Celgene Announces Phase 3 STYLE Study of OTEZLA® (apremilast) in Moderate to Severe Scalp Psoriasis Met Primary Endpoint

*A significantly greater proportion of patients achieved Scalp Physician’s Global Assessment (ScPGA) response at week 16 with OTEZLA compared with placebo*

**SUMMIT, N.J. --** October 8, 2018 – Celgene Corporation (NASDAQ: CELG) today announced results from the phase 3 STYLE study, which showed that OTEZLA® (apremilast) 30 mg twice daily achieved a highly statistically significant improvement in the primary endpoint of the Scalp Physician’s Global Assessment (ScPGA) response [defined as ScPGA score of clear (0) or almost clear (1) with at least a 2-point reduction from baseline] at week 16 compared with placebo.

In addition to achieving the primary endpoint, statistical significance was also met for the secondary endpoint of the whole body itch numeric rating scale (NRS) [defined as at least a 4-point reduction from baseline] at week 16 with OTEZLA versus placebo.

The safety profile was generally consistent with the known safety profile of OTEZLA, and no new safety signals were identified in the trial. Treatment-emergent adverse events that occurred in at least 5 percent of patients in either treatment group were diarrhea (30.5 percent for OTEZLA and 10.8 percent for placebo), nausea (21.5 percent and 5.9 percent, respectively), headache (11.5 percent and 4.9 percent) and vomiting (5.5 percent and 2.0 percent).

“The scalp is the most commonly affected area in moderate to severe plaque psoriasis, impacting up to 80 percent of patients,” said Terrie Curran, President, Celgene Inflammation and Immunology. “The area is difficult to treat with topical therapies, and clinical data from systemic therapies are limited. We are encouraged by the significant improvements in this trial and look forward to sharing these data to further enhance the OTEZLA label.”

**About STYLE**
STYLE is a phase 3, multicenter, randomized, placebo-controlled, double-blind study evaluating the efficacy and safety of OTEZLA in subjects with moderate to severe plaque psoriasis of the scalp. The study enrolled 303 people who were randomized 2:1 to receive OTEZLA 30 mg twice daily or placebo for the first 16 weeks.

**About Plaque Psoriasis**
Psoriasis affects 125 million people worldwide, including around 14 million people in Europe and 7.5 million people in the United States. It is a chronic and systemic inflammatory disorder, and is immune-mediated, meaning it is caused by an immune reaction in the body.

Psoriasis lesions can often be found on areas close to the joints such as the elbows and knees but can also appear on the scalp. Nail psoriasis affects up to 50 percent of people with psoriasis. Up to 84 percent of
people with psoriasis experience itching, and over a third of patients cite itch as the most important factor contributing to their disease.

Around 75 percent of people living with psoriasis believe it has a negative impact on their quality of life, and 83 percent of patients with psoriasis actively conceal the visible signs of their disease.

**About OTEZLA® (apremilast)**

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 is not well defined.

**U.S. PRESCRIBING INFORMATION**

**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**

Diarrhea, Nausea and Vomiting: Cases of severe diarrhea, nausea, and vomiting were associated with the use of OTEZLA. Most events occurred within the first few weeks of treatment. In some cases, patients were hospitalized. Patients 65 years of age or older and patients taking medications that can lead to volume depletion or hypotension may be at a higher risk of complications from severe diarrhea, nausea, or vomiting. Monitor patients who are more susceptible to complications of diarrhea or vomiting; advise patients to contact their healthcare provider. Consider OTEZLA dose reduction or suspension if patients develop severe diarrhea, nausea, or vomiting

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 depression. During clinical trials, 1.3% (12/920) of patients reported depression compared to 0.4% (2/506) on placebo; 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
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.

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).

**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 pharmaceutical 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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