Safety and Efficacy of Once-Daily Roflumilast Cream 0.3%, a Potent Phosphodiesterase-4 Inhibitor for the Treatment of Psoriasis in the DERMIS-1 and DERMIS-2 Phase 3 Trials

Mark Ledwith1; Leon H. Kircik2; Angela J. Moore3; Linda Stein Gold4; James Del Rosso5; Zoe D. Draslow6; Melissa J. Goodnair; Lawrence J. Green; Adriéle A. Hebert; Kim A. Papp; Jerry Bagel; Neal Bhatia; Laura K. Ferris; Terry Jones; Steven E. Kempers7; David M. Patin8; Paul S. Vemaech; Matthew Zirwas9; Amy Feng; Patrick Burnett; Robert E. Higham; David R. Jagl10

1School of Medicine of Mount Sinai, New York, NY, USA; 2Sun Health Research Institute, Scottsdale, AZ, USA; 3The Ohio State University; 4University of Miami Miller School of Medicine; 5Arcutis, Oceanside, CA, USA; 6UCLA School of Medicine; 7Lebwohl Medical Associates, Aventura, FL, USA; 8University of Nebraska Medical Center, Omaha, NE, USA; 9Arlington Research Center, Arlington, TX, USA; 10Arlington Research Center, Arlington, TX, USA; 11Kaiser Permanente, Southern California, Los Angeles, CA, USA; 12Arcutis, Oceanside, CA, USA; 13University of Nebraska Medical Center, Omaha, NE, USA; 14Arlington Research Center, Arlington, TX, USA; 15University of Nebraska Medical Center, Omaha, NE, USA; 16UCLA School of Medicine; 17University of Nebraska Medical Center, Omaha, NE, USA; 18Kaiser Permanente, Southern California, Los Angeles, CA, USA; 19Arlington Research Center, Arlington, TX, USA; 20University of Nebraska Medical Center, Omaha, NE, USA

INTRODUCTION

Psoriasis is a chronic autoimmune disease affecting more than 125 million people worldwide. It is characterized by scaling, red plaques, and pruritus. Psoriasis can have a significant impact on quality of life, with up to 30% of patients experiencing depression and anxiety.

METHODS

The primary endpoint was assessed using a Clinician Global Assessment (CGA) of severity in the intent-to-treat (ITT) population, and was defined as a reduction ≥4 in CGA score from baseline to Week 2 in the DERMIS-1 study.

RESULTS

In patients with psoriasis, roflumilast cream was well tolerated in both studies. The most common treatment-emergent adverse events (AEs) were nasopharyngitis and hypertension. The rates of serious AEs and discontinuations were low, consistent with the safety profile of roflumilast in previous studies. No new safety signals were identified in this study.

CONCLUSIONS

Once-daily roflumilast cream 0.3% is a novel, topical, phosphodiesterase inhibitor that significantly improves Psoriasis Area and Severity Index (PASI) and Investigator Global Assessment (IGA) success at the primary endpoint of 8 weeks. It is well tolerated and has a favorable safety profile compared to placebo. Further studies are ongoing to evaluate its long-term safety and efficacy.

REFERENCES


ACKNOWLEDGMENTS

The authors thank the patients and healthcare professionals who participated in this study. They also thank the institutional review boards and study monitors for their support. The authors also thank the study coordinators and site investigators for their contributions.

DISCLOSURES

Dr. Kircik reports grants/research support from Stiefel, Pfizer, and Janssen; receiving speaker honoraria from Stiefel, Pfizer, Janssen, and Galderma; and serving as a consultant to Stiefel, Pfizer, Janssen, and Galderma. Dr. Zirwas reports grants/research support from Galderma and Amgen; receiving speaker honoraria from Galderma, Amgen, and Stiefel; and serving as a consultant to Galderma and Amgen. Dr. Del Rosso reports grants/research support from Galderma; receiving speaker honoraria from Galderma; and serving as a consultant to Galderma. Dr. Papp reports receiving speaker honoraria and consulting fees from Galderma, Janssen, and Elan. Dr. Bagel reports receiving grant/research support from Galderma, Janssen, and Elan, and consulting fees from Galderma, Janssen, and Elan. Dr. Bhatia reports receiving grant/research support, consulting fees, and travel expenses from Galderma and Janssen. Dr. Ferris reports receiving grant/research support and consulting fees from Galderma, Janssen, Amgen, and Elan. Dr. Jones reports receiving grant/research support and consulting fees from Galderma, Janssen, Amgen, and Elan. Dr. Kempers reports receiving grant/research support from Galderma and Janssen. Dr. Higham reports receiving grant/research support from Galderma and Janssen. Dr. Jagl reports receiving grant/research support from Galderma and Janssen. Dr. Feng reports receiving grant/research support and consulting fees from Galderma, Janssen, and Amgen. Dr. Burnett reports receiving grant/research support from Galderma and Janssen. Dr. Higham reports receiving grant/research support, consulting fees, and travel expenses from Galderma and Janssen. Dr. Jagl reports receiving grant/research support from Galderma and Janssen.