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Celgene Provides Update on GED-0301 (mongersen) Inflammatory Bowel Disease Program

SUMMIT, N.J.--(BUSINESS WIRE)-- Celgene Corporation (NASDAQ: CELG) today announced that the GED-0301 (mongersen) phase III REVOLVE trial (CD-002) in Crohn's disease (CD) and the extension trial (SUSTAIN, CD-004) will discontinue. Celgene has decided to stop the trials following an October recommendation of the Data Monitoring Committee, which assessed overall benefit/risk during a recent interim futility analysis. There were no meaningful safety imbalances identified in the analysis.

At this time, the phase III DEFINE trial (CD-003) in Crohn's disease will not be initiated. Celgene is waiting to review the full dataset from the phase II trial with GED-0301 in ulcerative colitis (UC) to determine next steps.

"We thank the patients and the investigators involved in the REVOLVE trial," said Scott Smith, President and Chief Operating Officer for Celgene. "Crohn's disease is a debilitating condition with few effective long-term treatment options. While we are disappointed with the results of REVOLVE, we remain committed to advancing our portfolio of novel medicines for patients suffering from this disease and other inflammatory bowel disorders."

Celgene Inflammatory Bowel Disease Portfolio of Novel Medicines Advances

Ozanimod: At the World Congress of Gastroenterology meeting in October, two-year data from the phase II TOUCHSTONE trial in UC and phase II data from the STEPSTONE trial in CD were presented. The phase III TRUENORTH pivotal trial in UC is ongoing. Celgene expects to initiate a phase III pivotal trial in CD in the next few months.

OTEZLA®: A randomized, controlled, phase II trial (UC-001) in UC is ongoing with data expected by year-end 2017. Pending positive results, a broad phase III UC program could initiate in 2018.

About GED-0301 (mongersen)

The investigational oral antisense therapy GED-0301 (mongersen) is an oligonucleotide that decreases Smad7 protein, thereby potentially impacting TGF-β1 signaling. In patients with Crohn's disease, abnormally high levels of Smad7 interfere with TGF-β1 anti-inflammatory pathways in the gut, leading to increased inflammation.

GED-0301 is an investigational compound that is not approved for any use in any country.

About Ozanimod
Ozanimod is a novel, oral, selective, sphingosine 1-phosphate 1 (S1PR1) and 5 (S1PR5) receptor modulator in development for immune-inflammatory indications including relapsing multiple sclerosis, ulcerative colitis and Crohn's disease. Selective binding with S1PR1 is believed to inhibit a specific sub set of activated lymphocytes from migrating to sites of inflammation. The result is a reduction of circulating T and B lymphocytes that leads to anti-inflammatory activity. Importantly, immune surveillance is maintained.

Selective binding with S1PR5 is thought to activate specific cells within the CNS. This has the potential to enhance remyelination and prevent synaptic defects. Ultimately, neurological damage may be prevented.

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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.

INDICATIONS

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

OTEZLA® is indicated 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

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.

Psoriatic Arthritis: Treatment with OTEZLA® is associated with an increase in depression. During clinical trials, 1.0% (10/998) reported depression or depressed mood compared to 0.8% (4/495) treated with placebo. Suicidal ideation and behavior was observed in 0.2% (3/1441) of patients on OTEZLA®, compared to none in placebo treated patients. Depression was reported as serious in 0.2% (3/1441) of patients exposed to OTEZLA®, compared to none in placebo treated patients (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.

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 at least 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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