15001

Durable efficacy of certolizumab pegol dosed at 400 mg every two weeks over 128 weeks in patients with plaque psoriasis enrolled in three phase 3 trials (CIMPASI-1, CIMPASI-2, and CIMPACT)

Ken Gordon, MD, Department of Dermatology, Medical College of Wisconsin; Richard B. Warren, University of Manchester; Alice B. Gottlieb, MD, PhD, Icahn School of Medicine at Mount Sinai; Andrew Blauvelt, MD, MBA, Oregon Medical Research Center; Diamant Thaci, MD, Institute and Comprehensive Center Inflammation Medicine; Yves Poulin, MD, FRCPC, Hôpital Hôtel-Dieu; Marion Boehnlein, PhD, Fiona Brock, MSc, Catherine Arendt, UCB Pharma; Kristian Reich, MD, PhD, Center for Translational Research in Inflammatory Skin Diseases, Institute for Health Services Research in Dermatology and Nursing, University Medical Center Hamburg-Eppendorf, and Skinflammation Center Hamburg, Germany

Background: The Fc-free, PEGylated, anti−tumor necrosis factor certolizumab pegol (CZP) has demonstrated efficacy and safety in moderate to severe plaque psoriasis (PSO). Here, we report long-term response in patients with PSO receiving CZP 400 mg every 2 weeks (q2w) for up to 128 weeks.

Methods: Data were pooled from the CIMPASI-1 (NCT02326298), CIMPASI-2 (NCT02326272), and CIMPACT (NCT02346240) phase 3 trials in adults with PSO≥ 6 months (PASI ≥12%/≥10%, BSA-affected/PGA ≥3); study designs have been reported. This analysis includes patients randomized to placebo at wk 0 who did not achieve wk 16 PASI50 and entered an open-label CZP 400 mg q2w escape arm for up to 128 wks. Dosing adjustment to CZP 200 mg q2w was permitted from wk 48 based on PASI response and Investigator discretion. We report PASI75, PASI90, PGA0/1, and DLQI0/1 through 128 wks' CZP treatment. Responder rates reflect the simple average response, with missing data imputed using Markov Chain Monte Carlo methodology.

Results: 116 placebo-randomized patients entered the CZP 400 mg q2w escape arm. Following 16 wks' CZP 400 mg q2w treatment, 74.7%/48.7% achieved PASI75/PASI90; after 128 wks' CZP, responder rates were 75.5%/57.6%. Of the patients who achieved PASI75 after 16 wks' CZP treatment, 65.9% also achieved PASI90; 82.4% of these patients still achieved PASI75 after 128 wks' CZP, and 64.4% achieved PASI90. Similar trends were reported for DLQI0/1 and PGA0/1.

Conclusions: Response to CZP 400 mg q2w was durable over 128 wks.

Commercial disclosure: Funded by Dermira and UCB Pharma. Medical writing support was provided by Costello Medical, funded by UCB Pharma.

15003

Clinical burden of concomitant joint disease in psoriasis: A US linked claims and electronic medical records database analysis

Michelle Sckornicki, MPH, Patricia Prince, MPH, Aetion; Robert Suruki, ScD, UCB; Anthony Louder, PhD, RPh, Aetion

Background: Psoriasis (PSO) is an inflammatory skin condition, impacting physical and psychological well-being. PSO patients may develop psoriatic arthritis (PsA), a painful joint disease that further impacts quality of life. The objective was to examine rates of metabolic disease and depression in patients with PSO and PsA.

Methods: Claims data linked to electronic medical records were examined (Jan 2007−Mar 2018). Prevalent PSO patients were followed until end of data collection and categorized based on development of PsA ("PSO+PsA" cohort; defined by ICD9/10 codes in patients without PsA at baseline). Follow-up rates of comorbidities, including metabolic disease and depression, were compared for those with/without PsA, presented as cases per 1000 patient-years (1000PY).

Results: Progression to PsA occurred in 2311 (12%) patients. Follow-up rates of hyperlipidemia, hypertension, diabetes, and cardiovascular disease in the PSO+PsA cohort were 1.4-times (326 vs 234/1000PY), 1.6-times (357 vs 228/1000PY), 1.7-times (119 vs 72/1000PY), and 1.4-times (71 vs 50/1000PY) that observed in the PSO-only cohort, respectively. In patients without baseline metabolic disease, higher rates in PSO+PsA vs PSO-only remained (approximately 1.5-times and 1.3-times higher rates of hypertension and hyperlipidemia, respectively). The rate of depression was 140 vs 92/1000PY in the PSO+PsA vs PSO-only cohort; when examined in patients without baseline depression, rates were about half that observed in the overall population (72 vs 49/1000PY).

Conclusions: PSO+PsA patients had a substantial clinical burden, characterized by 1.4-1.7 times higher rates of metabolic disease and depression than for patients who did not progress to PsA.

Commercial disclosure: Funded by UCB Pharma.

15014

Cross-sectional study of the prevalence and predictors of pruritus in pemphigus as compared with bullous pemphigoid

Robin Rolader, BS, Emory University School of Medicine, Atlanta, Georgia; Lauren N. Daugherty, MD, Department of Dermatology, Emory University; Yuan Liu, PhD, Emory University; Ron J. Feldman, MD, PhD, Department of Dermatology, Emory University School of Medicine

Pemphigus is an autoimmune blistering disease that causes painful erosions, while bullous pemphigoid (BP) is classically known to cause pruritic blisters. Previous reports and anecdotal clinical observations suggest pemphigus patients also experience significant itch; we explored the prevalence and potential predictors of itch in pemphigus patients compared with BP. While the Bullous Pemphigoid Disease Area Index (BPDAI) has a subjective patient itch score (0-10 over 24 hours, week, and month), the Pemphigus Disease Area Index (PDAI) does not, so the BPDAI Pruritus component was administered to both BP and pemphigus patients. A retrospective cross-sectional analysis of BPDAI Pruritus scores was performed for 58 pemphigus and 77 BP patients. Average BPDAI Pruritus score (out of 30) was 11.06 $\pm$ 9.29 for BP and 10.97 $\pm$ 8.53 for pemphigus (P =.926). Percentage of encounters with patients experiencing itch was 80.95% for BP and 81.31% for pemphigus (P = .935). Diagnosis (pemphigus vulgaris vs foliaceous), disease site, and disease severity as defined by PDAI were significantly correlated with BPDAI Pruritus scores (P = .007, P = .006, and P = .010, respectively). Correlation of anti−desmoglein-1 levels and BPDAI Pruritus scores trended toward significance (P = .059). These results illustrate that patients with pemphigus and BP experience itch with similar frequency and severity, and that pemphigus patients with cutaneous disease report significant pruritus. Our study also highlights the need for a validated subjective measure of itch for pemphigus patients. Limitations include performance at a single academic center and inclusion of patients with primarily mild to moderate severity. Further research is needed to confirm the true prevalence of itch in this population.

Commercial disclosure: None identified.

15025

Correlation of in vitro gene expression analysis with in vivo efficacy

Tiffany Quinn, MS, Floratech, Robert Harper, PhD

The objective of this research was to conduct in vitro gene expression testing of a plant-derived skin lipid mimetic (SLM) [INCI Jojoba Oil/Macadamia Seed Oil Esters (and) Squalene (and) Phytosteryl Macadamiate (and) Phytosterols (and) Tocopherol] and determine if these results correlate with randomized, double-blind, vehicle-controlled in vivo efficacy studies. Gene expression testing of 3% SLM in a simple oil in water (o/w) emulsion produced the following statistically significant gene expression changes over the vehicle: down regulation of MMP, EDN1, ICAM1, CXCL8/IL8, IL10, IL1B, PTGS2, and TLR2. Literature shows the following associations 1) MMP with collagen degradation. Down-regulation may help to increase elasticity and reduce wrinkle-related signs of aging. 2) CXCL8/IL8, IL10, IL1B, PTGS2, and TLR2 with an inflammatory response/barrier disruption. Down-regulation may reduce inflammation and barrier disruption. Three small IRB-approved studies were carried out on an o/w emulsion containing 3% SLM to obtain efficacy data. In study 1, SLM produced statistically significant (P < .001) increases in skin elasticity compared with the vehicle, after one week of use on photoaged skin (15%, n = 13). In study 2, SLM produced statistically significant (P < .001) increases in barrier recovery of delipidized skin (using acetone) compared with the vehicle, 60 minutes after one application (63%, n = 15). In study 3 SLM produced statistically significant (P < .001) increases in skin barrier function compared with 3% petrolatum, after two weeks of twice daily applications and after a one week regression (29% and 19%, respectively, n = 18). These studies demonstrate the correlation between in vitro gene expression data and in vivo efficacy.

Commercial disclosure: This research was sponsored by Floratech.