Apremilast ESTEEM Program Meets Primary and Major Secondary Endpoint in Pivotal Phase III Psoriasis Trials

Clinical Data from two pivotal phase III (ESTEEM 1&2) randomized, placebo-controlled studies including approximately 1,250 patients demonstrated statistically significant and clinically meaningful improvements for the primary and major secondary endpoint.

NDA submission based on ESTEEM program in psoriasis planned for H2’2013; MAA submission for psoriasis and psoriatic arthritis planned for H2’2013.

No new safety signals were observed and tolerability improved over phase II psoriasis trial results; Safety and tolerability consistent with phase III psoriatic arthritis trials.

Data from the phase III ESTEEM program is planned for presentation at upcoming major medical meetings.

BOUDRY, Switzerland--(BUSINESS WIRE)--Jan. 7, 2013-- Celgene International Sàrl, a subsidiary of Celgene Corporation (NASDAQ: CELG), today announced that statistical significance for the primary endpoint of PASI 75 at week 16 was achieved for patients receiving apremilast 30 mg BID monotherapy in both the ESTEEM 1 & 2 phase III studies. ESTEEM 1 & 2 are the two pivotal phase III, randomized, placebo-controlled studies evaluating apremilast, the company’s oral small-molecule inhibitor of phosphodiesterase 4 (PDE4) in patients with moderate to severe chronic plaque psoriasis.

Patients on apremilast also achieved a statistically significant benefit over placebo in the major secondary endpoint, Static Physician Global Assessment (sPGA).

“Psoriasis is a common immune-mediated skin disease affecting nearly 125 million people worldwide,” said Kim Papp, M.D., Ph.D. of Probity Medical Research, Canada. “Despite advances in treatment over the last decade, a significant proportion of moderate to severe psoriasis patients remain inadequately treated. The primary reason for psoriasis patients not receiving adequate therapy is the burden associated with available treatment options. As a consequence, there is a high unmet medical need for an efficacious, safe, oral option that patients can take long-term.”

An NDA submission for psoriasis, based on ESTEEM 1 & 2 data, is expected in the second half of 2013. The company previously announced it expects to file an NDA for psoriatic arthritis (PsA) in the first quarter of 2013 and a combined MAA for psoriasis and psoriatic arthritis in Europe in the second half of the year.

The Phase III safety and tolerability data are improved over previously observed phase II psoriasis data and consistent with results from the phase III psoriatic arthritis trials. The overall psoriasis safety database includes nearly 2,000 patients to date. ESTEEM 1 & 2 are ongoing trials. Subjects are being evaluated for safety and efficacy in the long-term extension studies for up to an additional four years. Approximately one-third of the study population was treatment-naïve and two-thirds had prior exposure to either systemic and/or phototherapy; approximately one-third of the overall study population had prior biologic therapy.

To date, the five positive phase III studies from the ESTEEM and PALACE programs represent the most comprehensive clinical data for submission for patients with psoriatic disease. Clinical data from ESTEEM 1 & 2 are planned for presentation at upcoming major medical meetings.

About ESTEEM 1 & 2

ESTEEM 1 & 2 are two pivotal phase III randomized, placebo-controlled study evaluating apremilast in subjects with a diagnosis of moderate to severe chronic plaque psoriasis for at least 12 months prior to the screening, and at baseline, and who are also a candidate 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 randomization and PASI response.

About Apremilast
Apremilast, an oral small-molecule inhibitor of phosphodiesterase 4 (PDE4), works intracellularly to modulate 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 other 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.

About Celgene International Sàrl

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

Celgene Corporation
Investors:
+41 32 729 8303
ir@celgene.com
Media:
+41 32 729 8304
media@celgene.com