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Oral Apremilast Significantly Improved Nail and Scalp Psoriasis and Health-Related Quality-of-Life Measures in Phase III ESTEEM 1 Study

Patients in ESTEEM 1 trial with nail and scalp psoriasis showed significant improvement with apremilast at 16 weeks; improvements continued through 32 weeks

Significantly improved health-related quality-of-life parameters were seen in patients with plaque psoriasis treated with apremilast for 16 weeks; improvements were maintained through 32 weeks

Safety and tolerability profile consistent with other phase III findings

BOUDRY, Switzerland--(BUSINESS WIRE)--Oct. 3, 2013-- Celgene International Sàrl, a wholly-owned subsidiary of Celgene Corporation (NASDAQ:CELG), today announced results of pre-specified sub-analyses from ESTEEM 1 on nail and scalp psoriasis, as well as health-related quality-of-life outcomes, from the Company’s first phase III study in psoriasis, at the 22nd Congress of the European Academy of Dermatology and Venereology annual meeting in Istanbul, Turkey.

ESTEEM 1 is the largest of two registrational, randomized, placebo-controlled studies evaluating apremilast, an oral small-molecule specific inhibitor of phosphodiesterase 4 (PDE4), in more than 1,200 patients with moderate-to-severe plaque psoriasis. Previously reported findings from ESTEEM 1 showed that apremilast significantly improved general signs and symptoms of psoriasis across a wide-range of patient types.

“Up to 55 percent of patients with psoriasis at any given time have nail involvement, and more than half have scalp psoriasis, which can be particularly debilitating for individuals dealing with this difficult-to-treat disease,” said Professor Kristian Reich, M.D., SCIderm Research Institute and Dermatologikum, Hamburg, Germany. “These analyses demonstrate that apremilast may improve these conditions and may offer a much-needed new oral treatment option for psoriasis patients. Moreover, the encouraging health-related quality-of-life findings suggest that long-term treatment with oral apremilast may improve the mental and physical well-being of these patients.”

New analyses (abstract #2033) assessed the effects of apremilast on 558 patients in ESTEEM 1 with nail psoriasis and on 563 patients with at least moderate scalp psoriasis.

After 16 weeks of treatment, patients in the apremilast 30 mg twice daily (BID) group had significantly greater improvements in the Nail Psoriasis Severity Index (NAPSI) scores than the patients treated with placebo, showing an improvement of 22.5% vs. a worsening of 6.5%, respectively; \( P<0.0001 \). Improvements continued through 32 weeks of treatment for those patients on apremilast 30 mg BID (an improvement of 43.6%).

Psoriasis of the scalp, another difficult-to-treat area, was also improved by treatment with apremilast 30 mg BID. After 16 weeks of therapy, significantly more patients treated with apremilast 30 mg achieved a ScPGA score of 0-1 (clear or almost clear) compared with those in the placebo group (46.5% vs. 17.5%, respectively; \( P<0.0001 \)). This effect was generally maintained for those patients who remained on apremilast through week 32.

As shown in a separate analysis (abstract #0237), the treatment of 844 patients in ESTEEM 1 with apremilast also significantly improved health-related quality-of-life, as assessed by a variety of standardized measurements, including the Dermatology Quality of Life Index (DLQI), the Patient Health Questionnaire (PHQ-8), the European Quality of Life 5 Dimensions Questionnaire (EQ-5D), and the 36-item Short-Form Health Survey (SF-36) mental component summary (MCS).

Significant improvements in these measurement tools were seen after 16 weeks of treatment with apremilast; improvements were maintained through 32 weeks of treatment. Patients initially treated with placebo for 16 weeks who were then treated with apremilast for a subsequent 16 weeks also showed improvements in these measures.

In these analyses, the overall safety and tolerability profile of apremilast in patients with moderate to severe psoriasis was consistent with previously reported findings. The most commonly observed adverse events included diarrhea, nausea, upper
for psoriasis, in addition to a combined PsA/psoriasis.

A New Drug Application (NDA) to the U.S. Food and Drug Administration for psoriasis, in addition to a combined PsA/psoriasis Marketing Authorization Application (MAA) in Europe, is on-track for the fourth quarter of 2013. The Company previously announced it filed a separate NDA for psoriatic arthritis in the US and Canada in Q1 2013 and Q2 2013 respectively.

Earlier this year, Celgene announced that ESTEEM 1 and ESTEEM 2 had reached their primary endpoints. The ongoing studies included more than 1,200 patients with moderate-to-severe psoriasis. Approximately one-third of the ESTEEM 1 study population was naïve to systemic therapy or phototherapy. Nearly thirty percent of the overall study population had prior biologic therapy, including patients who did not respond to these therapies.

About ESTEEM 1 and 2

ESTEEM 1 and 2 are two large pivotal phase III randomized, placebo-controlled studies evaluating apremilast in subjects with a diagnosis of moderate to severe plaque psoriasis for at least 12 months prior to the screening, and at baseline, and who were also candidates for phototherapy and/or systemic therapy. Approximately 1,250 patients were randomized 2:1 to receive either apremilast 30 mg BID or placebo for the first 16 weeks, followed by a maintenance phase from weeks 16-32 in which placebo subjects were switched to apremilast 30 mg BID through week 32, and a randomized withdrawal phase for responders from Week 32-Week 52 based on their initial apremilast randomization and PASI response.

About Apremilast

Apremilast, an oral small-molecule specific 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 Psoriasis

Psoriasis is an immune-mediated, non-contagious chronic inflammatory skin disorder of unknown cause. The disorder is a chronic recurring condition which varies in severity from minor localized patches to complete body coverage. Plaque psoriasis is the most common type of psoriasis. About 80 percent of people who develop psoriasis have plaque psoriasis, which appears as patches of raised, reddish skin covered by silvery-white scales. These patches, or plaques, frequently form on the elbows, knees, lower back, and scalp. Psoriasis occurs nearly equally in males and females. Recent studies show that there may be an ethnic link. Psoriasis is believed to be most common in Caucasians and slightly less common in other ethnic groups. Worldwide, psoriasis is most common in Scandinavia and other parts of northern Europe. About 10 percent to 30 percent of patients with psoriasis also develop a condition called psoriatic arthritis, which causes pain, stiffness and swelling in and around the joints. To learn about the role of PDE4 in psoriasis, go to www.discoverpde4.com.

About Celgene

Celgene International Sàrl, located in Boudry, in the Canton of Neuchâtel, 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 the Company's website at 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.

Source: Celgene International Sàrl