June 13, 2013

**Data from Phase III Randomized Controlled Study (PALACE 3) of Apremilast in Psoriatic Arthritis Presented at EULAR**

Signs and symptoms in patients with psoriatic arthritis significantly improved with apremilast treatment in PALACE 3. Patients treated with apremilast demonstrated improvement across key secondary endpoints in PALACE 3. Safety and tolerability profile in PALACE 3 was comparable to previously-reported PALACE studies.

**ABSTRACT #SAT0299; OP0104; SAT0280**


The PALACE 3 study, which evaluated 495 patients, demonstrated statistical significance in achieving the primary endpoint of American College of Rheumatology (ACR) 20 score at week 16 for patients receiving apremilast compared to placebo (PBO), (PBO, 19%; apremilast 20 mg BID, 29%; apremilast 30 mg BID, 43%; p<0.05 and p≤0.0001, respectively). PALACE 3 is the third pivotal phase III, randomized, placebo-controlled study evaluating Celgene’s novel, oral small-molecule inhibitor of phosphodiesterase 4 (PDE4) in patients with active psoriatic arthritis who had previously received and/or failed an oral disease-modifying anti-rheumatic drug (DMARD) and/or biologic therapy. In this study, apremilast treatment was used alone or in combination with oral DMARDs. By design, PALACE 3 includes a subset of 270 patients with significant active psoriatic skin involvement.

Patients in the 30 mg BID active treatment arm also demonstrated significant and sustained improvements in psoriasis-related endpoints, including Psoriasis Area Severity Index (PASI) 50 and PASI-75 at week 24. Similar improvements in 30 mg BID-treated patients were also observed in key secondary endpoints, including various measures of physical function, signs and symptoms and quality of life.

The safety and tolerability profile of apremilast in PALACE 3 was consistent with other previously reported phase III studies of the therapy in psoriatic arthritis.

**Apremilast Pooled Safety Analysis Presented**

The company also presented results from a pooled safety data analysis encompassing multiple randomized controlled phase III studies, PALACE 1, 2 & 3.

In the 24-week placebo-controlled analysis, which included nearly 1,500 patients from the three phase III studies, the most common AEs (≥5%) were diarrhea, nausea, headache and URTI. The majority of AEs (93-96%) were mild or moderate in severity, with discontinuation rates due to AEs (PBO, 4.2%; apremilast 20 mg BID, 5.6%; apremilast 30 mg BID, 7.2%). Serious AEs occurred in 3.8%, 3.4% and 3.8% of PBO, apremilast 20 mg BID and apremilast 30 mg BID, respectively. Importantly, there were no safety signals with respect to major cardiac events, malignancies, including lymphoma or systemic opportunistic infections, and no cases of reactivations of tuberculosis.

These results are from investigational studies. Apremilast is not an approved product for any indication.

The NDA/NDS submissions, based on the combined data from PALACE 1, 2 & 3 for PsA, were submitted to health authorities in the U.S. and Canada in Q1 2013 and Q2 2013, respectively. The Company previously announced it expects to file a separate NDA/NDS in the US and Canada for psoriasis and a combined PsA/psoriasis MAA submission in Europe in the second half of 2013.

**About PALACE Program**
PALACE 1, 2, 3 & 4 are four pivotal phase III multi-center, double-blind, placebo-controlled, parallel-group studies with two active-treatment groups. In PALACE 1, 2 & 3, approximately 1,500 subjects were randomized 1:1:1 to receive either apremilast 20 mg BID, 30 mg BID, or identically-appearing placebo for 24 weeks, with a subsequent extension in which all patients are treated with apremilast. The three PALACE studies included a wide spectrum of patients with active psoriatic arthritis, including those who had been previously treated with DMARD, biologic DMARD, as well as patients who had previously failed a TNF blocker. PALACE-3 includes a subset of 270 patients with significant skin involvement with psoriasis.

The primary endpoint of the PALACE 1, 2 & 3 studies is the proportion of patients in each treatment group who achieved the American College of Rheumatology criteria for 20 percent improvement (ACR20) compared to baseline at week 16. Secondary endpoints include other measures of signs and symptoms, physical function and patient-reported outcomes.

In PALACE 4, more than 500 DMARD-naïve patients were randomized 1:1:1 to receive either apremilast 20 mg BID, 30 mg BID, or identically-appearing placebo for 24 weeks, with a subsequent extension in which all patients are treated with apremilast.

Taken together, the PALACE program includes the most comprehensive psoriatic arthritis studies to date intended for regulatory submission. Results from PSA-001, the phase II study of apremilast in psoriatic arthritis, were published online in the journal Arthritis & Rheumatism (http://onlinelibrary.wiley.com/doi/10.1002/art.34580/abstract).

About Apremilast

Apremilast, an oral small-molecule inhibitor of phosphodiesterase 4 (PDE4), intracellularly modulates a network of pro-inflammatory and anti-inflammatory mediators. PDE4 is a cyclic adenosine monophosphate (cAMP)-specific PDE and the dominant PDE in inflammatory cells. PDE4 inhibition elevates intracellular cAMP levels, which in turn down-regulates the inflammatory response by modulating the expression of TNF-α, IL-23, and other inflammatory cytokines. Elevation of cAMP also increases anti-inflammatory cytokines such as IL-10.

About Psoriatic Arthritis

Psoriatic arthritis is a painful, chronic inflammatory disease associated with the skin condition psoriasis. More than a million people in the U.S. and Europe are diagnosed with this arthritic condition. Up to 30 percent of people with psoriasis eventually develop psoriatic arthritis. Psoriatic arthritis is a chronic disorder with progressive and additive joint inflammation that can lead to deleterious effects on quality of life and work disability. In addition to psoriatic skin lesions, common symptoms of psoriatic arthritis include pain, stiffness and swelling in several to many joints, as well as the spine. Patients often experience psoriasis on average for 10 years before the onset of joint symptoms, and many psoriatic arthritis patients go undiagnosed. To learn about the role of PDE4 in psoriatic arthritis, go to www.discoverpde4.com.

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.

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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