Oral OTEZLA® (apremilast) Approved by the U.S. Food and Drug Administration for the Treatment of Patients with Moderate to Severe Plaque Psoriasis

In phase III studies, OTEZLA resulted in significant and clinically meaningful improvements in plaque psoriasis

OTEZLA demonstrated a consistent safety and tolerability profile across clinical trials

SUMMIT, N.J.--(BUSINESS WIRE)-- Celgene Corporation (NASDAQ: CELG) today announced that the U.S. Food and Drug Administration (FDA) has approved OTEZLA® (apremilast), the Company's oral, selective inhibitor of phosphodiesterase 4 (PDE4), for the treatment of patients with moderate to severe plaque psoriasis for whom phototherapy or systemic therapy is appropriate. OTEZLA is the first and only PDE4 inhibitor approved for the treatment of plaque psoriasis. Psoriasis, a chronic inflammatory disease of the skin resulting from an uncontrolled immune response, affects more than 125 million people worldwide.

"OTEZLA offers an important new treatment option for patients whose symptoms are not adequately improving with their current treatments. In clinical trials, OTEZLA reduced redness, thickness, and scaliness of plaques in patients with moderate or severe plaque psoriasis," said Dr. M. Shane Chapman, Section Chief of Dermatology at Dartmouth-Hitchcock Medical Center. "Because the product labeling does not require routine laboratory monitoring, oral OTEZLA may be a welcome new option for patients and physicians looking for a different treatment experience."

The approval of OTEZLA was based primarily on safety and efficacy results from two multi-center, randomized, double-blind, placebo-controlled studies - ESTEEM 1 and ESTEEM 2 - conducted in adult patients with moderate to severe plaque psoriasis: body surface area (BSA) involvement of ≥10%, static Physician Global Assessment (sPGA) of ≥3 (moderate or severe disease), Psoriasis Area and Severity Index (PASI) score ≥12, and candidates for phototherapy or systemic therapy.

"OTEZLA offers a valuable treatment option for a spectrum of plaque psoriasis patients - patients who are treatment-naïve as well as patients who are treatment-experienced, including those previously treated with biologic agents or conventional systemic agents," said Scott Smith, President Inflammation & Immunology for Celgene Corporation. "The FDA approval of OTEZLA for plaque psoriasis, together with the previous approval for psoriatic arthritis, reflects Celgene’s commitment to extending the reach of our research and science in an effort to improve the lives of people worldwide living with chronic inflammatory diseases."

In the ESTEEM studies, OTEZLA treatment resulted in significant and clinically meaningful improvements in plaque psoriasis as measured by PASI scores at week 16. Clinical improvement as measured by sPGA scores of clear to almost clear were also demonstrated in both studies.

The safety of OTEZLA was assessed in 1,426 patients from three clinical trials. Side effects of OTEZLA were diarrhea, nausea, upper respiratory tract infection, tension headache, and headache. Before starting OTEZLA, patients should inform their doctor if they have a history of depression or suicidal behavior and if these conditions or other mood changes develop or worsen while taking OTEZLA. Patients taking OTEZLA should have their weight checked regularly.

"Psoriasis is a serious autoimmune disorder commonly associated with comorbidities," said Randy Beranek, president and CEO, National Psoriasis Foundation. "Effectively treating psoriasis is an important part of managing a patient's overall health. Having a new treatment like OTEZLA is important so patients can have more options and can work closely with their providers to find what works best for them."

OTEZLA® is available in the U.S. and is dispensed through a comprehensive network of specialty pharmacies. For more information about OTEZLA distribution and the exclusive treatment support services (including reimbursement assistance and 24/7 nurse support), doctors and patients can contact Otezla SupportPlus™ at 844-4OTEZLA (1-844-468-3952) or visit www.OTEZLA.com for more information.

OTEZLA was approved on March 21, 2014 by the U.S. Food and Drug Administration (FDA) for the treatment of adults with active psoriatic arthritis. A New Drug Submission (NDS) for psoriatic arthritis was submitted to health authorities in Canada in the second quarter of 2013. A NDS for psoriasis in Canada as well as a combined psoriatic arthritis/psoriasis Marketing
Authorization Application (MAA) in Europe were all submitted to health authorities in the fourth quarter of 2013.

**Note to editors:** Additional information can be found at [http://smp.businesswire.com/pages/oral-otezla-apremilast-approved-us-food-and-drug-administration-treatment-patients-moderate](http://smp.businesswire.com/pages/oral-otezla-apremilast-approved-us-food-and-drug-administration-treatment-patients-moderate).

**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 PASI-75 response.

**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.

**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 also indicated for the treatment of adult patients with active psoriatic arthritis.

**ADDITIONAL IMPORTANT SAFETY INFORMATION**

Patients who are allergic to apremilast or to any of the ingredients in OTEZLA should not take OTEZLA. Certain medicines should not be taken when on OTEZLA as they may decrease its effectiveness. Patients should tell their doctor about all the medicines they take, including prescription and nonprescription medicines. Women should inform their doctor if they are pregnant, planning to become pregnant, or planning to breastfeed. OTEZLA has not been studied in pregnant women or in women who are breastfeeding. These are not all the possible side effects with OTEZLA. Patients should ask their doctor about other potential side effects and tell their doctor about any side effect that bothers them or does not go away.

Patients are encouraged to report negative side effects of prescription drugs to the FDA. Visit [www.fda.gov/medwatch](http://www.fda.gov/medwatch), or call 1-800-332-1088.

Please click here for Full Prescribing Information.

**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. An estimated 125 million people worldwide have psoriasis. To learn more about the role of PDE4 in inflammatory diseases, go to [www.discoverpde4.com](http://www.discoverpde4.com).

**About Celgene**

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](http://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 other reports filed with the Securities and Exchange Commission.

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