March 3, 2017

Celgene to Present New Data from Clinical Trials on Oral OTEZLA® (apremilast) at American Academy of Dermatology Congress

UNVEIL evaluated the efficacy and safety of oral OTEZLA at 16 weeks in patients with moderate plaque psoriasis who were naïve to systemic and biologic therapy

SUMMIT, N.J.--(BUSINESS WIRE)-- Celgene Corporation (NASDAQ:CELG) today announced that findings from ongoing clinical trials of OTEZLA® (apremilast), the Company's oral, selective inhibitor of phosphodiesterase 4 (PDE4), conducted in patients with moderate or moderate to severe plaque psoriasis, and in adult patients (18 years or older) with active psoriatic arthritis, will be presented at the 75th Annual Meeting of the American Academy of Dermatology (AAD) in Orlando, Florida. Ten abstracts will be presented at the meeting.

Among the data that will be presented is an analysis of the phase 4 UNVEIL trial, which evaluates the clinical efficacy and safety of oral OTEZLA 30 mg twice daily compared with placebo at week 16 in patients with moderate plaque psoriasis [defined as a body surface area (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.

"We are excited to present new clinical research to the scientific community at AAD showing the efficacy and safety of OTEZLA in a variety of studies in patients with plaque psoriasis, including longer-term data," said Scott Smith, President, Celgene Inflammation & Immunology. "Furthermore, we are eager to share the results from UNVEIL, which is the first trial to evaluate a systemic therapy in patients with moderate plaque psoriasis who have not previously been treated with a systemic therapy, including biologics."

The following abstracts will be presented at American Academy of Dermatology as an exchange of scientific and clinical information (all times, EST):

Abstracts at a Glance

UNVEIL DATA

Abstract 4892; Sunday, March 5, 2017, 8:55 - 9:00 AM
Efficacy and Safety of Apremilast in Patients With Moderate Plaque Psoriasis (UNVEIL Phase 4 Study); Bruce Strober

Abstract 5432; Sunday, March 5, 2017, 10:30 - 10:35 AM
Efficacy of Apremilast on Quality of Life Measures in Patients With Moderate Plaque Psoriasis (UNVEIL Phase 4 Study); Jerry Bagel

LONG-TERM DATA

Abstract 4927; Sunday, March 5, 2017, 8:40 - 8:45 AM
Long-term Safety of Apremilast Treatment in Psoriasis and Psoriatic Arthritis Patients: Pooled Analysis for 156 Weeks and Beyond in the ESTEEM 1 and 2 and PALACE 1-3 Phase 3 Trials; Jeffrey Crowley

Abstract 5139; Sunday, March 5, 2017, 11:10 - 11:15 AM
Apremilast, an Oral Phosphodiesterase 4 Inhibitor, Is Associated With Long-term (104-Week) Improvement in Fatigue in Patients With Psoriatic Arthritis: Pooled Results From 3 Phase III, Randomized, Controlled Trials; Arthur Kavanaugh

Abstract 5390; Sunday, March 5, 2017, 3:45 - 3:50 PM
Low Serious Infection Rates in Patients with Psoriasis and Psoriatic Arthritis Treated With Apremilast for 156 Weeks and Beyond: Pooled Analysis of the Phase 3 ESTEEM 1 and 2 and PALACE 1-3 Trials; David Pariser

Abstract 5436; Sunday, March 5, 2017, 8:25 - 8:30 AM
Safety and Efficacy of Apremilast Through 104 Weeks in Patients With Moderate to Severe Psoriasis Who Continued on Apremilast or Switched From Etanercept Treatment in the LIBERATE Study; Kristian Reich

OTHER DATA
Abstract 5413; Sunday, March 5, 2017, 10:25 - 10:30 AM
Apremilast Reduces IL-17F, IL-17A, IL-22, and TNF-α Plasma Protein Levels in Patients With Moderate to Severe Plaque Psoriasis: Pharmacodynamic and Correlative Results From Phase 2/3 Studies; James G. Krueger

Abstract 5137; Sunday, March 5, 2017, 11:50 - 11:55 AM
First "Real-World" Insights on Apremilast Therapy for Patients With Plaque Psoriasis From the LAPIS-PSO Study: An Interim Analysis; Kristian Reich

Abstract 5437; Sunday, March 5, 2017, 1:00 - 1:05 PM
Real-World Burden of Comorbidities in US Patients With Psoriasis; Kamal Shah

Abstract 5439; Sunday, March 5, 2017, 12:35 - 12:40 PM
Evaluation of the PGAxBSA Composite Tool in Patients With Moderate vs. Moderate to Severe Plaque Psoriasis; Kristina Callis Duffin

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. The primary endpoint was the mean percentage change from baseline in the product of Physician's Global Assessment (PGA) and BSA (%) at week 16.

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 or psoriatic arthritis 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 and for the treatment of adult patients with active psoriatic arthritis.

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: 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.

Psoriasis: 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.

Psoriatic Arthritis: During clinical trials, 1.0% (10/998) of patients treated with Otezla reported depression or depressed mood compared to 0.8% (4/495) treated with placebo; 0.3% (4/1441) of patients treated with Otezla discontinued treatment due to depression or depressed mood compared with none in placebo treated patients (0/495). Depression was reported as serious in 0.2% (3/1441) of patients exposed to Otezla, compared to none in placebo treated patients (0/495). Suicidal ideation and behavior were observed in 0.2% (3/1441) of patients on Otezla, compared to none on placebo (0/495). Two patients who received placebo committed suicide compared to none on Otezla.

Weight Decrease: Monitor body weight regularly; evaluate unexplained or clinically significant weight loss, and consider discontinuation of Otezla.

Psoriasis: 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.

Psoriatic Arthritis: Body weight loss of 5-10% was reported in 10% of patients taking Otezla and in 3.3% of patients taking 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

Psoriasis: 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).

Psoriatic Arthritis: Adverse reactions reported in ≥2% of patients taking Otezla, that occurred at a frequency at least 1% higher than that observed in patients taking placebo, for up to 16 weeks (after the initial 5-day titration), were (Otezla%, placebo%): diarrhea (7.7, 1.6); nausea (8.9, 3.1); headache (5.9, 2.2); upper respiratory tract infection (3.9, 1.8); vomiting (3.2, 0.4); nasopharyngitis (2.6, 1.6); upper abdominal pain (2.0, 0.2).

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 Securities and Exchange Commission.

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