Celgene Announces New Data to be Presented at European League Against Rheumatism Annual Congress

New two-year pooled analysis of PALACE trials evaluated effects of OTEZLA on enthesitis and dactylitis in patients with active psoriatic arthritis

Data assessed the impact of investigational compound CC-220 on levels of systemic lupus erythematosus-associated transcription factors

11 featured abstracts underscore the expansion of the Company’s clinical development program in immune disorders

BOUDRY, Switzerland--(BUSINESS WIRE)-- Celgene International Sàrl, a wholly-owned subsidiary of Celgene Corporation (NASDAQ:CELG), today announced that data from 11 abstracts (two oral presentations, six poster presentations and three published in The Abstract Book) evaluating Celgene investigational and marketed products will be presented at the European League Against Rheumatism (EULAR) Annual Congress in Rome, Italy, June 10 - 13, 2015. The data will include the latest research findings on Otezla® (apremilast), the Company's oral, selective inhibitor of phosphodiesterase 4 (PDE4), in psoriatic arthritis and plaque psoriasis, as well as CC-220, an investigational immunomodulatory compound for systemic lupus erythematosus (lupus).

Among the data presented will be long-term (104-week) results from Celgene's PALACE program, including pooled results of three phase III trials (PALACE 1, 2 and 3) assessing the effects of OTEZLA on two distinct manifestations of psoriatic arthritis - enthesitis (inflammation at sites where tendons or ligaments insert into bone) and dactylitis (inflammation of an entire digit). Additional analyses of PALACE trials will evaluate long-term safety and efficacy of OTEZLA in patients with active psoriatic arthritis, as well as the impact of OTEZLA on work productivity and physical function in these patients.

Data will also be presented on the effect of CC-220 on blood cell levels of Ikaros and Aiolos - transcription factors that, when mutated, are associated with an increased risk of systemic lupus erythematosus. The presentation will include phase I data on the impact of CC-220 on the immune response in healthy volunteers. Additional preclinical studies on CC-220 in lupus will be presented.

"We are excited about the presentation of these new long-term data of OTEZLA in psoriatic arthritis at EULAR. Additionally, data presented on our investigational compound CC-220 provide one example of the depth of Celgene's clinical trial programs in other serious inflammatory diseases with high unmet medical need, including lupus," said Scott Smith, President, Celgene Inflammation & Immunology. "We remain committed to further developing our new and existing therapies to provide innovative treatment options for patients living with painful, debilitating chronic immune conditions."

Celgene will also host a variety of educational programs during the Congress on the unmet needs of patients with psoriatic arthritis, including a symposium for healthcare professionals as well as programs for patient/professional advocacy organizations and media.

The following abstracts will be presented at EULAR as an exchange of scientific and clinical information (all times, CEST):

OTEZLA (apremilast) Abstracts at a Glance

Oral Presentation 3594; Friday, June 12, 10:30 AM - 12:00 PM
Apremilast, an Oral Phosphodiesterase 4 Inhibitor, is Associated with Long-Term (104-Week) Improvements in Enthesitis and Dactylitis in Patients with Psoriatic Arthritis: Pooled Results from Three Phase III Randomized, Controlled Trials; Dafna Gladman, MD
Location: Hall 3, 10:45 AM - 10:55 AM

Poster Number 1113; Poster Tour Presentation Thursday, June 11, 12:05 PM - 1:45 PM
Apremilast, an Oral Phosphodiesterase 4 Inhibitor: Improvements in Nail and Scalp Psoriasis and Psoriasis Area and Severity Index in Patients with Moderate to Severe Plaque Psoriasis (ESTEEM 1 and 2); Kim Papp, MD
Poster Tour Presentation location and time: Hall 5, 12:05 PM

Poster Number 2907; Poster Display Thursday, June 11, 8:00 AM - 5:30 PM
Long-Term (104-Week) Efficacy and Safety Profile of Apremilast, an Oral Phosphodiesterase 4 Inhibitor, in Patients with Psoriatic Arthritis: Results from a Phase III, Randomised, Controlled Trial and Open-Label Extension (PALACE 1); Arthur Kavanaugh, MD

Poster Tour Presentation location and time: Hall 5, 12:00 PM - 1:45 PM

Poster Number 2889; Poster Tour Presentation Thursday, June 11, 12:00 PM - 1:45 PM
Disease Activity and Safety During Long-Term (104-Week) Treatment with Apremilast, an Oral Phosphodiesterase 4 Inhibitor, in Patients with Psoriatic Arthritis: Results from a Phase III, Randomized, Controlled Trial and Open-Label Extension (PALACE 3); Christopher Edwards, MD

Poster Tour Presentation location and time: Hall 5, 11:20 AM

Poster Number 3582; Poster Display Thursday, June 11, 8:00 AM - 5:30 PM
Long-Term (104-Week) Safety Profile of Apremilast, an Oral Phosphodiesterase 4 Inhibitor, in Patients with Psoriatic Arthritis: Pooled Safety Analysis of Three Phase III, Randomized, Controlled Trials; Philip Mease, MD

Poster Tour Presentation location and time: Hall 5, 12:00 PM - 1:45 PM

Poster Number 3590; Poster Display Saturday, June 13, 8:15 AM - 2:00 PM
Long-Term Work Productivity Improvement Associated with Apremilast, an Oral Phosphodiesterase 4 Inhibitor, in Patients with Psoriatic Arthritis: Pooled Analysis of Three Phase III Studies; Frank Zhang, MD

Poster Tour Presentation location and time: Hall 5, 10:15 AM - 12:00 PM

Publication Number 4114
Long-Term Impact of Apremilast on Physical Function in Patients with Psoriatic Arthritis Using the HAQ-DI Assessment; Frank Zhang, MD

CC-220 Abstracts at a Glance

Oral Presentation 3498; Thursday, June 11, 10:30 AM - 12:00 PM
The CRL4<sup>CRBN</sup> E3 Ubiquitin Ligase Modulator CC-220 Induces Degradation of the Transcription Factors Aiolos and Ikaros: Immunomodulation in Healthy Volunteers and Relevance to Systemic Lupus Erythematosus; Peter Schafer, Ph.D.
Oral Presentation location and time: Hall 8 - Room 8A, 11:35 AM (preliminary)

Publication Number 3187
B-Cell Proliferation and Plasmablast Generation from Naïve and Memory B Cells are Differentially Regulated by Baff, Il-21, and Cd40l and Inhibited by the Systemic Lupus Erythematosus Drug Candidate CC-220; Yumi Nakayama, MD

Publication Number 3487
Effects of CC-220, a CRL4<sup>CRBN</sup> E3 Ubiquitin Ligase Modulator, on Immune Responses; Ying Ye, Ph.D.

About the PALACE Program

PALACE 1, 2, 3 and 4 are pivotal phase III multi-center, double-blind, placebo-controlled, parallel-group studies with two active treatment groups. In PALACE 1, 2 and 3, approximately 1,500 patients were randomized 1:1:1 to receive either OTEZLA 20 mg twice daily, OTEZLA 30 mg twice daily or identically-appearing placebo, for 16 weeks. At week 16, some placebo-treated patients were randomized to one of the two OTEZLA groups, while others remained on placebo through week 24. After week 24, patients began a subsequent long term, open-label, active treatment phase. The PALACE 1, 2 and 3 studies included a wide spectrum of patients with active psoriatic arthritis, including those who had been previously treated with oral disease-modifying antirheumatic drugs (DMARDs), and/or biologics, with some patients who had previously failed a tumor necrosis factor (TNF) blocker.

In PALACE 4, more than 500 DMARD-naïve patients were randomized 1:1:1 to receive either OTEZLA 20 mg or 30 mg twice daily, or identically appearing placebo, for 24 weeks, with a subsequent active treatment phase up to 52 weeks, followed by a long-term safety phase in which all patients are treated with OTEZLA.

The primary endpoint of the PALACE 1, 2, 3 and 4 studies was the modified American College of Rheumatology criteria for 20 percent improvement (ACR20) at week 16. Secondary endpoints included other measures of signs and symptoms of psoriatic
arthritis, physical functioning and patient-reported outcomes.

Taken together, the PALACE program is the largest psoriatic arthritis program to date intended for regulatory submission.

About ESTEEM

ESTEEM 1 and 2 are two large pivotal phase III 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 (ESTEEM2).

About OTEZLA

OTEZLA 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.

OTEZLA is approved:

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

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.
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.

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

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.

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 (eg, rifampin, phenobarbital, carbamazepine, phenytoin) is not recommended.

Adverse Reactions

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).

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 International Sàrl, located in Boudry, Switzerland, is a wholly-owned subsidiary and international headquarters of Celgene Corporation. 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 gene and protein regulation. For more information, please visit www.celgene.com. Follow Celgene on Social Media: @Celgene, Pinterest, LinkedIn 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 other reports filed with the Securities and Exchange Commission.
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