P3307
Efficacy and safety of ABT-874 versus methotrexate in patients with moderate to severe psoriasis
K. Reich, Dermatologikum Hamburg, Hamburg, Germany; J. Valdes, Abbott Laboratories, Abbott Park, IL, United States; R. Langle, Dalhousie University, Halifax, Nova Scotia, Canada; S. Yoo, Abbott Laboratories, Abbott Park, IL, United States

Aims: To compare the efficacy and safety of ABT-874 with that of methotrexate for treatment of moderate to severe psoriasis.

Methods: Phase III, 52-week, double-blind, active-controlled trial (NCT00679731). Patients were randomized 1:1 to: ABT-874 (200 mg at weeks 0 and 4, followed by 100 mg ABT-874 every 4 weeks for weeks 8-48) or methotrexate (5-25 mg weekly). Nonresponder imputation (patients with Psoriasis Area and Severity Index [PASI] >75 and Physician’s Global Assessment [PGA] >0/1 at week 24 or PASI <50 and PGA >3 after week 24) were discontinued from the study. The four primary endpoints were the percentage of patients with: PASI 75 at week 24, PGA of 0 or 1 at week 24, PASI 75 at week 52, and PGA score of 0 or 1 at week 52. Safety assessments were made throughout the study. Nonresponder imputation (NRI) was used to handle missing data.

Results: Three hundred seventeen patients were enrolled in the study. 68.8% of ABT-874-treated patients achieved PASI 75 at week 24, compared to 39.9% of methotrexate-treated patients (P < .001) and a PGA of 0 or 1 was achieved by 80.5% of ABT-874 patients versus 54.4% of methotrexate patients (P < .001). At week 52, 66.2% of ABT-874 patients achieved PASI 75 versus 23.9% of methotrexate patients (P < .001), and 63.0% of ABT-874 patients versus 20.2% of methotrexate patients achieved a PGA of 0 or 1 (P < .001). Numbers of patients with serious adverse events or discontinuing due to adverse events were similar for both treatment groups.

Conclusion: At 24 and 52 weeks, ABT-874 was superior to methotrexate with respect to the primary endpoints of PASI 75 and PGA 0/1 in patients with moderate to severe psoriasis.

Commercial support: Funded by Abbott Laboratories.

P3308
Oral apremilast is active in the treatment of moderate to severe plaque psoriasis
Kim Papp, MD, PhD, K. Papp Clinical Research, Waterloo, Canada; Angela Hu, Celgene Corporation, Basking Ridge, NJ, United States; Robert Day, PhD, Celgene Corporation, Basking Ridge, NJ, United States

Background: Apremilast (APR) is a novel oral pluripotent immunomodulator that specifically inhibits phosphodiesterase-4 (PDE4) and therefore modulates multiple pro- and anti-inflammatory mediators implicated in psoriasis.

Methods: This was a phase IIb randomized, double-blind, placebo (PBO)-controlled, dose-ranging multicenter study conducted in the US and Canada. Subjects with moderate to severe plaque psoriasis (PASI ≥ 12, BSA ≥ 10%) were equally randomized at baseline to APR (BID 10, 20 or 30 mg) or PBO. At week 16, APR-treated subjects were randomized to BID APR 20 or 30 mg for the remainder of the treatment period, which ended at week 24.

Results: Three hundred fifty-two subjects were randomized: 63% male; mean age 44; mean BMI 31; mean psoriasis duration 19 years; mean PASI 18.5; mean BSA 22%. Treatment groups were well-balanced at baseline. At week 16, a significantly greater proportion of subjects achieved PASI <75 in the 30 mg BID (40.9%; n = 88) and 20 mg BID (28.7%; n = 87) groups (PBO 5.7%; n = 88; P < .001; the 10 mg BID group (11.2%; n = 89) was not significant. A consistent dose response was seen across all efficacy parameters. During the 16-week BID-controlled period, discontinuations related to AEs were 11%, 9%, and 1% for the 30, 20, and 10 mg BID groups, respectively (6% PBO). Discontinuations because of a lack of efficacy were 2%, 2%, and 3%, respectively (5% PBO). More than 96% of AEs were mild or moderate. Nausea, URI, diarrhea, nasopharyngitis, headache, tension headache, visual URIT, arthralgia (PBO group), gastroenteritis, and dyspepsia occurred in <5% of subjects throughout week 16. Eight SAEs were reported by week 24 (3 for 50 mg BID, 3 for 20 mg BID, and 2 for PBO); none were related to APR. There were no apparent effects on LFTs, WBC, hemoglobin, or electrolytes.

Conclusion: Both APR 20 mg BID and 30 mg BID doses were efficacious in reducing the severity of moderate to severe plaque psoriasis. APR 30 mg BID showed an incremental increase of response without significant safety signals and with an acceptable tolerability profile. Therefore, 30 mg BID has a better overall risk-benefit profile and will be studied in larger phase three clinical trials to support product registration.

P3309
Anxiety in patients with psoriasis
Nogaeser Morillas Palomo, Dermatology Service, University Hospital Virgen de las Nieves, Granada, Spain; Garcia Mellado Valentin, Dermatology Service, University Hospital Virgen de las Nieves, Granada, Spain; Gonzalez Domenech Pablo, Psychiatry Service, University Hospital Virgen de las Nieves, Granada, Spain; Martinez Torrega Jose Maria, Department of Psychiatry and Institute of Neurosciences, Faculty of Medicine, University of Granada, Granada, Spain; Martinez Peinado Carmen, Dermatology Service, University Hospital Virgen de las Nieves, Granada, Spain

Several studies have shown that patients with psoriasis may suffer pain, annoyance, and discomfort and psychological and social difficulties including stigmatization, embarrassment, and social inhibition. Anxiety and depression have been found to have higher prevalence among psoriasis patients than controls without psoriasis.

Methods: The sample included 116 participants: 58 patients with moderate-severe psoriasis and 58 controls. Each patient was matched with controls by age, sex, and sociocultural level. In both groups, the Hospital Anxiety and Depressive Scale (HAD) scale was used to evaluate the levels of anxiety. To examine the skin disease severity all patients were assessed by Psoriasis Activity and Severity Index (PASI).

Results: Both groups were comprised of 57% (33/58) of males and 43% (25/58) of females; and the average age (± SD) was 49.6 ± 17.5 years. There was the highest proportion of females at age of 20, 40, and 60 years old. The proportion of high anxiety level (HAD > 10) was significantly higher in patients than in controls (52% vs 3%; P < .001). The highest level of anxiety was associated with females, and within them, with housewives, unemployed, and teachers. The PASI score was significantly associated with anxiety and depression.

Conclusions: Patients with psoriasis, especially women linked to some professional situations, showed the highest levels of anxiety.

Commercial support: None identified.

P3310
Resource utilization and costs associated with switching from etanercept to adalimumab versus dose escalating with etanercept in patients with psoriasis
Kim Papp, Prothro Medical Research, Waterloo, Ontario, Canada; Annie Guerin, Analysis Group, Montreal, Quebec, Canada; Parvez Mulani, Abbott Laboratories, Abbott Park, IL, United States

Objective: To compare the health care resource utilization and costs for patients with psoriasis treated with etanercept who escalated etanercept dosage and who switched to adalimumab.

Methods: The Thomson MarketScan and the Ingenix Impact National Managed Care databases (2007/Q2–2009/Q2) were combined to select continuously enrolled patients with psoriasis who escalated etanercept dosage and who switched to adalimumab.

Results: Compared with the switching cohort (N = 728), the dose-escalation cohort (N = 572) had significantly more urgent care (emergency department and inpatient admission) service utilization (IRR = 1.32, P = .04), total number of inpatient days (IRR = 1.49, P < .01), and outpatient visits (IRR = 1.06, P = .02). Consequently, the dose-escalation cohort had an adjusted incremental 6-month total pharmacy cost per patient of $1758 (P < .01), mainly owing to etanercept therapy costs ($1573, P < .01). Overall, the dose-escalation cohort incurred an incremental $2451 in total cost over a 6-month period (P = .01) compared with the switching cohort, after adjustment for potential confounding factors.

Conclusions: Patients with psoriasis treated with etanercept who switched to adalimumab had significantly lesser resource utilization and costs compared with those who had increased the dosage of etanercept.

Commercial support: Funded by Abbott Laboratories.

FEBRUARY 2011 J AM ACAD DERMATOL AB147