**Investigator- and Patient-Rated Local Tolerability in Phase 3 Trials of Topical Roflumilast in Patients With Psoriasis, Seborrheic Dermatitis, and Atopic Dermatitis**

Christopher G. Bunik1, Neal Bhutani, James Del Rossio, Zoe D. Desai5, Lawrence F. Fishenfeld6, Leon H. Kirc1,8, Mark G. Leibovich7, Melissa Goodherm2, Lawrence J. Green6, Adelaide A. Hebert, Ronald B. Vender1,11, Matthew Zipursan1,12, Eric L. Simpson1,13, Linda Stein Gold1, Melissa Seal,1 Scott Snyder,11 David W. Osborne,15 Patrick Burnett,15 Robert C. Higham,15 David H. Chu,17 David R. Berk18

1Department of Dermatology and Program in Translational Biomedicine, Van Anda College, New Haven, CT, USA; 2Medical University of South Carolina, Charleston, SC, USA; 3Dermatology and Cutaneous Surgery, University of Miami, Miami, FL, USA; 4Clinical Affairs, RxSolutions, Inc., Seattle, WA, USA; 5Cedar-Sinai Medical Center, Los Angeles, CA, USA; 6The University of Alabama at Birmingham, Birmingham, AL, USA; 7Texas Health University of Texas, Dallas, TX, USA; 8Medellin University Health Recherche, Medellin, CO, USA; 9Dermatologists of the Central States, Probity, LLC, Lakeville, IL, USA; 10Dermatologists of the Central States, Probity, LLC, Lakeville, IL, USA; 11Department of Dermatology, University of North Carolina at Chapel Hill, Chapel Hill, NC, USA; 12Evolve Medical, Inc., Westlake Village, CA, USA; 13Kooyman Vlietman Medical School, Netherlands, Netherlands; 14Henry Ford Medical Center, Detroit, MI, USA; 15Arcutis Biotherapeutics, Inc., Westlake Village, CA, USA; 16Aesthetic Skin Institute, Inc., Los Angeles, CA, USA; 17Henry Ford Medical Center, Detroit, MI, USA; 18Saint Barnabas Medical Center, Middletown, NJ, USA

**INTRODUCTION**

The formulation of a topical product and the occurrence of local skin reactions are both important factors contributing to patient treatment adherence and satisfaction. Excipients such as propylene glycol, polyethylene glycol, and ethanol are in almost all topical preparations, which can irritate the skin. These excipients may irritate the skin, causing local tolerability reactions such as burning and stinging, which can reduce patient satisfaction and adherence to treatment.[1]

Topical corticosteroids, a highly potent (Kd~0.7 nM) phosphodiesterase 4 inhibitor, formulated as a water-based foam and a cream with an occlusive penetration enhancer, are topically applied. - Vehicle excipients in topical corticosteroids include: 10% propylene glycol, cetyl alcohol, and stearyl alcohol. The corticosteroid is absorbed by receptor, activates nuclear receptor, and decreases pruritis, inflammation, edema, erythema, and papules.[2]

Patient-reported outcomes (PRO) are a key aspect of rheumatology and dermatology trials. One of the most commonly used PROs is the Patient Global Assessment (PGA). However, PROs such as the Patient Global Assessment (PGA) and the Investigator Global Assessment (IGA) can provide different interpretations of the same treatment outcomes.[3]

**METHODS**

Three phase-3, placebo-controlled, parallel-group, double-blind, vehicle-controlled, multicenter Phase III studies were conducted in patients with atopic dermatitis, including in patients with involvement in sensitive areas such as the face, genital, and intertriginous areas. A total of 885 patients were enrolled in the study.

**RESULTS**

Topical roflumilast, is a highly potent (Kd~0.7 nM) phosphodiesterase 4 inhibitor, formulated as a water-based foam and a cream with an occlusive penetration enhancer, is topically applied. - Vehicle excipients in topical roflumilast include: ceteareth-10 phosphate, cetearyl phosphate, and polyethylene glycol (KCI). The corticosteroid is absorbed by receptor, activates nuclear receptor, and decreases pruritis, inflammation, edema, erythema, and papules.[2]

**CONCLUSIONS**

Topical roflumilast, is a highly potent (Kd~0.7 nM) phosphodiesterase 4 inhibitor, formulated as a water-based foam and a cream with an occlusive penetration enhancer, is topically applied. - Vehicle excipients in topical roflumilast include: ceteareth-10 phosphate, cetearyl phosphate, and polyethylene glycol (KCI). The corticosteroid is absorbed by receptor, activates nuclear receptor, and decreases pruritis, inflammation, edema, erythema, and papules.[2]

**REFERENCES**

