# AMGEN PRESENTS NEW RESEARCH IN EARLY PSORIATIC ARTHRITIS AT ACR 2023

November 7, 2023

**FOREMOST Study Finds Oral Otezla® (apremilast) Significantly Improved Disease Control vs. Placebo**

THOUSAND OAKS, Calif., Nov. 7, 2023 /PRNewswire/ -- Amgen (NASDAQ:AMGN) today announced results from the global Phase 4 FOREMOST study evaluating Otezla® (apremilast) in patients with early oligoarticular psoriatic arthritis. FOREMOST is the first placebo-controlled study designed to specifically assess people with oligoarticular psoriatic arthritis with early disease duration of five or fewer years. Results will be presented at the American College of Rheumatology (ACR) Convergence 2023, Nov. 10-15 in San Diego.

"Patients with early oligoarticular psoriatic arthritis who received Otezla were twice as likely as patients receiving placebo to achieve MDA-Joints, a composite endpoint representing minimal disease activity at 16 weeks," said Philip Mease, M.D., MACR, director, Rheumatology Research, Providence Swedish Medical Center, clinical professor, University of Washington School of Medicine, Seattle, and FOREMOST presenting author at ACR. "These patients experienced a significant reduction in psoriatic disease activity, a crucial finding for those in the early stages of the condition."

"Psoriatic arthritis patients with a smaller number of affected joints have been underrepresented in clinical trials, even though oligoarticular psoriatic arthritis is very common and can cause patients significant pain and functional impairment," said Laure Gossec, M.D., Ph.D., professor of rheumatology, Sorbonne Université and Pitié Salpêtrière Hospital, Rheumatology, Paris. "FOREMOST found that people with oligoarticular disease experienced significant improvements with Otezla. This is a key trial, which will help clinicians and patients with this disease type to discuss treatment choices in a data-driven manner."

"Otezla has been studied in numerous trials and prescribed to 840,000 patients, yet we continue to identify unmet needs and opportunity to benefit patients," said Ponda Motsepe-Ditshego, vice president, Global Medical at Amgen. "This research builds on our ongoing goal to reduce the burden of psoriatic disease and improve outcomes for patients."

The multicenter, randomized, double-blind, placebo-controlled, parallel-group Phase 4 FOREMOST study met the primary endpoint of modified minimal disease activity (MDA-Joints) and key secondary endpoints at week 16. In patients with early psoriatic arthritis disease duration (≤5 years) and ≤4 tender and ≤4 swollen joints affected, Otezla plus standard of care doubled the modified minimal disease activity (MDA-Joints) response compared to placebo plus standard of care. In the study, standard of care was defined as nonsteroidal anti-inflammatory drugs (NSAIDs), oral glucocorticosteroids or ≤1 conventional synthetic disease-modifying antirheumatic drugs (csDMARDs).

Detailed study findings include:

- 33.9% of patients treated with Otezla achieved MDA-Joints response versus 16.0% with placebo, (p=0.0008), the primary endpoint.
- 70.2% of patients treated with Otezla achieved Clinical Disease Activity in psoriatic arthritis (cDAPSA) remission (REM ≤4) or low disease activity (LDA >4 to ≤13) versus 51.8% with placebo, as measured by patient global assessment score (p=0.0017), the key secondary endpoint.
- Common treatment-emergent adverse events (TEAEs) that occurred in more than 5% of Otezla patients were diarrhea (23.0%), nausea (10.8%) and headache (7.8%). TEAEs were consistent with the known safety profile of Otezla.

The study randomized 308 patients with a mean disease duration of 9.9 months, of whom 39.9% were using a csDMARD. MDA-Joints was a composite endpoint consisting of tender joint count ≤1 and swollen joint count ≤1 plus achieving 3 of the following: psoriasis Body Surface Area (BSA) ≤3%, patient assessment of pain visual analog scale (VAS) on a 100-mm scale ≤15, Patient Global Assessment (PtGA) of disease activity on a 100-mm scale ≤20, physical function [HAQ-DI] ≤0.5, and enthesitis count ≤1 based on the Leeds Enthesitis Index.

The FOREMOST oral presentation is one of more than 20 Amgen-sponsored abstracts at ACR highlighting new scientific and clinical research across its expanded rheumatology pipeline.

**About Psoriatic Arthritis**

Psoriatic arthritis is a chronic, inflammatory form of arthritis, which can cause swelling, stiffness and pain in and around the joints that worsens over time and can decrease physical function. It is estimated that nearly 38 million people worldwide have psoriatic arthritis.[1] Around a third of people living with psoriasis may go on to develop psoriatic arthritis.[1] If left untreated, psoriatic arthritis can cause disability.

**About Otezla® (apremilast)**

Otezla® (apremilast) 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 is not well defined.

Since its initial FDA approval in 2014, Otezla has been prescribed to more than 840,000 patients worldwide.[2]

**Otezla® (apremilast) U.S. INDICATIONS**

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Otezla® (apremilast) is indicated for the treatment of adult patients with plaque psoriasis who are candidates for phototherapy or systemic therapy.

Otezla is indicated for the treatment of adult patients with active psoriatic arthritis.

Otezla is indicated for the treatment of adult patients with oral ulcers associated with Behçet's Disease.

**Otezla® (apremilast) U.S. IMPORTANT SAFETY INFORMATION**

**Contraindications**

- Otezla® is contraindicated in patients with a known hypersensitivity to apremilast or to any of the excipients in the formulation

**Warnings and Precautions**

- Hypersensitivity: Hypersensitivity reactions, including angioedema and anaphylaxis, have been reported during postmarketing surveillance. If signs or symptoms of serious hypersensitivity reactions occur, discontinue Otezla and institute appropriate therapy
- Diarrhea, Nausea, and Vomiting: Cases of severe diarrhea, nausea, and vomiting were associated with the use of Otezla. Most events occurred within the first few weeks of treatment. In some cases, patients were hospitalized. Patients 65 years of age or older and patients taking medications that can lead to volume depletion or hypotension may be at a higher risk of complications from severe diarrhea, nausea, or vomiting. Monitor patients who are more susceptible to complications of diarrhea or vomiting; advise patients to contact their healthcare provider. Consider Otezla dose reduction or suspension if patients develop severe diarrhea, nausea, or vomiting
- 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
    - Plaque Psoriasis: Treatment with Otezla is associated with an increase in depression. During clinical trials in patients with moderate to severe plaque psoriasis, 1.3% (12/920) of patients reported depression compared to 0.4% (2/506) on placebo. 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
    - Psoriatic Arthritis: Treatment with Otezla is associated with an increase in depression. During clinical trials, 1.0% (10/998) reported depression or depressed mood compared to 0.8% (4/495) treated with placebo. Suicidal ideation and behavior was observed in 0.2% (3/1441) of patients on Otezla, compared to none in placebo-treated patients. Depression was reported as serious in 0.2% (3/1441) of patients exposed to Otezla, compared to none in placebo-treated patients (0/495). Two patients who received placebo committed suicide compared to none on Otezla
    - Behçet's Disease: Treatment with Otezla is associated with an increase in depression. During the clinical trial, 1% (1/104) reported depression or depressed mood compared to 1% (1/103) treated with placebo. No instances of suicidal ideation or behavior were reported in patients treated with Otezla or treated with placebo
- Weight Decrease: Monitor body weight regularly; evaluate unexplained or clinically significant weight loss, and consider discontinuation of Otezla
    - Plaque Psoriasis: Body weight loss of 5-10% occurred in 12% (96/784) of patients with moderate to severe plaque psoriasis 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
    - Psoriatic Arthritis: Body weight loss of 5-10% was reported in 10% (49/497) of patients taking Otezla and in 3.3% (16/495) of patients taking placebo
    - Behçet's Disease: Body weight loss of >5% was reported in 4.9% (5/103) of patients taking Otezla and in 3.9% (4/102) of patients taking 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 (e.g., rifampin, phenobarbital, carbamazepine, phenytoin) is not recommended

**Adverse Reactions**

- Plaque Psoriasis: The most common adverse reactions (≥ 5%) are diarrhea, nausea, upper respiratory tract infection, and headache, including tension headache. Overall, the safety profile of Otezla in patients with mild to moderate plaque psoriasis was consistent with the safety profile previously established in adult patients with moderate to severe plaque psoriasis
- Psoriatic Arthritis: The most common adverse reactions (≥ 5%) are diarrhea, nausea, and headache
- Behçet's Disease: The most common adverse reactions (≥ 10%) are diarrhea, nausea, headache, and upper respiratory tract infection

**Use in Specific Populations**

- Otezla has not been studied in pregnant women. Advise pregnant women of the potential risk of fetal loss.

Please click here for Otezla® Full Prescribing Information.

**About Amgen**
Amgen is committed to unlocking the potential of biology for patients suffering from serious illnesses by discovering, developing, manufacturing and delivering innovative human therapeutics. This approach begins by using tools like advanced human genetics to unravel the complexities of disease and understand the fundamentals of human biology.

Amgen focuses on areas of high unmet medical need and leverages its expertise to strive for solutions that improve health outcomes and dramatically improve people's lives. A biotechnology pioneer since 1980, Amgen has grown to be one of the world's leading independent biotechnology companies, has reached millions of patients around the world and is developing a pipeline of medicines with breakaway potential.

Amgen is one of the 30 companies that comprise the Dow Jones Industrial Average and is also part of the Nasdaq-100 index. In 2023, Amgen was named one of "America's Greatest Workplaces" by Newsweek, one of "America's Climate Leaders" by USA Today and one of the "World's Best Companies" by TIME.

For more information, visit Amgen.com and follow us on X (formerly known as Twitter), LinkedIn, Instagram, TikTok, YouTube and Threads.

**Amgen Forward-Looking Statements**
This news release contains forward-looking statements that are based on the current expectations and beliefs of Amgen. All statements, other than statements of historical fact, are statements that could be deemed forward-looking statements, including any statements on the outcome, benefits and synergies of collaborations, or potential collaborations, with any other company (including BeiGene, Ltd. or Kyowa Kirin Co., Ltd.), the performance of Otezla® (apremilast) (including anticipated Otezla sales growth and the timing of non-GAAP EPS accretion), our acquisitions of Teneobio, Inc., ChemoCentryx, Inc., or Horizon Therapeutics plc (including the prospective performance and outlook of Horizon's business, performance and opportunities and any potential strategic benefits, synergies or opportunities expected as a result of such acquisition), as well as estimates of revenues, operating margins, capital expenditures, cash, other financial metrics, expected legal, arbitration, political, regulatory or clinical results or practices, customer and prescriber patterns or practices, reimbursement activities and outcomes, effects of pandemics or other widespread health problems on our business, outcomes, progress, and other such estimates and results. Forward-looking statements involve significant risks and uncertainties, including those discussed below and more fully described in the Securities and Exchange Commission reports filed by Amgen, including our most recent annual report on Form 10-K and any subsequent periodic reports on Form 10-Q and current reports on Form 8-K. Unless otherwise noted, Amgen is providing this information as of the date of this news release and does not undertake any obligation to update any forward-looking statements contained in this document as a result of new information, future events or otherwise.

No forward-looking statement can be guaranteed and actual results may differ materially from those we project. Discovery or identification of new product candidates or development of new indications for existing products cannot be guaranteed and movement from concept to product is uncertain; consequently, there can be no guarantee that any particular product candidate or development of a new indication for an existing product will be successful and become a commercial product. Further, preclinical results do not guarantee safe and effective performance of product candidates in humans. The complexity of the human body cannot be perfectly, or sometimes, even adequately modeled by computer or cell culture systems or animal models. The length of time that it takes for us to complete clinical trials and obtain regulatory approval for product marketing has in the past varied and we expect similar variability in the future. Even when clinical trials are successful, regulatory authorities may question the sufficiency for approval of the trial endpoints we have selected. We develop product candidates internally and through licensing collaborations, partnerships and joint ventures. Product candidates that are derived from relationships may be subject to disputes between the parties or may prove to be not as effective or as safe as we may have believed at the time of entering into such relationship. Also, we or others could identify safety, side effects or manufacturing problems with our products, including our devices, after they are on the market.

Our results may be affected by our ability to successfully market both new and existing products domestically and internationally, clinical and regulatory developments involving current and future products, sales growth of recently launched products, competition from other products including biosimilars, difficulties or delays in manufacturing our products and global economic conditions. In addition, sales of our products are affected by pricing pressure, political and public scrutiny and reimbursement policies imposed by third-party payers, including governments, private insurance plans and managed care providers and may be affected by regulatory, clinical and guideline developments and domestic and international trends toward managed care and healthcare cost containment. Furthermore, our research, testing, pricing, marketing and other operations are subject to extensive regulation by domestic and foreign government regulatory authorities. Our business may be impacted by government investigations, litigation and product liability claims. In addition, our business may be impacted by the adoption of new tax legislation or exposure to additional tax liabilities. If we fail to meet the compliance obligations in the corporate integrity agreement between us and the U.S. government, we could become subject to significant sanctions. Further, while we routinely obtain patents for our products and technology, the protection offered by our patents and patent applications may be challenged, invalidated or circumvented by our competitors, or we may fail to prevail in present and future intellectual property litigation. We perform a substantial amount of our commercial manufacturing activities at a few key facilities, including in Puerto Rico, and also depend on third parties for a portion of our manufacturing activities, and limits on supply may constrain sales of certain of our current products and product candidate development. An outbreak of disease or similar public health threat, such as COVID-19, and the public and governmental effort to mitigate against the spread of such disease, could have a significant adverse effect on the supply of materials for our manufacturing activities, the distribution of our products, the commercialization of our product candidates, and our clinical trial operations, and any such events may have a material adverse effect on our product development, product sales, business and results of operations. We rely on collaborations with third parties for the development of some of our product candidates and for the commercialization and sales of some of our commercial products. In addition, we compete with other companies with respect to many of our marketed products as well as for the discovery and development of new products. Further, some raw materials, medical devices and component parts for our products are supplied by sole third-party suppliers. Certain of our distributors, customers and payers have substantial purchasing leverage in their dealings with us. The discovery of significant problems with a product similar to one of our products that implicate an entire class of products could have a material adverse effect on sales of the affected products and on our business and results of operations. Our efforts to collaborate with or acquire other companies, products or technology, and to integrate the operations of companies or to support the products or technology we have acquired, may not be successful. There can be no guarantee that we will be able to realize any of the strategic benefits, synergies or opportunities arising from the Horizon acquisition, and such benefits, synergies or opportunities may take longer to realize than expected. We may not be able to successfully integrate Horizon, and such integration may take longer, be more difficult or cost more than expected. A breakdown, cyberattack or information security breach of our information technology systems could compromise the

confidentiality, integrity and availability of our systems and our data. Our stock price is volatile and may be affected by a number of events. Our business and operations may be negatively affected by the failure, or perceived failure, of achieving our environmental, social and governance objectives. The effects of global climate change and related natural disasters could negatively affect our business and operations. Global economic conditions may magnify certain risks that affect our business. Our business performance could affect or limit the ability of our Board of Directors to declare a dividend or our ability to pay a dividend or repurchase our common stock. We may not be able to access the capital and credit markets on terms that are favorable to us, or at all.

The scientific information discussed in this news release related to our product candidates is preliminary and investigative. Such product candidates are not approved by the U.S. Food and Drug Administration, and no conclusions can or should be drawn regarding the safety or effectiveness of the product candidates. Further, any scientific information discussed in this news release relating to new indications for our products is preliminary and investigative and is not part of the labeling approved by the U.S. Food and Drug Administration for the products. The products are not approved for the investigational use(s) discussed in this news release, and no conclusions can or should be drawn regarding the safety or effectiveness of the products for these uses.

CONTACT: Amgen, Thousand Oaks
Kate Meyer, 872-867-0754 (media)
Jessica Akopyan, 805-440-5721 (media)
Justin Claeys, 805-313-9775 (investors)

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[1] National Psoriasis Foundation. Psoriasis Statistics. Available at: https://www.psoriasis.org/psoriasis-statistics/. Accessed October 16, 2023.
[2] Amgen Data on File. March 2023.

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