Once-Daily Roflumilast Cream 0.3%, a Potent Phosphodiesterase-4 Inhibitor, Provided Safe and Effective Treatment for Psoriasis in DERMIS-1 and DERMIS-2 Phase 3 Trials

Mark Johansen1, Leon H. Kircik2, Angela Y. Moore3, Linda Stein Gold4, James Del Rosso5, Zoe D. Gualini6, Melinda J. Goodenham7, Lawrence J. Green8, Adriëlle A. Habert9, Kim A. Pepp10, Kerry Bagel11, Nayal Bhatia12, Laura K. Fersi13, Terry Jones14, Steven E. Kempers15, David M. Pariser16, Paul S. Tamachia17, Matthew Zirwas18, Amy Feng19, Patrick Bumet20, Robert C. Higham21, David R. Berk22

1Naalla School of Medicine at Mount Sinai, New York, NY, USA; 2Yale School of Medicine-Medtronic, New York, NY, USA; 3Scripps Moxley Center, Indiannapolis, IN; 4Physician Skin Care, PLLC, Jackson, MS; 5Summa Health, Akron, OH; 6Research Triangle Institute, Research Triangle Park, NC; 7Icahn School of Medicine at Mount Sinai, New York, NY; 8Icahn School of Medicine at Mount Sinai, New York, NY; 9Icahn School of Medicine at Mount Sinai, New York, NY; 10Tulane University School of Medicine, New Orleans, LA, USA; 11Cameo Dermatology, Cresskill, NJ; 12Lancaster University Medical School, Lancaster, UK; 13University of New Mexico, Albuquerque, NM; 14Florida Dermatology and Skin Health, Jacksonville, FL; 15AstraZeneca PLC, Läunda, UK; 16Psoriasis Treatment Center of Central New Jersey, Windsor, NJ, USA; 17Psoriasis Treatment Center of Central New Jersey, Windsor, NJ, USA; 18Medical University of South Carolina, Charleston, SC; 19University of California, Irvine, CA; 20Icahn School of Medicine at Mount Sinai, New York, NY, USA; 21Icahn School of Medicine at Mount Sinai, New York, NY, USA; 22Icahn School of Medicine at Mount Sinai, New York, NY, USA.

INTRODUCTION

- Roflumilast, a selective phosphodiesterase-4 inhibitor, has been approved for the treatment of moderate-to-severe asthma and chronic obstructive pulmonary disease (COPD).
- This treatment is effective in the management of chronic inflammation and has been shown to improve outcomes such as symptom relief and quality of life.
- The purpose of this study was to evaluate the efficacy and safety of once-daily roflumilast cream 0.3%, a potent phosphodiesterase-4 inhibitor, for the treatment of plaque psoriasis.

METHODS

- The primary outcome was assessed using a Cured/Improved scale that included 5 levels: cleared, improved, moderately improved, moderately worsened, and not evaluable.
- Other measures included the Physician’s Global Assessment (PGA) and Patient’s Global Assessment (PGA).
- Patients were randomized to roflumilast cream 0.3% or vehicle cream in a 2:1 ratio.
- Safety and tolerability were monitored throughout the study.

RESULTS

- Over 96% of patients in each group had no evidence of irritation at Weeks 4 or 8 as assessed by the investigators.
- Significant improvement was observed in the PGA and IGA scores in the roflumilast cream group compared to the vehicle group.

CONCLUSIONS

- Once-daily roflumilast cream 0.3% demonstrated clinical efficacy and safety in patients with plaque psoriasis.

REFERENCES