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Efficacy and safety of ABT-874 versus methotrexate in patients with moderate to severe psoriasis

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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). Nonresponding patients (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 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 completed the study compared with 27.6% of methotrexate-treated patients. At week 24, PASI 75 was achieved by 81.8% of ABT-874-treated patients versus 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 34.4% 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.

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Oral apremilast is active in the treatment of moderate to severe plaque psoriasis

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Background: Apremilast (APR) is a novel oral pluripotent immunomodulator that specifically inhibits phosphodiesterase-4 (PDE4) and therefore modulates multiple pro- and antiinflammatory 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 $\geq 10\%$) were equally randomized at baseline to APR (BID 10, 20 or 30 mg) or PBO. At week 16, PBO-treated subjects were rerandomized 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 PBO-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, URTI, diarrhea, nasopharyngitis, headache, tension headache, viral URTI, arthralgia (PBO group), gastroenteritis, and dyspepsia occurred in >5% of subjects through week 16. Eight SAEs were reported by week 24 (3 for 30 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.

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Anxiety in patients with psoriasis

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Background: 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 Depression 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 ($\pm$ SD) was 49.6 $\pm$ 17.5 years. There was the highest proportion of psoriasis 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 correlated with HAD score ($r = 0.4$; $P = .001$).

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

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P3310

Resource utilization and costs associated with switching from etanercept to adalimumab versus dose escalating with etanercept in patients with psoriasis

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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 adult patients with psoriasis (≥ 1 psoriasis diagnoses within 6 months before etanercept initiation). Patients who initiated etanercept and experienced treatment failure, defined as switching to adalimumab or escalation of etanercept dosage, were analyzed. Study outcomes were measured during the 6-month period after the switch or dose-escalation date (ie, index date) and included health care resource utilization and costs. Adjusted incidence rate ratios (IRRs) and 6-month incremental costs (2008 US$) between the two cohorts were estimated using Poisson models and generalized nonlinear models, respectively. Multivariate models controlled for age, sex, and 6-month preindex characteristics including comorbidities with a prevalence $\geq 5\%$, most frequently prescribed treatments, duration of etanercept use, and resource use.

Results: Compared with the switching cohort (N = 728), the dose-escalation cohort (N = 372) 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 medical service cost per patient of $762 ($P < .01$), mostly attributable to urgent care ($557; $P = .01$) and outpatient visits ($308; $P < .05$). Moreover, 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.

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