AMGEN ANNOUNCES POSITIVE PHASE 3 RESULTS FOR DAZODALIBEP IN SJÖGREN'S DISEASE

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Only Global Phase 3 Trial to Show Clinically Meaningful Improvements in Systemic Disease Activity and Patient-Reported Symptoms of Sjögren's Disease

THOUSAND OAKS, Calif., Nov. 11, 2026 /PRNewswire/ -- Amgen (NASDAQ: AMGN) today announced results from the Phase 3 OASIZ-301 study of dazodalibep, the only global Phase 3 trial to demonstrate clinically meaningful improvements in systemic disease activity and symptoms in patients with Sjögren's disease. The findings build on positive topline results announced in September and represent an important advance for a disease with no U.S. Food and Drug Administration (FDA)-approved treatments. The full results will be presented during a late-breaking session (LB22) at the American College of Rheumatology (ACR) Convergence 2026.

"These Phase 3 results support dazodalibep's potential as a first-in-class treatment for Sjögren's disease and strengthen the clinical rationale for targeting CD40L-mediated immune signaling in these patients," said Jay Bradner, M.D., executive vice president, Research and Development, Artificial Intelligence and Data at Amgen. "In OASIZ-301, improvements in systemic disease activity were observed as early as Week 4 and sustained through Week 48. We look forward to building on these findings as we advance a broader Phase 3 program."

In the randomized, double-blind, placebo-controlled OASIZ-301 study, patients had a mean baseline score of 10.2 on the European Alliance of Associations for Rheumatology Sjögren's Syndrome Disease Activity Index (ESSDAI), which measures systemic disease activity. Both dazodalibep dosing regimens (1,500 mg every four weeks and 3,000 mg every 12 weeks) met the primary endpoint at Week 48, demonstrating statistically significant reductions in systemic disease activity compared with placebo, as measured by the ESSDAI score. The 1,500 mg every four weeks regimen (n=217) showed a least-squares mean reduction of 5.6 points from baseline in ESSDAI score, compared with 3.8 points for placebo (difference of 1.8 points; adjusted $p<0.001$). The 3,000 mg every 12 weeks regimen (n=217) showed a reduction of 5.2 points, compared with 3.8 points for placebo (difference of 1.4 points; adjusted $p=0.010$). A treatment effect with dazodalibep was observed as early as Week 4 and sustained through Week 48.

At Week 48, dazodalibep 1,500 mg every four weeks also significantly improved patient-reported dryness, a debilitating symptom of Sjögren's disease, compared with placebo. The placebo-adjusted least-squares mean differences in change from baseline were −1.17 points on the dryness domain of the EULAR Sjögren's Syndrome Patient Reported Index (ESSPRI) and −0.93 points on the dryness domain of the Diary for Assessing Sjögren's Patient Reported Index (DASPRI) (adjusted $p<0.001$ for both).

"Sjögren's disease is complex and heterogeneous. People may experience dry eyes and mouth, fatigue and joint pain, as well as systemic manifestations affecting organs such as the lungs, kidneys or nervous system, underscoring the complexity of recognizing and managing the disease," said Ghaith Noaiseh, M.D., associate professor of Medicine at the University of Kansas Medical Center and lead investigator of the study. "In OASIZ-301, both dosing regimens reduced systemic disease activity compared with placebo, and the every four weeks regimen also improved patient-reported dryness. These results are encouraging and represent important progress in our effort to better address patients' unmet needs."

The ACR presentation will also include additional OASIZ-301 analyses of systemic disease activity, patient-reported outcomes and oral dryness, including:

- At Week 48, greater proportions of patients receiving dazodalibep achieved clinically meaningful reductions of at least 3, 5 or 7 points on the EULAR Sjögren's Syndrome Disease Activity Index (ESSDAI) compared with placebo. These responder analyses show how many patients reached different levels of improvement in systemic disease activity and complement the average ESSDAI change.
- Over 48 weeks, total ESSPRI and DASPRI scores favored dazodalibep over placebo. Mean improvement in total ESSPRI exceeded 1.5 points with both dosing regimens, consistent with clinically meaningful improvement.
- Dazodalibep showed consistent improvement in ESSDAI domain-level responses at Week 48. These domains reflect some of the most common systemic manifestations, including constitutional, glandular, articular, lymphadenopathy, cutaneous, and biological.
- A greater proportion of patients receiving dazodalibep than placebo met the STAR response criteria at Week 48, a composite assessment that considers both patient-reported symptoms and objective measures of disease activity.
- Patients treated with dazodalibep showed greater increases in stimulated salivary flow, an objective measure of oral dryness, compared with placebo.

"For people living with Sjögren's disease, the need for new treatment options is significant, particularly given the wide-ranging and often debilitating impact of this disease," said Janet Church, president and chief executive officer, Sjögren's Foundation. "For our community, continued progress in research is important. The Sjögren's Foundation is encouraged by the momentum in Sjögren's research and hopeful that ongoing clinical development will lead to new treatment options that can help address the diverse needs of people living with Sjögren's disease."

The most common adverse events (≥ 5% incidence, reported at a higher rate in dazodalibep compared with placebo) were nasopharyngitis, urinary tract infection, hypertension, and infusion-related reactions, and were generally mild to moderate in nature. Serious adverse events and discontinuations due to adverse events were balanced across all three treatment groups. No imbalance in the incidence of thromboembolic events or opportunistic infections was observed across treatment groups, and malignancy rates were low and comparable across groups.

About Dazodalibep
Dazodalibep is a potential first-in-class CD40L antagonist fusion protein that is designed to target immune activation by disrupting interactions between T cells, glandular epithelial cells, B cells and other antigen-presenting cells. Dazodalibep is being studied in two Sjögren's disease patient groups: those with moderate-to-severe systemic disease and those with high symptom burden and low systemic disease who suffer from dryness, fatigue, and/or pain that profoundly impact daily life.

About OASIZ-301 and the Dazodalibep Development Program
OASIZ-301 is a Phase 3, randomized, double-blind, placebo-controlled study to evaluate the efficacy and safety of dazodalibep in patients with Sjögren's disease with moderate-to-severe systemic disease activity (ESSDAI ≥ 5) (n=648). The primary endpoint of the study is change from baseline in ESSDAI score at Week 48.

Key secondary endpoints evaluated dryness, tender and swollen joints, fatigue, and ESSDAI[5] response, defined as a decrease of at least 5 points from baseline.

Additionally, Amgen is conducting OASIZ-303, a Phase 3, randomized, double-blind, placebo-controlled study evaluating the efficacy and safety of dazodalibep in patients with high symptom burden with low systemic Sjögren's disease activity. Amgen is also conducting OASIZ-304, an open-label, long-term extension study evaluating the long-term safety and tolerability of dazodalibep in eligible participants from OASIZ-301 and OASIZ-303.

About Sjögren's Disease
Sjögren's disease (SjD) is a heterogeneous autoimmune disease, where patients can experience persistent dryness, fatigue, and pain, often alongside systemic involvement that can be progressive. Although SjD is the second most common autoimmune rheumatic disease, it remains widely underrecognized, with the full extent of its systemic severity and debilitating symptomatic impact on patients' lives often underestimated. Despite this burden, there are currently no approved therapies for SjD, and many patients continue to experience persistent systemic disease activity and debilitating symptoms.

About Amgen
Amgen discovers, develops, manufactures and delivers innovative medicines to fight some of the world's toughest diseases. Harnessing the best of biology and technology, Amgen reaches millions of patients with its medicines.

More than 45 years ago, Amgen helped establish the biotechnology industry at its U.S. headquarters in Thousand Oaks, California, and it remains at the cutting edge of innovation, using technology and human genetic data to push beyond what is known today. Amgen is advancing a broad and deep pipeline and portfolio of medicines to treat cancer, inflammatory conditions, rare diseases, heart disease and obesity and obesity-related conditions.

Amgen has been consistently recognized for innovation and workplace culture, including honors from Fast Company and Forbes. Amgen is one of the 30 companies that comprise the Dow Jones Industrial Average®, and it is also part of the Nasdaq-100 Index®, which includes the largest and most innovative non-financial companies listed on the Nasdaq Stock Market based on market capitalization.

For more information, visit Amgen.com and follow Amgen on X, LinkedIn, Instagram, YouTube, Facebook, TikTok 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 BeOne Medicines Ltd.), the performance of Otezla® (apremilast), our acquisitions of ChemoCentryx, Inc., Dark Blue Therapeutics, Ltd. 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, including those resulting from geopolitical relations and government actions. 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. 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, 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, and may result in unanticipated costs, delays or failures to realize the benefits of the transactions. 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 sustainability 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.

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