9-1-2022

34613 Tapinarof cream 1% once daily (QD) for plaque psoriasis: Secondary efficacy outcomes from a long-term extension (LTE) trial

Linda F. Stein Gold

Benjamin Ehst

Laura K. Ferris

Philip M. Brown

David S. Rubenstein

See next page for additional authors

Authors

Linda F. Stein Gold, Benjamin Ehst, Laura K. Ferris, Philip M. Brown, David S. Rubenstein, Anna M. Tallman, and Jerry Bagel

34613

Tapinarof cream 1% once daily (QD) for plaque psoriasis: Secondary efficacy outcomes from a long-term extension (LTE) trial

Linda Stein Gold, MD, Henry Ford Health System, Detroit, MI; Benjamin Ehst, MD, PhD, Oregon Medical Research Center, Portland, OR; Laura K. Ferris, MD, PhD, UPMC Department of Dermatology, Pittsburgh, PA; Philip M. Brown, MD, JD, Dermavant Sciences, Morrisville, NC; David S. Rubenstein, MD, PhD, Dermavant Sciences, Morrisville, NC; Anna M. Tallman, PharmD, Dermavant Sciences, Morrisville, NC; Jerry Bagel, MD, MS, Psoriasis Treatment Center of New Jersey, East Windsor, NJ

Background: Tapinarof cream 1% QD was efficacious and well tolerated versus vehicle in adults with mild-to-severe plaque psoriasis in 2 double-blind 12-week Phase 3 trials (PSOARING 1&2). We report secondary efficacy from PSOARING 3, the LTE trial assessing tapinarof during intermittent treatment based on Physician Global Assessment (PGA) score.

Methods: Eligible PSOARING 1&2 completers could enroll for 40-weeks' open-label tapinarof 1% QD and 4-weeks' follow-up in PSOARING 3. Patients entering with PGA ≥1 were treated until PGA = 0. Patients entering with/achieving PGA = 0 discontinued tapinarof until PGA ≥2, then retreated until PGA = 0.

Results: 91.6% (n = 763) eligible patients enrolled in PSOARING 3. Efficacy improved beyond 12-week pivotal trials and was maintained over time. In PSOARING 1&2, overall mean baseline body surface area (BSA) affected was 7.6−7.9% and Psoriasis Area Severity Index (PASI) was 8.87−9.12. PSOARING 3 baseline mean BSA affected was 4.7% (3.3% and 7.3% previously treated with tapinarof and vehicle, respectively) and mean PASI was 4.76 (3.28 and 7.69 tapinarof and vehicle, respectively). At week 40, significant improvements beyond pivotal trials were observed: overall mean improvement from baseline in BSA affected was −2.0%; PASI75 and PASI90 responses were 29.4% and 17.5%, respectively (beyond the PASI75 of 36.1% and 47.6%; PASI90 of 18.8% and 20.9% in PSOARING 1&2, respectively). No new safety signals were observed.

Conclusion: Continued improvements beyond 12 weeks and durable responses/no tachyphylaxis were observed across secondary efficacy outcomes which, together with previously reported high rates of complete disease clearance (PGA = 0) and ~4-month remittive effect off-therapy, differentiate tapinarof from other topical therapies.

Commercial Disclosure: 100% is sponsored by Dermavant Sciences, Inc.

34615

Tapinarof cream 1% once daily for plaque psoriasis: Dermatology Life Quality Index and local tolerability scores from a long-term extension trial

April W. Armstrong, MD, MPH, Keck School of Medicine University of Southern California, Los Angeles, CA; Seemal R. Desai, MD, Department of Dermatology, The University of Texas Southwestern Medical Center, Dallas, TX Innovative Dermatology, Plano, TX; Melinda Gooderham, MSc, MD, FRCPC, SKiN Centre for Dermatology, Peterborough, Ontario, Canada; David S. Rubenstein, MD, PhD, Dermavant Sciences, Morrisville, NC; Philip M. Brown, MD, JD, Dermavant Sciences, Morrisville, NC; Anna M. Tallman, PharmD, Dermavant Sciences, Morrisville, NC; Leon Kircik, MD, Skin Sciences, PLLC Louisville, KY

Background: We present Dermatology Life Quality Index (DLQI) and local tolerability scores of tapinarof cream 1% once daily during repeated, intermittent treatment for plaque psoriasis in PSOARING 3 (n = 763), the long-term extension trial of two 12-week, double-blinded, vehicle-controlled Phase 3 trials (PSOARING 1&2).

Methods: Eligible PSOARING 1&2 completers could enroll for 40-weeks' open-label treatment and 4-weeks' follow-up in PSOARING 3. Patients entering with Physician Global Assessment (PGA) score ≥1 received tapinarof until complete disease clearance (PGA = 0). Patients with PGA = 0 discontinued tapinarof. Clear patients who then developed PGA≥2 were retreated until PGA = 0. DLQI (range 0−30, lower = better quality-of-life), patient- and investigator-reported local tolerability were assessed (range 0−4, lower = better tolerability).

Results: Mean baseline DLQI scores in PSOARING 1&2 were 8.2−8.7. At baseline in PSOARING 3, mean DLQI was 4.3 overall (3.3 and 6.2 if previously treated with tapinarof or vehicle, respectively). DLQI scores continued to improve and were maintained over time. At week 40, mean DLQI was 1.8 overall. Tapinarof was well tolerated with long-term use, with mean overall patient-reported local tolerability of 0.93 (none-to-slight irritation) and investigator-assessed irritation of 0.07 (no irritation) at week 40.

Conclusions: Tapinarof cream showed continued and durable improvement in quality of life and was well tolerated with long-term use, as reported by patients and investigators, irrespective of intermittent treatment during PSOARING 3. Together with previously reported efficacy and safety, including a high rate of disease clearance (PGA = 0), ~4-month remittive effect, and no tachyphylaxis, these findings differentiate tapinarof cream from other topical therapies for psoriasis.

Commercial Disclosure: 100% is sponsored by Dermavant Sciences, Inc.

33152

Targeted combined endpoint improvement in patient and disease domains in atopic dermatitis (AD) among adults with moderate-to-severe AD treated with upadacitinib

Shawn G. Kwatra, MD, Department of Dermatology, Johns Hopkins University School of Medicine, Baltimore, MD; Marjolein De Bruin-Weller, MD, PhD, University Medical Center Utrecht, Utrecht, Netherlands; Peter Lio, MD, Feinberg School of Medicine, Northwestern University, Chicago, IL; Mette Deleuran, MD, MDSc, Department of Dermatology, Aarhus University Hospital, Aarhus, Denmark; Sarah Ofori, PharmD, RPh, MBA, AbbVie Inc., North Chicago, IL; Henrique D. Teixeira, PhD, MBA, AbbVie Inc., North Chicago, IL; Brian Calimlim, DRPH, MS, AbbVie Inc., North Chicago, IL; Yingyi Liu, PhD, AbbVie Inc., North Chicago, IL; Stephen Weidinger, MD, Department of Dermatology and Allergy, University Hospital Schleswig-Holstein, Campus Kiel, Kiel, Germany

Recommendations for a treat-to-target approach were recently developed to guide systemic therapy for disease control in adults with AD. Recommendations outlined criteria for a 3-month initial acceptable target goal: reduction from baseline ≥1 on a 5-level Patient Global Impression of Severity (PGIS) scale and ≥1 specific disease domain target (≥50% improvement from baseline in Eczema Area and Severity Index [EASI-50]; ≥50% reduction in Scoring of AD [SCORAD-50]; and a reduction from baseline in Worst Pruritus Numerical Rating Scale [WP-NRS] ≥3, Dermatology Life Quality Index [DLQI] ≥4, or Patient Oriented Eczema Measure [POEM] ≥4); and a 6-month optimal target goal: PGIS ≤2 and ≥1 specific disease domain target (EASI-75 or EASI ≤7, SCORAD-75 or SCORAD ≤24, WP-NRS ≤4, DLQI ≤5, POEM ≤7). Achievement of these criteria with once-daily upadacitinib (15 mg and 30 mg) monotherapy was compared with placebo using integrated adult data from MU1 and MU2 trials and nonresponder imputation incorporating multiple imputation for missing values due to COVID-19. Greater proportions of patients treated with upadacitinib 15 mg|30 mg vs placebo ($P < .001$ for all) achieved the initial acceptable target goal at week 2 (78.9%|82.6% vs 25.0%) and week 16 (72.5%|80.2% vs 22.9%), and the optimal target goal at week 2 (52.8%|64.3% vs 6.3%) and week 16 (56.2%|70.1% vs 13.9%). These results suggest that once-daily oral upadacitinib (15 mg and 30 mg) may help improve standards of care in patients with moderate-to-severe AD by achieving 6-month target goals at 16 weeks and as early as 2 weeks for most patients.

Commercial Disclosure: SGK has served as an investigator and/or adviser to AbbVie, Celldex Therapeutics, Galderma, Incyte, Kiniksa Pharmaceuticals, Novartis, Pfizer, Regeneron Pharmaceuticals, and Sanofi. MDB-W is a principal investigator, advisory board member, and consultant.

32663

Testing clinical efficacy of exfoliants against pollution and photoaging for healthy skin maintenance

Nalini Kaul, MSc, PhD, Princeton Cosumer Corp, Elsie Kohoot, Princeton Consumer Research, Barrie Drewitt, Princeton Consumer Research

Photoaging/environmental aging causes damage and wrecks human skin over the course of a life span. With pollutants, particulate matter, and photoaging, photodamage is superimposed on changes occurring with intrinsic aging. Clinical characteristics of cutaneous photoaging include fine lines, wrinkles, roughness, dullness, laxity, mottled pigmentation, and age spots/hyperpigmentation. The skin needs additional supportive care besides photoprotection with sunscreen and with antioxidants. Addition of plant exfoliants is becoming increasingly popular in keeping skin clean by breaking down the accumulation of particulate matter, removing dead cells/debris from the epidermis, exposing new cells, unclogging pores, and helping with age spots, brightening. and blurring lines. Plant-based superficial peel exfoliants like alpha and beta hydroxy acid or enzymes like papain and bromelain or retinol star - bakuchiol are increasingly gaining popularity because they are affordable and convenient with freedom of self-use. Our objective was to test the efficacy of exfoliants on various antiaging attributes in a 4-week clinical design on 70 healthy volunteers (F-35-65 y). Assessments include lines, wrinkles, roughness, skin tone, pores, and hyperpigmentation by a trained grader, antipollution assessment with particulate matter, brightness with colorimeter, elasticity, firmness with cutometer, analysis of digital photographs taken with VISIAR CR along with volunteer self-perception. Our results showed product efficacy with exfoliation introduced antiaging skin modifications in terms of antipollution, skin brightness, softness, tightness, pore size, hyperpigmentation, and age spots. In conclusion, topical plant-based exfoliants enriched with other natural ingredients help remove pollutants, dead cells, reduce blemishes, discoloration, wrinkles besides stimulating cell growth, and thus are integral to healthy skin maintenance.

Commercial Disclosure: None identified.