



AMGEN PRESENTS NEW DATA THAT SHOW BLOOD PRESSURE DECREASES FOR ADULTS TREATED WITH KRISTEXXA® (PEGLOTICASE)

November 2, 2023

THOUSAND OAKS, Calif., Nov. 2, 2023 /PRNewswire/ -- Amgen (NASDAQ:AMGN) today announced new data for KRISTEXXA® (pegloticase) showing a decrease in blood pressure during treatment of adults living with chronic gout refractory to oral urate-lowering treatment – uncontrolled gout – both with and without chronic kidney disease (CKD). The data will be presented at the American Society of Nephrology Kidney Week, taking place Nov. 2-5, in Philadelphia.

"As we seek to address the overall burden of uncontrolled gout, especially in those with coexisting chronic kidney disease, it is critical to further understand the benefits of treatment," said Brad Marder, M.D., medical director, nephrology at Amgen. "Recognizing the high prevalence of hypertension among these patients, we're excited to present data that offers new insight into the potential role of urate reduction with KRISTEXXA with methotrexate in regulating blood pressure."

In the MIRROR randomized controlled trial, 152 adults were randomized 2:1 to receive KRISTEXXA with methotrexate (n=100) or KRISTEXXA with placebo (n=52) for 52 weeks. Treatment groups had similar blood pressure prior to treatment. The decrease in systolic blood pressure during treatment was greater at Week 24 of treatment (-6 ± 16 vs. -1 ± 18 mmHg) and more sustained over the full 52-week treatment period in patients receiving KRISTEXXA with methotrexate than in those receiving KRISTEXXA with placebo. Compared to those with pre-treatment CKD (eGFR less than 60 ml/min/1.73 m²), patients without pre-treatment CKD had a more pronounced decrease in blood pressure after Week 24 of treatment, with differences persisting through Week 52 of treatment.

"Given the myriad of comorbidities uncontrolled gout patients live with, it is critical that clinicians understand the systemic connections and potential benefits of urate reduction," said Richard J. Johnson, M.D., professor, Division of Renal Diseases and Hypertension, University of Colorado Denver - Anschutz Medical Campus. "These new data add to prior studies and further support the potential role that both KRISTEXXA urate-lowering and methotrexate administration played in the blood pressure changes observed."

Additional presentations include data from a validated microsimulation model used to project the potential health and economic benefits of effective serum urate reduction in those with both CKD and gout. In patients projected to have oral urate-lowering therapy inefficacy, treatment with KRISTEXXA was projected to prevent 300,000 cases of uncontrolled gout by 2035 in this vulnerable CKD population.

About KRISTEXXA® (pegloticase)

KRISTEXXA® (pegloticase) is the first and only biologic approved by the FDA to treat adults living with uncontrolled gout, a painful and debilitating inflammatory condition with which people continue to have abnormally high levels of uric acid and symptoms despite the use of conventional therapies.

In 2022, the FDA approved expanded labeling to include co-administration with the immunomodulator methotrexate, based on results from the MIRROR randomized controlled trial, which showed significant improvements in efficacy and safety, including a reduction in infusion reactions.

About Uncontrolled Gout

Gout is a chronic, progressive inflammatory form of arthritis that is caused by high urate levels in the body. Tiny needle-like crystals can form and build up almost anywhere in the body. Patients with uncontrolled gout continue to have high levels of uric acid and ongoing symptoms of gout despite the use of oral urate-lowering therapies. Uncontrolled gout is a chronic, systemic disease, and if not addressed can have significant clinical consequences.

INDICATION

KRISTEXXA® (pegloticase) is indicated for the treatment of chronic gout in adult patients who have failed to normalize serum uric acid and whose signs and symptoms are inadequately controlled with xanthine oxidase inhibitors at the maximum medically appropriate dose or for whom these drugs are contraindicated.

Limitations of Use: KRISTEXXA is not recommended for the treatment of asymptomatic hyperuricemia.

IMPORTANT SAFETY INFORMATION

WARNING: ANAPHYLAXIS AND INFUSION REACTIONS, G6PD DEFICIENCY ASSOCIATED HEMOLYSIS AND METHEMOGLOBINEMIA

- Anaphylaxis and infusion reactions have been reported to occur during and after administration of KRISTEXXA.
- Anaphylaxis may occur with any infusion, including a first infusion and generally manifests within 2 hours of the infusion. Delayed hypersensitivity reactions have also been reported.
- KRISTEXXA should be administered in healthcare settings and by healthcare providers prepared to manage anaphylaxis and infusion reactions.
- Patients should be premedicated with antihistamines and corticosteroids and closely monitored for anaphylaxis for an appropriate period after administration of KRISTEXXA.
- Serum uric acid levels should be monitored prior to each infusion and treatment discontinued if levels increase to above 6 mg/dL, particularly when 2 consecutive levels above 6 mg/dL are observed.
- Patients at risk for glucose-6-phosphate dehydrogenase (G6PD) deficiency should be screened prior to starting KRISTEXXA. Hemolysis and methemoglobinemia have been reported with KRISTEXXA in patients with G6PD deficiency. KRISTEXXA is contraindicated in patients with G6PD deficiency.

CONTRAINDICATIONS:

- In patients with G6PD deficiency.
- In patients with history of serious hypersensitivity reactions, including anaphylaxis, to KRYSTEXXA or any of its components.

WARNINGS AND PRECAUTIONS

Gout Flares: An increase in gout flares is frequently observed upon initiation of anti-hyperuricemic therapy, including KRYSTEXXA. Gout flare prophylaxis with a non-steroidal anti-inflammatory drug (NSAID) or colchicine is recommended starting at least 1 week before initiation of KRYSTEXXA therapy and lasting at least 6 months, unless medically contraindicated or not tolerated.

Congestive Heart Failure: KRYSTEXXA has not been formally studied in patients with congestive heart failure, but some patients in the pre-marketing placebo-controlled clinical trials experienced exacerbation. Caution should be exercised in patients who have congestive heart failure and patients should be closely monitored following infusion.

ADVERSE REACTIONS

The most commonly reported adverse reactions ($\geq 5\%$) are:

- **KRYSTEXXA co-administration with methotrexate trial:** gout flares, arthralgia, COVID-19, nausea and fatigue; **KRYSTEXXA alone:** gout flares, arthralgia, COVID-19, nausea, fatigue, infusion reactions, pain in extremity, hypertension and vomiting.
- **KRYSTEXXA pre-marketing placebo-controlled trials:** gout flares, infusion reactions, nausea, contusion or ecchymosis, nasopharyngitis, constipation, chest pain, anaphylaxis and vomiting.

Please see [Full Prescribing Information](#), including **Boxed Warning**.

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), the Tenebio, Inc. acquisition, the ChemoCentryx, Inc. acquisition, or the Horizon Therapeutics plc acquisition (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 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 acquisition or 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.

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