitis, affecting sleep and quality of life[1]
  - Patient perception of pruritus varies greatly among skin diseases[2-4]
- Phosphodiesterase 4 (PDE4) inhibitors may reduce pruritus by inhibiting production of inflammatory itch mediators[5]
  - PDE4 inhibitors also act through neuronal pathways independent of the anti-inflammatory action of PDE4 in mouse models of dermatoses[6-9]
- In this poster, we evaluate the reduction in pruritus in seven phase 3 clinical trials of topical roflumilast in patients with psoriasis, seborrheic dermatitis, and atopic dermatitis

## METHODS

### Outcomes

- WI/SI-NRS success, ≥4-point improvement from baseline among patients with baseline score ≥4
- WI/SI-NRS 0/1, no (0) or minimal (1) itch among patients with baseline score ≥2

**Study Designs**

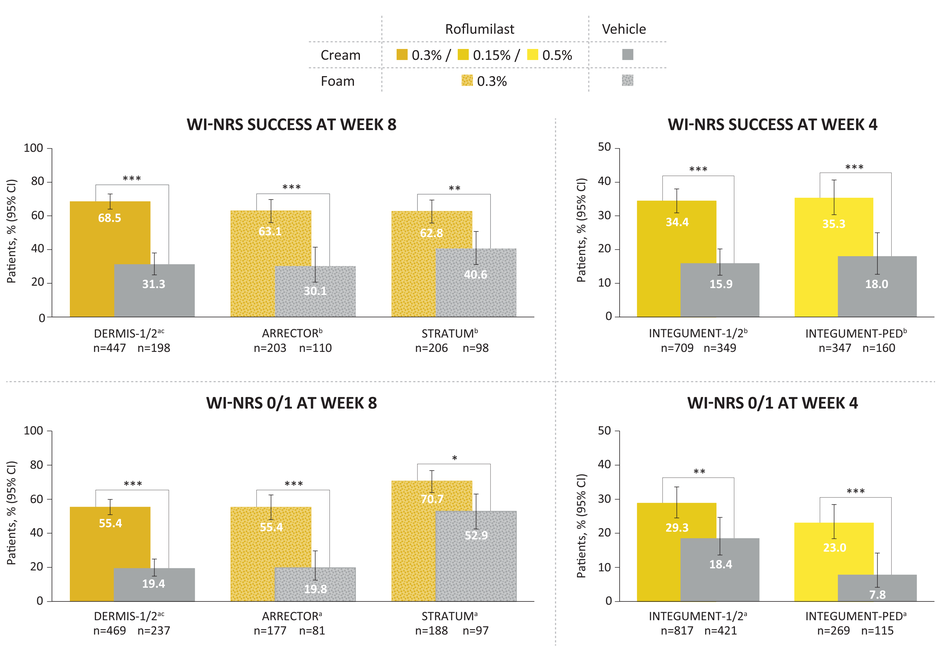
| Trial | Treatment Groups | Inclusion Criteria | Itch Assessment Timing | Baseline Itch Scores, Mean (SD) |
|---|---|---|---|---|
| DERMIS-1/2[10] (Psoriasis; NCT04211363 and NCT04211389) | Roflumilast cream 0.3% (n=576); Vehicle cream (n=305) | Aged ≥2 years<br>BSA 2–20%<br>IGA ≥2 (mild)<br>PASI ≥2 | Baseline, Weeks 2, 4, 6, 8 | Roflumilast: 5.7 (2.7)<br>Vehicle: 5.9 (2.8) |
| ARRECTOR[11] (Psoriasis of the Scalp and Body; NCT05028582) | Roflumilast foam 0.3% (n=281); Vehicle cream (n=151) | Aged ≥12 years<br>BSA ≤25% (≤20% non-scalp, ≥10% scalp<br>S-IGA ≥3 (moderate<br>B-IGA ≥2 (mild)<br>PSSI ≥6<br>PASI ≥2 | Baseline, Days 2–56 | WI-NRS<br>Roflumilast: 5.6 (2.8)<br>Vehicle: 5.5 (2.8)<br><br>SI-NRS<br>Roflumilast: 5.9 (2.8)<br>Vehicle: 6.1 (2.5) |
| STRATUM[12] (Seborrheic Dermatitis; NCT04973228) | Roflumilast foam 0.3% (n=304); Vehicle foam (n=153) | Aged ≥9 years<br>BSA ≤20%<br>IGA ≥3 (moderate) | Baseline, Days 2–56 | Roflumilast: 5.1 (2.3)<br>Vehicle: 4.7 (2.3) |
| INTEGUMENT-1/2[13] (Atopic Dermatitis; NCT04773587 and NCT04773600) | Roflumilast cream 0.15% (n=884); Vehicle cream (n=453) | Aged ≥6 years<br>BSA ≥3%[a]<br>vIGA-AD 2 (mild)/ 3 (moderate)<br>EASI ≥5 | Baseline, Days 2–29 | Roflumilast: 6.1 (2.1)<br>Vehicle: 5.9 (2.2) |
| INTEGUMENT-PED[14] (Atopic Dermatitis; NCT04845620) | Roflumilast cream 0.05% (n=437); Vehicle cream (n=215) | Aged 2–5 years<br>BSA ≥3[a]<br>vIGA-AD 2 (mild)/ 3 (moderate)<br>EASI ≥5 | Baseline, Days 2–29 | Roflumilast: 6.2 (2.3)<br>Vehicle: 5.9 (2.2) |

[a]No upper limit.

## RESULTS

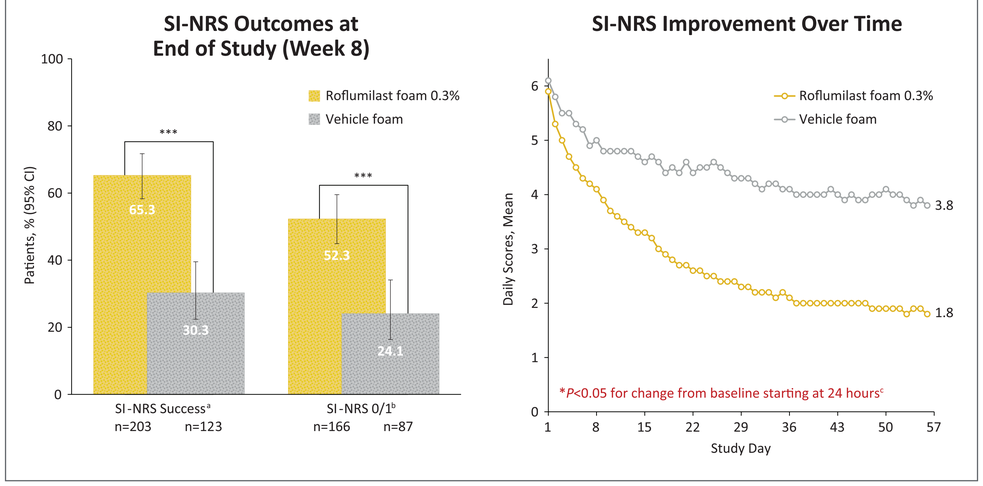
- Efficacy, safety, and tolerability for all seven phase 3 studies were previously reported[10-14]
- Greater proportions of patients treated with roflumilast versus vehicle achieved improvement in pruritus as measured by WI-NRS success and SI-NRS success at the final assessment in each trial
- Differences favoring roflumilast were also observed for achievement of WI-NRS 0/1 at the final assessment for all trials
- Pruritus scores were signficantly improved compared with vehicle as early as 24 hours in patients with psoriasis (ARRECTOR) and atopic dermatitis (INTEGUMENT) and by 48 hours in patients with seborrheic dermatitis (STRATUM)

### WI-NRS Outcomes at End of Study



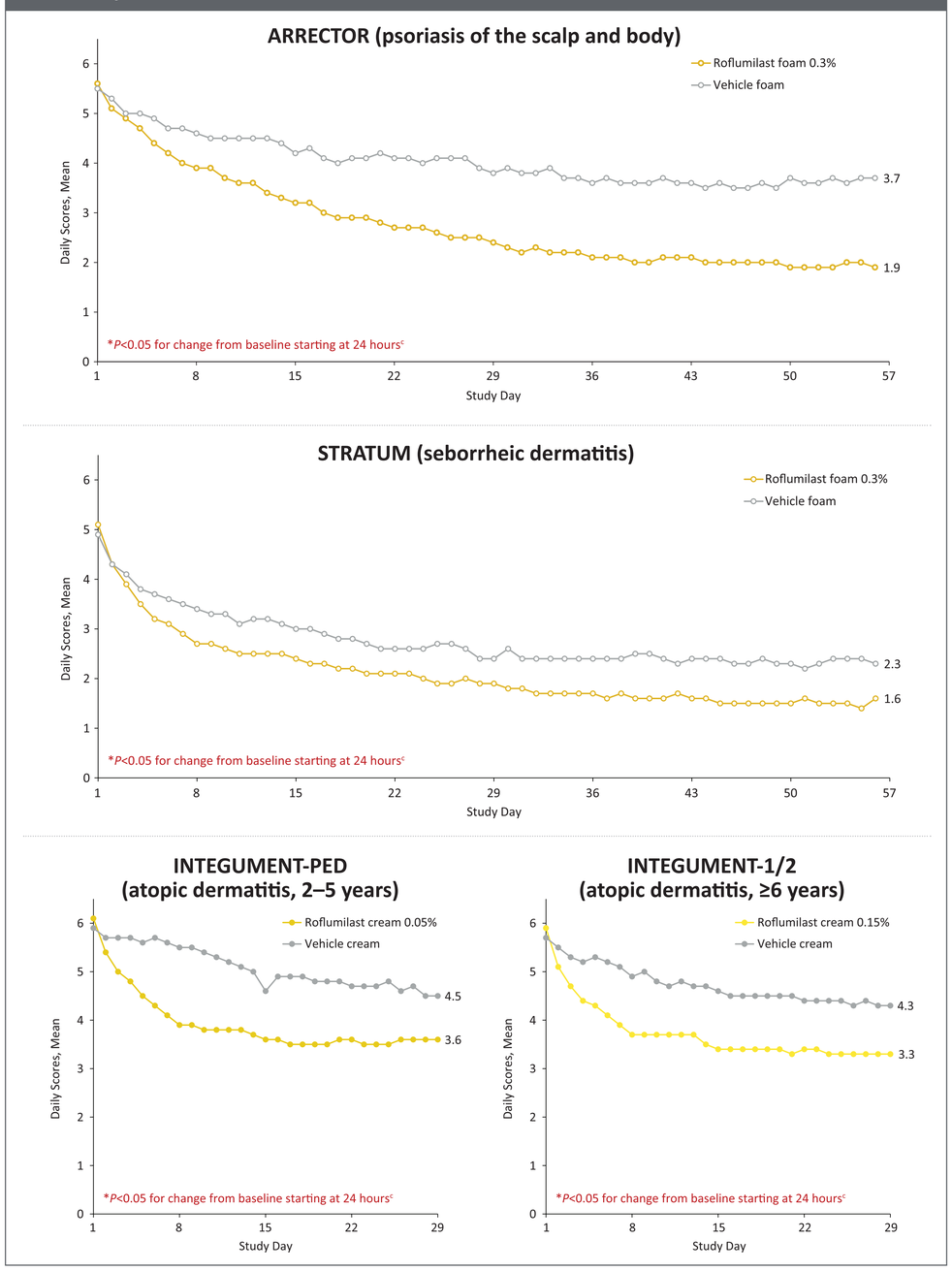

***P<0.0001. **P<0.001. *P<0.01.
[a]Observed data. [b]Multiple imputation. [c]Among patients aged ≥12 years.

### SI-NRS Outcomes and Improvement (ARRECTOR, psoriasis of the scalp and body)




***P<0.0001.
[a]Multiple imputation. [b]Observed data. [c]P<0.05 for analysis of change from baseline from 24 hours post application and for all timepoints assessed after.

### WI-NRS Improvement Over Time




[a]P<0.05 for analysis of change from baseline from 24 or 48 hours (STRATUM only) post application and for all timepoints assessed after.

## CONCLUSIONS

- Once-daily topical roflumilast provided consistent and rapid improvements in itch across psoriasis, seborrheic dermatitis, and atopic dermatitis, with improvement as early as 24–48 hours, compared with vehicle
  - Across indications, significant proportions of patients achieved an itch-free state (WI-NRS 0/1 and SI-NRS 0/1)
- These results highlight the potential for roflumilast to reduce this burdensome symptom substantially across inflammatory dermatoses

## ABBREVIATIONS

B-IGA, Body-IGA; BSA, body surface area; EASI, Eczema Area and Severity Index; IGA, Investigator Global Assessment; PASI, Psoriasis Area and Severity Index; PSSI, Psoriasis Scalp Severity Index; S-IGA, Scalp-IGA; SD, standard deviation; SI-NRS, Scalp Itch-Numeric Rating Scale; vIGA-AD, Validated IGA for Atopic Dermatitis; WI-NRS, Worst Itch-Numeric Rating Scale.

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