March 5, 2017

Oral OTEZLA® (Apremilast) Demonstrated Significant Improvement versus Placebo in Trial of Patients with Moderate Plaque Psoriasis Who Were Naïve to Systemic and Biologic Therapy

Data from UNVEIL, the first trial of patients with moderate plaque psoriasis (BSA 5-10 percent) who were naïve to systemic and biologic therapy, presented at American Academy of Dermatology Congress

OTEZLA demonstrated significant improvements versus placebo for the primary and key secondary endpoints at week 16

Safety profile for OTEZLA in UNVEIL was consistent with that of previous trials

SUMMIT, N.J.--(BUSINESS WIRE)-- Celgene Corporation (NASDAQ:CELG) today 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 naïve 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 (PGA×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 PGA×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 PGA×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.

About UNVEIL

UNVEIL is the first prospective, randomized, controlled study to evaluate the clinical efficacy and safety of OTEZLA in patients with moderate plaque psoriasis (defined as a BSA involvement of 5-10 percent and sPGA of 3 based on a 0 to 5 scale) who were naïve to systemic and biologic therapies. Patients (n=221) were randomized 2:1 to receive either OTEZLA 30 mg twice daily or placebo for 16 weeks, followed by an open-label extension phase in which placebo patients were switched to OTEZLA through week 52. All doses were titrated over the first week of treatment. At baseline, more than 80 percent of patients had previously received topical therapy.

About OTEZLA®

OTEZLA® (apremilast) 30 mg tablets is an oral small-molecule inhibitor of phosphodiesterase 4 (PDE4) specific for cyclic adenosine monophosphate (cAMP). PDE4 inhibition results in increased intracellular cAMP levels which is thought to indirectly modulate the production of inflammatory mediators. The specific mechanism(s) by which OTEZLA exerts its therapeutic action in patients with psoriasis is not well defined.

INDICATION

Otezla® (apremilast) is indicated for the treatment of patients with moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy.

IMPORTANT SAFETY INFORMATION

Contraindications

Otezla® (apremilast) is contraindicated in patients with a known hypersensitivity to apremilast or to any of the excipients in the formulation.

Warnings and Precautions

Depression: Treatment with OTEZLA is associated with an increase in adverse reactions of depression. During clinical trials, 1.3% (12/920) of patients treated with OTEZLA reported depression compared to 0.4% (2/506) on placebo; 0.1% (1/1308) of OTEZLA patients discontinued treatment due to depression compared with none on placebo (0/506). Depression was reported as serious in 0.1% (1/1308) of patients exposed to OTEZLA, compared to none in placebo-treated patients (0/506). Suicidal behavior was observed in 0.1% (1/1308) of patients on OTEZLA, compared to 0.2% (1/506) on placebo. One patient treated with OTEZLA attempted suicide; one patient on placebo committed suicide.

Carefully weigh the risks and benefits of treatment with OTEZLA for patients with a history of depression and/or suicidal thoughts/behavior, or in patients who develop such symptoms while on OTEZLA. Patients, caregivers, and families should be advised of the need to be alert for the emergence or worsening of depression, suicidal thoughts or other mood changes, and they should contact their healthcare provider if such changes occur.

Weight Decrease: Body weight loss of 5-10% occurred in 12% (96/784) of patients treated with OTEZLA and in 5% (19/382) of patients treated with placebo. Body weight loss of ≥10% occurred in 2% (16/784) of patients treated with OTEZLA compared to 1% (3/382) of patients treated with placebo. Monitor body weight regularly; evaluate unexplained or clinically significant weight loss, and consider discontinuation of OTEZLA.

Drug Interactions: Apremilast exposure was decreased when OTEZLA was co-administered with rifampin, a strong CYP450 enzyme inducer; loss of OTEZLA efficacy may occur. Concomitant use of OTEZLA with CYP450 enzyme inducers (e.g., rifampin, phenobarbital, carbamazepine, phenytoin) is not recommended.

Adverse Reactions

Adverse reactions reported in ≥5% of patients were (OTEZLA%, placebo%): diarrhea (17, 6), nausea (17, 7), upper respiratory tract infection (9, 6), tension headache (8, 4), and headache (6, 4).

Use in Specific Populations

Pregnancy and Nursing Mothers: OTEZLA is Pregnancy Category C; it has not been studied in pregnant women. Use during pregnancy only if the potential benefit justifies the potential risk to the fetus. It is not known whether apremilast or its

metabolites are present in human milk. Caution should be exercised when OTEZLA is administered to a nursing woman.

Renal Impairment: OTEZLA dosage should be reduced in patients with severe renal impairment (creatinine clearance less than 30 mL/min); for details, see Dosage and Administration, Section 2, in the Full Prescribing Information.

Please click here for Full Prescribing Information.

About Celgene

Celgene Corporation, headquartered in Summit, New Jersey, is an integrated global biopharmaceutical company engaged primarily in the discovery, development and commercialization of innovative therapies for the treatment of cancer and inflammatory diseases through next-generation solutions in protein homeostasis, immuno-oncology, epigenetics, immunology and neuro-inflammation. For more information, please visit www.celgene.com/. Follow Celgene on Social Media: @Celgene, Pinterest, LinkedIn, Facebook and YouTube.

Forward-Looking Statements

This press release contains forward-looking statements, which are generally statements that are not historical facts. Forward-looking statements can be identified by the words "expects," "anticipates," "believes," "intends," "estimates," "plans," "will," "outlook" and similar expressions. Forward-looking statements are based on management's current plans, estimates, assumptions and projections, and speak only as of the date they are made. We undertake no obligation to update any forward-looking statement in light of new information or future events, except as otherwise required by law. Forward-looking statements involve inherent risks and uncertainties, most of which are difficult to predict and are generally beyond our control. Actual results or outcomes may differ materially from those implied by the forward-looking statements as a result of the impact of a number of factors, many of which are discussed in more detail in our Annual Report on Form 10-K and our other reports filed with the U.S. Securities and Exchange Commission.

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