# AMGEN PRESENTS NEW DATA FROM PHASE 2 TRIAL OF DAZODALIBEP IN SJÖGREN'S SYNDROME AT ACR 2023

November 7, 2023

**First Phase 2 Trial in Sjögren's to Achieve the Primary Endpoint Both in Patients With Severe Symptomatology and Those With Systemic Disease**

**Results From Crossover Period Provide Further Evidence of the Clinical Efficacy and Safety of Dazodalibep in Sjögren's**

THOUSAND OAKS, Calif., Nov. 7, 2023 /PRNewswire/ -- Amgen (NASDAQ:AMGN) today announced new data from its Phase 2 study evaluating dazodalibep, an investigational medicine, for the treatment of Sjögren's. These results will be featured in presentations at the American College of Rheumatology (ACR) Convergence 2023, Nov. 10-15, in San Diego. Findings from the study demonstrate that dazodalibep may improve both the systemic and symptomatic disease burden of two different patient populations.

The Phase 2 study of dazodalibep, a CD40 ligand antagonist in clinical development, was a randomized, double-blind, placebo-controlled crossover study evaluating two Sjögren's populations: patients with moderate to severe systemic disease activity and those with moderate to severe symptomatology despite lacking additional organ involvement. In May 2023, presentations at the 2023 EULAR Congress reported that at Day 169, both patient groups treated with dazodalibep achieved the study's primary endpoint. The presentations at ACR highlight results from the crossover period, when at Day 169, patients initially treated with dazodalibep transitioned to placebo, and patients that initially received placebo switched to dazodalibep. After administration of the last dose, patients were followed for an additional 12 weeks for safety.

"To date, there are no FDA-approved disease-modifying treatments for Sjögren's and the positive results from the Phase 2 trial provide evidence that dazodalibep may address the underlying causes of the disease by reducing systemic disease activity and improving the debilitating symptoms such as dryness and fatigue," said David M. Reese, M.D., executive vice president of Research and Development at Amgen.

The company is advancing a Phase 3 trial evaluating the benefit of dazodalibep in Sjögren's.

**Patients with Moderate to Severe Systemic Disease Activity**
The first patient population included patients with moderate to severe systemic disease activity as defined by a EULAR Sjögren's Syndrome Disease Activity Index (ESSDAI) score ≥5.

Key findings include:

- Patients who transitioned from placebo to dazodalibep experienced an improvement in their disease activity from Day 169 (4.1-point reduction in total ESSDAI score) to Day 365 (6.3-point reduction).
- At Day 365, patients who transitioned to dazodalibep also showed greater improvements in ESSDAI response rate (3- to 4-point reduction), EULAR Sjögren's Syndrome Patient Reported Index (ESSPRI) score and fatigue compared to those who transitioned to placebo.
- Dazodalibep was generally safe and well tolerated.

**Patients with Moderate to Severe Symptomatology**
The second patient population studied included those with moderate to severe symptomatology including dryness, fatigue and pain despite lacking additional organ involvement as defined by an ESSPRI score ≥5 and an ESSDAI score of <5.

Key findings include:

- Patients who transitioned from placebo to dazodalibep experienced further improvement in total ESSPRI score from Day 169 (0.5-point reduction) to Day 365 (1.3-point reduction).
- For patients who transitioned from dazodalibep to placebo, the improvements in total ESSPRI score achieved at Day 169 (1.8-point reduction) were largely sustained through Day 365 (1.9-point reduction).
- Patients who transitioned to dazodalibep also showed improvements in measurements of fatigue and the Patient Global Impression of Severity (PGI-S) from Day 169 to Day 365.
- Dazodalibep was generally safe and well tolerated.

"Sjögren's can be a devastating disease that significantly impacts a person's quality of life and can lead to serious medical outcomes," said E. William St. Clair, M.D., professor of medicine, Duke University Medical Center. "The results from this Phase 2 clinical trial are very encouraging and provide evidence that dazodalibep may be an effective therapy for addressing the significant disease burden of people living with Sjögren's."

**About Dazodalibep**
Dazodalibep is a CD40 ligand antagonist that blocks T cell interaction with CD40-expressing B cells, disrupting the overactivation of the CD40 ligand co-stimulatory pathway. Several autoimmune diseases are associated with the overactivation of this pathway. Amgen also plans to investigate dazodalibep in focal segmental glomerulosclerosis, a rare kidney disorder characterized by scarring of glomeruli.

**About Sjögren's Syndrome**
Sjögren's syndrome is a chronic, systemic autoimmune disease affecting exocrine glands, primarily the salivary and tear glands, with severe cases affecting multiple organs. Like other autoimmune diseases, Sjögren's syndrome primarily affects women. The disease also has an increased risk of non-Hodgkin's B-cell lymphoma and there is an unmet medical need for patients with extraglandular disease manifestations, as currently there is no

therapy that can improve or slow the course of the disease. Disease manifestations include dry mouth, dry eyes, arthritis and kidney or lung dysfunction.

**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)

View original content to download multimedia:https://www.prnewswire.com/news-releases/amgen-presents-new-data-from-phase-2-trial-of-dazodalibep-in-sjogrens-syndrome-at-acr-2023-301979208.html

SOURCE Amgen