Oral OTEZLA® (apremilast) Data from Open-Label Phase of ESTEEM and LIBERATE™ Trials to Be Presented at American Academy of Dermatology Congress

Pooled ESTEEM 1 and 2 182-week data will report on long-term exposure of OTEZLA in patients with moderate to severe plaque psoriasis

One-year data from LIBERATE™ trial assesses efficacy of OTEZLA in patients continuing on OTEZLA and those who switched from etanercept

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), in patients with moderate to severe plaque psoriasis and patients with active psoriatic arthritis will be presented at the 74th Annual Meeting of the American Academy of Dermatology (AAD) in Washington, DC. Nine abstracts will be presented, including findings on safety and selected efficacy measures from the open-label phase of these trials. Cost-effectiveness data of OTEZLA in patients with moderate to severe plaque psoriasis will also be shown at the meeting.

The abstracts include an analysis of pooled 182-week (3.5-year) data collected from patients in ESTEEM 1 and 2 who were initially treated with OTEZLA 30 mg twice daily for a duration up to 182 weeks. This study will be summarized in the AAD “Pearls from the Posters” symposium session.

Data from the LIBERATE™ study will assess the 52-week (one year) effect of either sustained treatment with oral OTEZLA 30 mg twice daily or of switching at week 16 from weekly subcutaneous etanercept 50 mg to OTEZLA 30 mg in patients with moderate to severe plaque psoriasis. Additional one year results from the LIBERATE study will be presented, including effect on difficult-to-treat areas (scalp and nails), pruritus (itching) and Dermatology Quality-of-Life Index scores, as well as a cost-per-responder analysis of 16 weeks of treatment. LIBERATE was not designed or powered to directly compare OTEZLA to etanercept.

"Celgene looks forward to sharing additional data with the scientific community that relates to the safety of long-term exposure of OTEZLA in patients with moderate to severe plaque psoriasis or psoriatic arthritis," said Scott Smith, President, Celgene Inflammation & Immunology. "Celgene's strong presence at this year's congress, and the maturation of data from OTEZLA clinical trials presented there, underscore our continued commitment to the dermatology community and to providing these patients with an oral non-biologic treatment option.”

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
Abstract 2585; Sunday, March 6, 2016, 11:15 - 11:20 AM
Effect of Apremilast and Etanercept on Pruritus and Health-Related Quality of Life in Patients With Moderate to Severe Plaque Psoriasis: Results From the LIBERATE Study; Lawrence Green
Location: E-Poster Presentation Center 3

Abstract 2586; Sunday, March 6, 2016, 2:30 - 2:35 PM
Long-term Safety and Tolerability of Apremilast in Patients With Moderate to Severe Psoriasis: Results From the LIBERATE Study; Jeff Crowley
Location: E-Poster Presentation Center 3

Abstract 2625; Monday, March 7, 2016, 10:10 - 10:15 AM
Sustained Efficacy of Apremilast in Patients With Moderate to Severe Psoriasis Who Continued on Apremilast or Switched From Etanercept Treatment: 52-Week Results From the LIBERATE Study; Kristian Reich
Location: E-Poster Presentation Center 1
About ESTEEM

ESTEEM 1 and 2 are two large pivotal phase 3 randomized, placebo-controlled studies evaluating OTEZLA in patients with a diagnosis of moderate to severe plaque psoriasis for at least 12 months prior to screening, and who were also candidates for phototherapy and/or systemic therapy. Approximately 1,250 patients were randomized 2:1 to receive either OTEZLA 30 mg twice daily or placebo after an initial five-day titration period, for the first 16 weeks, followed by a maintenance phase from weeks 16-32 in which placebo patients were switched to OTEZLA 30 mg twice daily through week 32, and a randomized withdrawal phase for responders from week 32 to week 52 based on their initial OTEZLA randomization and Psoriasis Area and Severity Index (PASI)-75 response (ESTEEM 1) or (PASI)-50 (ESTEEM 2). A 5-year extension study of ESTEEM 1 and 2 is ongoing.

About LIBERATE™

LIBERATE (PSOR-010; EvaLuatIOn from a PlaceBo-controllEd Study of ORal ApremilasT and Etanercept in Plaque Psoriasis) is a phase 3b, multicenter, randomized, placebo-controlled, double-blind, double-dummy study of the efficacy and safety of OTEZLA, etanercept and placebo, in subjects with moderate to severe plaque psoriasis. The primary objective of the LIBERATE study was to evaluate the clinical efficacy and safety of oral OTEZLA 30 mg twice daily compared with placebo at week 16. Secondary objectives of the study included: the evaluation of the clinical efficacy and safety of etanercept 50 mg SC once weekly (QW) compared with placebo at week 16, and the evaluation of the relative safety of a crossover from etanercept to OTEZLA 30 mg twice daily after week 16, as compared with OTEZLA dosed since week 0. Subjects were required to have inadequate response, intolerance or contraindication to at least one conventional systemic agent and no prior exposure to biologics. The study enrolled 250 subjects who were randomized 1:1:1:1 to receive OTEZLA 30 mg twice daily, etanercept 50 mg QW or placebo, for 16 weeks. Following the first 16 weeks, all subjects were switched to (or continued on) OTEZLA 30 mg twice daily through week 104. The primary endpoint was the proportion of subjects with either OTEZLA 30 mg twice daily or placebo who achieved PASI-75 at week 16. Secondary endpoints included other measures of disease activity and quality of life for the comparison of OTEZLA 30 mg twice daily versus placebo and the comparison of etanercept 50 mg SC QW versus placebo.

About OTEZLA

OTEZLA is an oral small-molecule inhibitor of phosphodiesterase 4 (PDE4) specific for cyclic adenosine monophosphate.
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.

OTEZLA is approved:

- In the U.S.:
  - For the treatment of adults with active psoriatic arthritis
  - For the treatment of patients with moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy

- In the European Union:
  - For the treatment of moderate-to-severe chronic plaque psoriasis in adult patients who failed to respond to or who have a contraindication to, or are intolerant to other systemic therapy including cyclosporine, methotrexate or psoralen and ultraviolet-A light (PUVA)
  - Alone or in combination with Disease Modifying Antirheumatic Drugs (DMARDs), for the treatment of active psoriatic arthritis (PsA) in adult patients who have had an inadequate response or who have been intolerant to a prior DMARD therapy

- In Switzerland:
  - For the treatment of adult patients with moderate to severe plaque psoriasis who have not responded to another systemic therapy or do not tolerate such therapy or where such therapy is contraindicated
  - As monotherapy or in combination with disease-modifying anti-rheumatic drugs (DMARDs) for the treatment of active psoriatic arthritis in adults who have not responded to a previous DMARD therapy, who have not tolerated it, or where DMARD therapy is contraindicated

- In Canada:
  - For the treatment of patients with moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy
  - For the treatment of active psoriatic arthritis, alone or in combination with methotrexate, in adult patients who have had an inadequate response, intolerance or contraindication to a prior disease-modifying anti-rheumatic drug (DMARD)

- In Australia:
  - For the treatment of signs and symptoms of active psoriatic arthritis in adult patients
  - For the treatment of adult patients with moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy

Important Safety Information (based on US labeling)

**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](http://www.celgene.com). Follow Celgene on Social Media: [@Celgene](https://twitter.com/Celgene), [Pinterest](https://www.pinterest.com/celgene/), [LinkedIn](https://www.linkedin.com/company/celgene-corporation), [Facebook](https://www.facebook.com/Celgene) and [YouTube](https://www.youtube.com/Celgene).

**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. Celgene Corporation undertakes 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 Celgene's 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 Celgene's Annual Report on Form 10-K and other reports filed with the U.S. Securities and Exchange Commission.*

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