AMGEN ANNOUNCES POSITIVE NEW DATA AT EADV 2022 FOR OTEZLA® (APREMILAST)

September 8, 2022

SPROUT Data Show Otezla Resulted in Significant Improvements in Measures of Moderate to Severe Plaque Psoriasis at Week 16 Compared With Placebo in Children Ages 6-17[1]

DISCREET 16-week Data Demonstrated Statistically Significant Improvements in Genital Psoriasis, Including Skin, Itch and Quality of Life, in Patients With Moderate to Severe Disease[2]

Adverse Events Were Consistent With Known Safety Profile of Otezla in Both Studies

THOUSAND OAKS, Calif., Sept. 8, 2022 /PRNewswire/ -- Amgen (NASDAQ:AMGN) today announced results from two significant Phase 3 clinical studies of oral Otezla® (apremilast), demonstrating efficacy in pediatric patients with moderate to severe plaque psoriasis and in adults with moderate to severe genital psoriasis, at the 31st European Academy of Dermatology and Venereology (EADV) Congress, taking place in Milan, Italy, Sept. 7-10, 2022.

SPROUT study in pediatric moderate to severe plaque psoriasis

The SPROUT study[1] investigated the efficacy and safety of Otezla in pediatric patients aged 6 to 17 years with moderate to severe plaque psoriasis inadequately controlled by or intolerant to topical therapy. The primary endpoint of the static Physician's Global Assessment (sPGA) response (defined as an sPGA score of clear [0] or almost clear [1] with at least a 2-point reduction from baseline) at week 16 was met with a 33.1% sPGA response for Otezla versus 11.5% for placebo (95% CI: 11.2%, 32.1%; *P*<0.0001). The major secondary endpoint was also met: a greater proportion of patients achieving a 75% or more reduction in the Psoriasis Area and Severity Index (PASI 75) score, with 45.4% for Otezla versus 16.1% for placebo (95% CI: 17.8%, 40.9%; *P*<0.0001).

The adverse events were consistent with the known safety profile of Otezla. The most commonly reported (in at least 5% of patients) adverse events were diarrhea (20.2%), nausea (19.6%), abdominal pain (19.6%), vomiting (17.8%), headache (10.4%), pyrexia (6.7%), nasopharyngitis (6.1%) and upper abdominal pain (5.5%).

"The SPROUT data are extremely encouraging and could provide a valuable new alternative option for children, who currently only have access to a few therapeutic options that have been studied and approved to treat moderate-to-severe pediatric plaque psoriasis," said Anna Belloni Fortina, MD, co-author of the study and Head of the Pediatric Dermatology Unit, Department of Medicine, University of Padua Medical School. "We are grateful to the patients, families and clinicians who have contributed to this study as we look to deliver a new therapeutic option for children with unmet need in moderate to severe plaque psoriasis."

DISCREET study in moderate to severe genital psoriasis

16-week data from the DISCREET study[2] in adult patients with moderate to severe genital psoriasis, demonstrated a clinically meaningful and statistically significant improvement in genital psoriasis, with twice as many patients achieving the primary endpoint of a clear (0) or almost clear (1) score on the Physician Global Assessment of Genitalia (sPGA-G) scale when receiving Otezla, when compared with placebo (38.7% for Otezla versus 19.1% for placebo; *P* = 0.0003).

The secondary endpoints of the study were also met. The data showed improvements in sPGA response, with 21.5% responding for Otezla versus 7.2% for placebo (95% CI: 6.0, 22.5; *P* = 0.0007), and Genital Psoriasis Itch Numeric Rating Scale response (GPI-NRS), at 46.0% for Otezla versus 19.6% for placebo (95% CI: 14.5, 38.0; *P* < 0.0001). Additionally, data showed greater reduction in affected body surface area (BSA), with a 4.12% mean reduction with Otezla versus 0.79% with placebo (95% CI: -5.18, -1.47; *P* = 0.0005); a Dermatology Life Quality Index (DLQI) burden score reduction of 5.3 for Otezla versus 2.6 for placebo (95% CI: -4.2, -1.1; *P* = 0.0008); a Genital Psoriasis Symptoms Scale (GPSS) reduction in mean score of 20.5 for Otezla versus 5.3 for placebo (95% CI: -20.3, -10.0; *P* < 0.0001); and a reported improvement in sexual health impacted by psoriasis with Otezla. The adverse events were consistent with the known safety profile of Otezla, with the most commonly reported (in at least 5% of patients) in either treatment group being diarrhea, headache, nausea and nasopharyngitis.

"With more than 700,000 patients treated worldwide, the data from SPROUT and DISCREET add to the robust safety and efficacy data on Otezla, and furthers our understanding of how Otezla works in patient populations where there remains a high unmet need. These data are greatly encouraging for those adults and children who currently have limited options," said David M. Reese, M.D., executive vice president of Research and Development at Amgen. "Based on these results, Amgen looks forward to discussions with regulatory authorities about the potential inclusion of data from these important trials in the Otezla prescribing information."

Amgen is committed to investigating the potential of Otezla in adults and children with plaque psoriasis, including underserved patients with genital psoriasis, juvenile psoriatic arthritis and other areas of high burden.

About SPROUT (PPS0-003)

SPROUT (PPS0-003) is a Phase 3, multi-center, randomized, double-blind, placebo-controlled study to assess the efficacy and safety of OTEZLA® (apremilast) in pediatric patients from 6 through 17 years of age with moderate to severe plaque psoriasis (defined as BSA involvement of ≥ 10, PASI score of ≥ 12, sPGA score of ≥ 3). A total of 245 patients were randomized 2:1 to receive Otezla 20 mg (patients 20kg to 50 kg) twice daily or Otezla 30 mg (patients ≥ 50 kg) twice daily or placebo for the first 16 weeks. All patients then received Otezla during an open-label extension phase through week 52.[1]

The primary endpoint was the percentage of patients with sPGA response [defined as a sPGA score of clear (0) or almost clear (1) with ≥ 2-point

reduction from baseline] at week 16.

About DISCREET (PSOR-025)

DISCREET (PSOR-025) is a Phase 3, multicenter, randomized, placebo-controlled, double-blind study evaluating the efficacy and safety of Otezla in patients with moderate to severe genital psoriasis (defined as modified sPGA-G score ≥ 3). Patients also had moderate to severe plaque psoriasis (sPGA score ≥ 3) with BSA involvement ≥ 1% in a non-genital area and had an inadequate response or intolerance to topical therapy for psoriasis affecting the genital area. The study randomized 289 patients 1:1 to receive Otezla 30 mg twice daily or placebo for the first 16 weeks. Following the 16-week placebo-controlled, double-blind phase of the trial, patients continued or switched to Otezla during the extension phase of the study and will be treated through week 32.

The primary endpoint was the proportion of patients who achieve modified sPGA-G response at week 16 (defined as modified sPGA-G score of clear (0) or almost clear (1) with at least a 2-point reduction from baseline at Week 16).

About Psoriasis

Psoriasis is a serious, chronic inflammatory disease that causes raised, red, scaly patches to appear on the skin, typically affecting the outside of the elbows, knees or scalp, though it can appear on any location.[3] Approximately 125 million people worldwide have psoriasis, including around 14 million people in Europe and more than 8 million people in the United States.[4,5] About 80% of those patients have plaque psoriasis.[6]

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 700,000 patients worldwide.[7]

Otezla® (apremilast) U.S. INDICATIONS

INDICATIONS

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

- 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 2021, Amgen was named one of the 25 World's Best Workplaces™ by Fortune and Great Place to Work™ and one of the 100 most sustainable companies in the world by Barron's.

For more information, visit www.amgen.com and follow us on www.twitter.com/amgen.

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., Kyowa-Kirin Co., Ltd., or any collaboration to manufacture therapeutic antibodies against COVID-19), the performance of Otezla® (apremilast) (including anticipated Otezla sales growth and the timing of non-GAAP EPS accretion), the Five Prime Therapeutics, Inc. acquisition, the Teneobio, Inc. acquisition, or the recently announced proposed acquisition of ChemoCentryx, Inc., 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 such as the ongoing COVID-19 pandemic on our business, 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. A breakdown, cyberattack or information security breach 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.

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