



Correlation of Itch Response to Roflumilast Cream With Disease Severity and Patient-Reported Outcomes in Patients with Chronic Plaque Psoriasis

Linda Stein Gold¹, Javier Alonso-Llamazares², Zoe D. Draelos³, Melinda J. Gooderham⁴, Steven E. Kempers⁵, Mark G. Lebwohl⁶, Darryl P. Toth⁷, Gil Yosipovitch⁸, Robert C. Higham⁹, Lynn Navale⁹, David R. Berk⁹

¹Henry Ford Medical Center, Detroit, MI, USA; ²Driven Research LLC, Coral Gables, FL, USA; ³Dermatology Consulting Services, High Point, NC, USA; ⁴SkiN Centre for Dermatology, Probity Medical Research and Queen's University, Peterborough, ON, Canada; ⁵Minnesota Clinical Study Center, Fridley, MN, USA; ⁶Icahn School of Medicine at Mount Sinai, New York, NY, USA; ⁷XLR8 Medical Research, Probity Medical Research, Windsor, ON, Canada; ⁸University of Miami, Miami, FL, USA; ⁹Arcutis Biotherapeutics, Inc., Westlake Village, CA, USA

Disclosures: Javier Alonso-Llamazares, Melinda J. Gooderham, Steven E. Kempers, Mark G. Lebwohl, and Darryl P. Toth are investigators and/or consultants for Arcutis Biotherapeutics, Inc. and received grants/research funding and/or honoraria; Robert C. Higham, Lynn Navale, and David R. Berk are employees of Arcutis Biotherapeutics, Inc. Additional disclosures provided on request.

This work was supported by Arcutis Biotherapeutics, Inc.

Introduction and Methods

Introduction

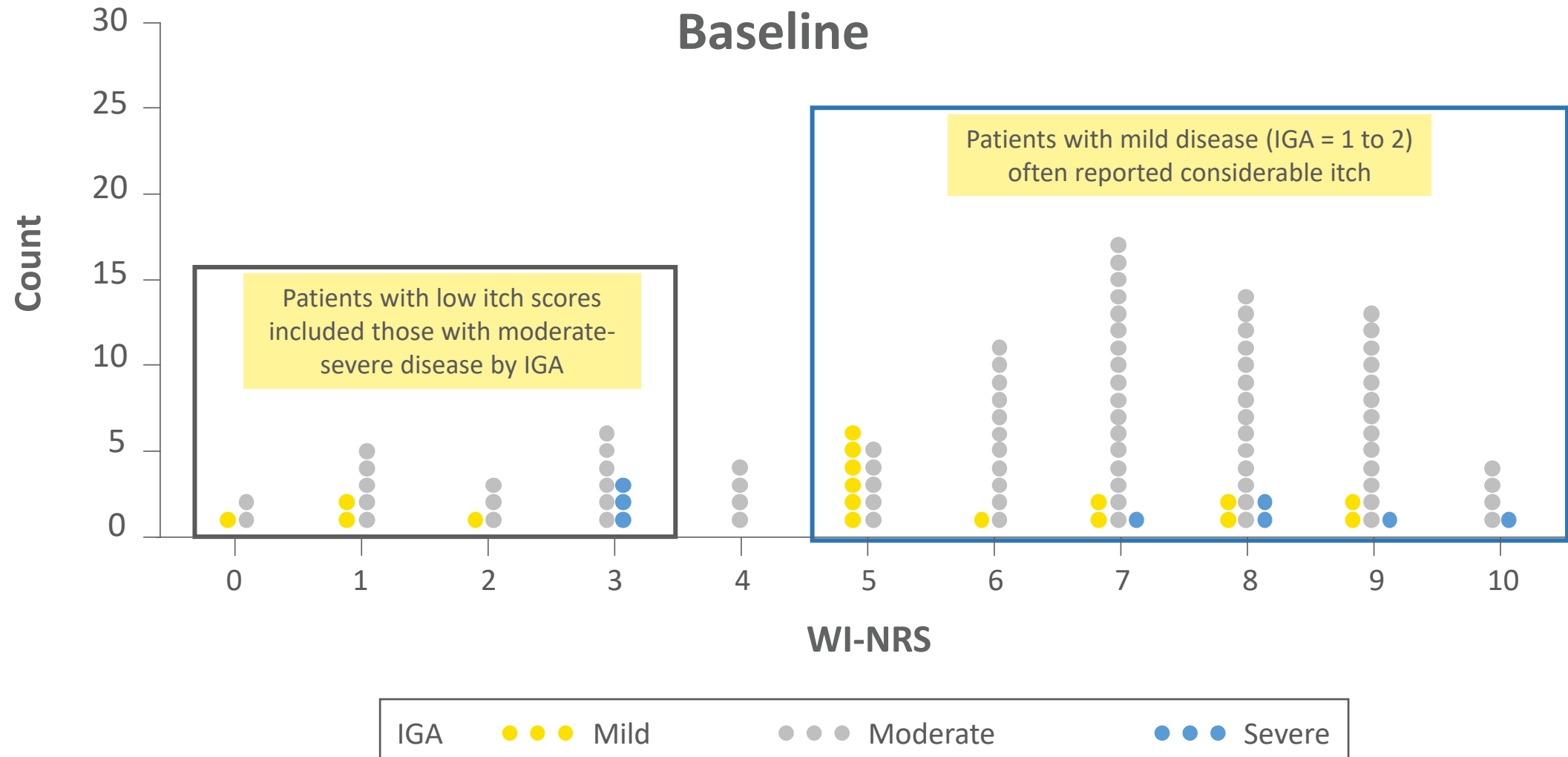
- Around 90% of patients with psoriasis report pruritus and many patients with psoriasis identify itch as their most bothersome symptom¹
- Severity of itching is not always correlated with severity of psoriasis^{2,3}
- In the Multinational Assessment of Psoriasis and Psoriatic Arthritis (MAPP) survey of psoriasis patients and physicians, the top factor contributing to disease severity in psoriasis for patients was **itch** but for physicians was **location/size of lesions**⁴

Methods

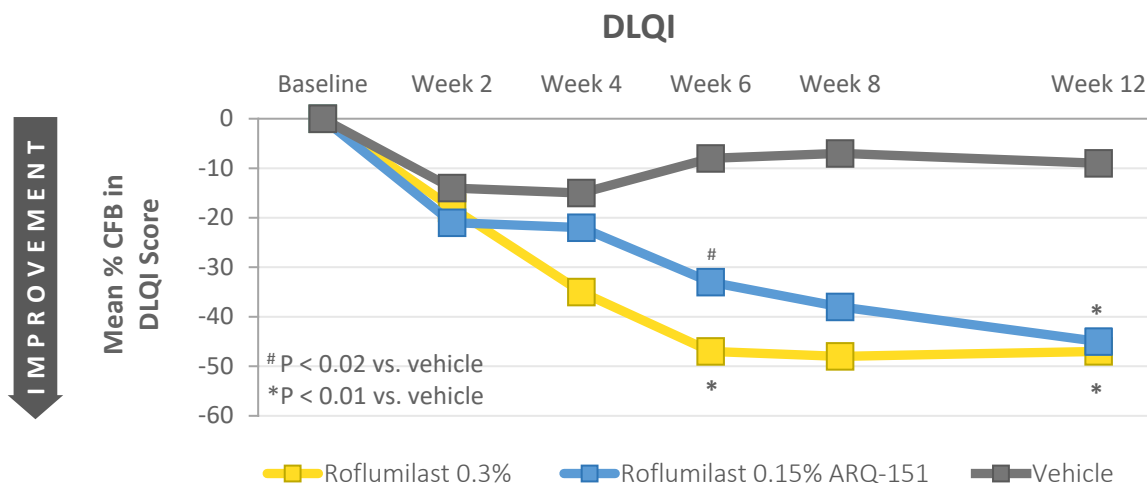
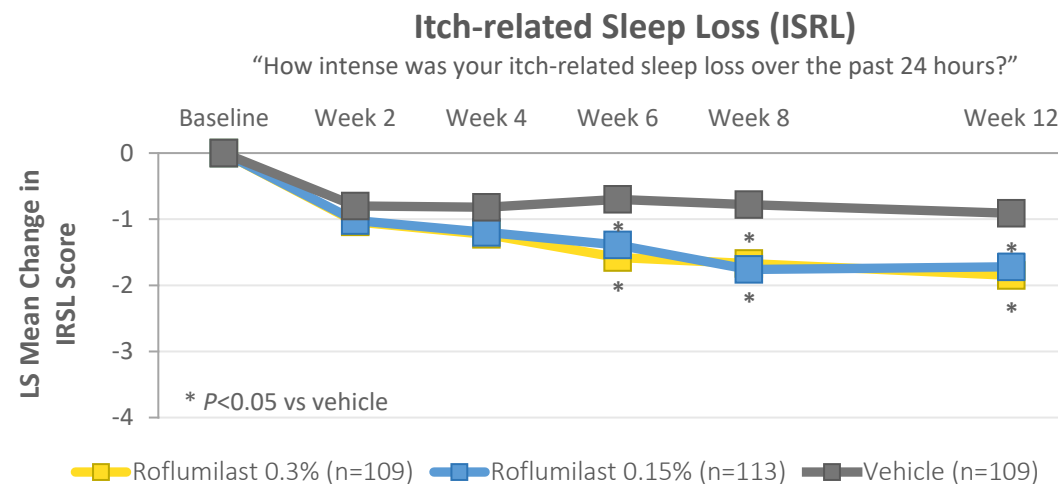
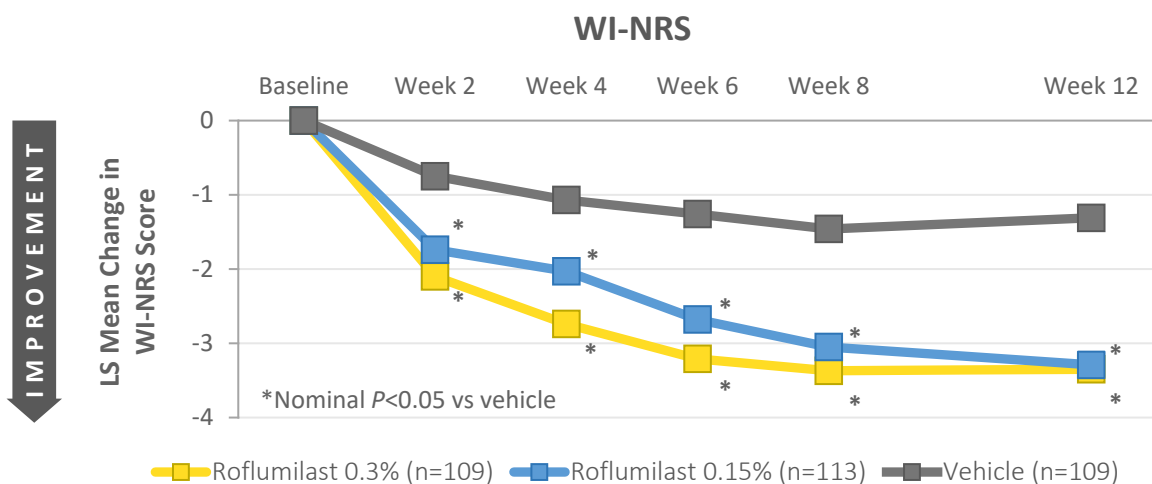
- In a randomized, double-blind, phase 2b trial of 331 adults with chronic plaque psoriasis (NCT03638258), roflumilast cream administered once daily was superior to vehicle cream⁵
- Primary endpoint of achievement of clear or almost-clear skin based on IGA at Week 6 was met⁵
 - Roflumilast 0.3%: 28.0% (P<0.001 vs vehicle)
 - Roflumilast 0.15%: 22.8% (P=0.004 vs vehicle)
 - Vehicle: 8.3%
- Treatment-related adverse events, including application site pain, were uncommon and the frequency was similar in all groups⁵
- Itch and its impact were evaluated via patient-reported outcomes (PROs): Worst Itch Numeric Rating Scale (WI-NRS), Itch-related Sleep Loss (IRSL), and Dermatology Life Quality Index (DLQI)
- Posthoc analyses were performed to determine relationship of WI-NRS with disease severity

1. Elewski B et al. *J Eur Acad Dermatol Venereol* 2019;33:1465-76; 2. Reich A and Szepietowski JC. In: *Itch: Mechanisms and Treatment*. Boca Raton, FL: CRC Press/Taylor & Francis; 2014. 3. Yosipovitch G et al. *Br J Dermatol* 2000;143:969-73; 4. Lebwohl MG, et al. US Perspectives in the Management of Psoriasis and Psoriatic Arthritis: Patient and Physician Results from the Population-Based Multinational Assessment of Psoriasis and Psoriatic Arthritis (MAPP) Survey. *Am J Clin Dermatol*. 2016;17:87-97. 5. Lebwohl MG et al. *NEJM* 2020;383:229-39.

Patient-reported itch (WI-NRS) and physician-assessed disease severity (IGA) were not always aligned



Significant improvements in itch, itch-related sleep loss, and quality of life were observed in patients treated with roflumilast cream



†Evaluated on a scale from 0 (no itch-related sleep loss) to 10 (sleep loss as bad as it can be) in response to the question “How intense was your itch-related sleep loss over the past 24 hours?”

‡DLQI added mid-study via amendment; analysis population N=180 total (54% of ITT); P-values from post hoc test. DLQI: Dermatology Life Quality Index; ISRL: Itch-related Sleep Loss; WI-NRS: Worst Itch Numeric Rating Scale.

Summary and Conclusions

- In this phase 2b study, treatment with roflumilast cream resulted in rapid and robust improvement in the severity of itch, itch-related sleep loss, and quality of life
- Disease severity is not always consistent with patient assessments of itch severity
 - These findings are consistent with the Multinational Assessment of Psoriasis and Psoriatic Arthritis (MAPP) survey which showed that the top factors contributing to disease severity in psoriasis for patients was itch but location/size of lesions for physicians¹
- The improvements of symptoms, including itch and itch-related sleep loss in patients with chronic plaque psoriasis warrant further investigation of once-daily roflumilast cream, a potent PDE-4 inhibitor, as an effective topical treatment for chronic plaque psoriasis

1. Lebwohl MG, et al. US Perspectives in the Management of Psoriasis and Psoriatic Arthritis: Patient and Physician Results from the Population-Based Multinational Assessment of Psoriasis and Psoriatic Arthritis (MAPP) Survey. *Am J Clin Dermatol*. 2016;17:87-97