BioSpectrum
the business of Bio & Health Sciences
ASIA EDITION

# Oral OTEZLA demonstrated significant improvement versus Placebo in clinical trial

14 March 2017 | News | By BioSpectrum Bureau

**Oral OTEZLA demonstrated significant improvement versus Placebo in clinical trial**


Celgene Corporation announced that results from its phase 4 UNVEIL trial evaluating OTEZLA (apremilast), the Company's oral, selective inhibitor of phosphodiesterase 4 (PDE4), in patients with moderate plaque psoriasis with a body surface area (BSA) of 5-10 percent, were presented at the American Academy of Dermatology's Annual Meeting in Orlando, Florida.

The UNVEIL study evaluated the clinical efficacy and safety of oral OTEZLA 30 mg twice daily compared with placebo at week 16 in 221 patients with moderate plaque psoriasis [defined as a BSA involvement of 5-10 percent and a static Physician's Global Assessment (sPGA) of 3] who were naÃ¯ve to systemic and biologic therapy. At baseline, more than 80 percent of patients enrolled in the trial had previously received topical therapy. The primary endpoint was the mean percentage change from baseline in the product of PGA and BSA (PGAÃ—BSA) at week 16. The PGAxBSA composite tool is a simple assessment that has been developed as a measure of clinically meaningful responses of psoriasis patients in clinical trials.

At week 16, patients who received OTEZLA had a significantly greater improvement in mean percentage change from baseline in PGAÃ—BSA compared with those who received placebo (-48.1 vs. -10.2, respectively; P<0.0001). In addition, a 75 percent or greater improvement in PGAÃ—BSA score was achieved by 35.1 percent of patients treated with OTEZLA vs. 12.3 percent of patients treated with placebo (P<0.0001). A significantly greater percentage of patients receiving OTEZLA versus placebo achieved a PGA score of 0 (clear) or 1 (almost clear) at week 16 (30.4 percent vs. 9.6 percent; P<0.0001).

In other secondary endpoints, enrolled patients who had scalp psoriasis (n=167), a significantly greater percentage who received OTEZLA achieved a Scalp Physician's Global Assessment score of 0 (clear) or 1 (minimal) with a greater than two-point reduction from baseline compared with placebo (38.0 percent vs. 20.0 percent, respectively; P=0.0178).

"Patients with moderate plaque psoriasis are often inadequately treated, and there remains an unmet medical need for safe

and effective treatment options in this population," said Dr. Bruce Strober, professor and chair of the Department of Dermatology at UConn Health. "While most trials focus on moderate to severe plaque psoriasis, this is the first randomized clinical trial of patients with moderate plaque psoriasis, and the results provide encouraging data for patients."

In a separate pre-specified analysis, patients in UNVEIL reported satisfaction scores based on the Treatment Satisfaction Questionnaire version II that were significantly greater with OTEZLA than placebo in global satisfaction (63.2 vs. 48.7, respectively; P<0.0001) and effectiveness (57.3 vs. 38.8; P<0.0001) at week 16. Patients reported no significant difference versus placebo in terms of convenience (66.9 vs. 65.7; P=NS) or side effects (78.5 vs. 75.0; P=NS).

Adverse events reported in at least five percent of patients taking OTEZLA and greater than placebo in the UNVEIL study were diarrhea (29 percent vs. 16 percent), headache (20 percent vs. 11 percent), nausea (18 percent vs. 10 percent), upper respiratory tract infection (7 percent vs. 4 percent) and vomiting (6 percent vs. 3 percent). The safety and tolerability data for OTEZLA observed in the UNVEIL study were consistent with previously reported data from six phase 3 studies of OTEZLA in psoriasis or psoriatic arthritis; no new safety signals were observed.

OTEZLA is not indicated for the treatment of plaque psoriasis patients with BSA involvement of less than 10 percent or sPGA less than 3.