AMGEN ANNOUNCES POSITIVE TOPLINE PHASE 3 RESULTS FOR SUBCUTANEOUS TEPEZZA® IN ADULTS LIVING WITH MODERATE-TO-SEVERE ACTIVE THYROID EYE DISEASE

April 6, 2026

Primary and Key Secondary Endpoints Met

77% of Patients Achieved Highly Statistically Significant Proptosis Response

Study Showed Clinically Meaningful Reduction in Proptosis; Greater Than 3 mm

THOUSAND OAKS, Calif., April 6, 2026 /PRNewswire/ -- Amgen (NASDAQ: AMGN) today announced positive topline results from a Phase 3 trial of TEPEZZA (teprotumumab-trbw) administered by subcutaneous injection via an on-body injector (OBI) in participants with moderate-to-severe active Thyroid Eye Disease (TED). TEPEZZA OBI provides comparable efficacy to, and builds upon the success of, intravenous (IV) TEPEZZA, the first and only medicine approved for the treatment of TED, which has now treated more than 25,000 patients worldwide.

The Phase 3 TEPEZZA OBI trial met its primary endpoint in moderate-to-severe active TED, showing a statistically significant and clinically meaningful 77% proptosis response rate during the 24-week placebo-controlled period (76.7% TEPEZZA OBI vs. 19.6% placebo [p<0.0001]). Importantly, the mean proptosis reduction, a key secondary endpoint, was -3.17 mm at week 24 (-3.17 mm TEPEZZA OBI vs. -0.80 mm placebo; p<0.0001).

"These results extend and support the best-in-class efficacy of TEPEZZA for people living with Thyroid Eye Disease, now with subcutaneous administration delivering IV-level efficacy," said Jay Bradner, M.D., executive vice president of Research and Development at Amgen. "With a well-understood mechanism and established impact in the clinic, we can evolve how the medicine is delivered to potentially reach even more patients through a more convenient subcutaneous option."

The trial also showed statistically significant and clinically meaningful improvements across the following additional secondary endpoints: overall responder rate; percentage of patients achieving a Clinical Activity Score (CAS) of 0 or 1; change in diplopia as ordinal response categories; diplopia response rate; complete diplopia responder rate; and mean change from baseline in week 24 in the Graves' Ophthalmopathy Quality of Life (GO-QoL) appearance subscale. Although not statistically significant, there was a numerical trend favoring TEPEZZA OBI in the mean change in baseline at week 24 in the GO-QoL visual functioning subscale. Full results from the study will be presented at an upcoming medical congress.

The overall safety results were generally consistent with the known safety profile of TEPEZZA IV[1,2]. Mild-to-moderate injection site reactions were observed with subcutaneous administration in some patients, which did not result in treatment interruption or discontinuation. The most common adverse events (≥10%) were muscle spasms, tinnitus, weight decrease, ear discomfort, nausea and diarrhea.

TED is a serious, progressive and potentially vision-threatening rare autoimmune disease that can cause proptosis (eye bulging), diplopia (double vision), eye pain, redness and swelling.[3]

"Thyroid Eye Disease can be a profoundly debilitating condition, affecting not only vision but also daily functioning with symptoms like double vision and eye bulging," said Dr. Madhura A. Tamhankar, M.D., professor of ophthalmology and neurology at the Scheie Eye Institute, University of Pennsylvania. "Expanding administration options through subcutaneous delivery opens the possibility of a more accessible experience for patients with Thyroid Eye Disease and is critical to serving diverse patient needs. The potential to achieve comparable efficacy to IV makes this advancement compelling."

About the Phase 3 TEPEZZA OBI Trial
This Phase 3, randomized, double-masked, placebo-controlled, parallel-group, multicenter trial was to evaluate the efficacy and safety of subcutaneous TEPEZZA vs. placebo in patients with active TED. The primary endpoint was proptosis responder rate (percentage of participants with a ≥2-mm reduction from baseline in proptosis in the study eye without deterioration [≥2-mm increase] of proptosis in the fellow eye) at Week 24.

During the study, participants received TEPEZZA or placebo via an on-body injector every two weeks for a total of 12 injections. Inclusion criteria required a diagnosis of moderate-to-severe active TED within 15 months, as well as proptosis of ≥3 mm from baseline (prior to TED diagnosis), among other factors. Of note, participants with baseline hearing impairment, whether identified through medical history or audiogram, were allowed to participate in the study.

TEPEZZA IV Post-Marketing Requirement Study
Additionally, a separate Phase 3b/4 trial, conducted to fulfill an FDA post-marketing requirement for TEPEZZA IV, has been completed. The primary objective of the study was to evaluate the safety and tolerability of three treatment durations (four, eight and 16 infusions) of TEPEZZA IV and assess the need for retreatment. The study was descriptive in nature. The observed risk profile was consistent with the known profile of TEPEZZA IV. The post-marketing data will be submitted to regulatory authorities and presented at an upcoming medical congress.

About Thyroid Eye Disease (TED)
TED is a serious, progressive and potentially vision-threatening rare autoimmune disease.[4] It often occurs in people living with Graves' disease, but is a distinct disease that is caused by autoantibodies activating an insulin-like growth factor-1 receptor (IGF-1R)-mediated signaling complex on cells within the retro-orbital space.[5,6] This can lead to a cascade of potential negative effects, which may be vision threatening.[7,8] Early signs and symptoms of TED may include dry eyes and grittiness; redness, swelling and excessive tearing; eyelid retraction; proptosis; pressure and/or pain behind the eyes; and diplopia.

About TEPEZZA
TEPEZZA IV was approved in 2020 and remains the first and only approved medicine for TED and has changed the way the disease is treated by targeting a root cause of the condition. Its ability to significantly reduce proptosis and double vision - two hallmark symptoms of TED - has been

consistently demonstrated in multiple global clinical studies[2,3] and reinforced by six years of real-world experience in more than 25,000 patients.[9,*]

INDICATION
TEPEZZA is indicated for the treatment of Thyroid Eye Disease regardless of Thyroid Eye Disease activity or duration.

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

Infusion Reactions: TEPEZZA may cause infusion reactions. Infusion reactions have been reported in approximately 4% of patients treated with TEPEZZA. Reported infusion reactions have usually been mild or moderate in severity. Signs and symptoms may include transient increases in blood pressure, feeling hot, tachycardia, dyspnea, headache, and muscular pain. Infusion reactions may occur during an infusion or within 1.5 hours after an infusion. In patients who experience an infusion reaction, consideration should be given to premedicating with an antihistamine, antipyretic, or corticosteroid and/or administering all subsequent infusions at a slower infusion rate.

Inflammatory Bowel Disease: TEPEZZA may cause an exacerbation of inflammatory bowel disease (IBD). IBD has been reported in some patients without a prior diagnosis of IBD. Monitor patients for signs and symptoms of IBD. If IBD exacerbation is suspected, discontinue use of TEPEZZA.

Hyperglycemia: Increased blood glucose or hyperglycemia may occur in patients treated with TEPEZZA. In clinical trials, 10% of patients (two-thirds of whom had preexisting diabetes or impaired glucose tolerance) experienced hyperglycemia. Hyperglycemic events should be controlled with medications for glycemic control, if necessary. Assess patients for elevated blood glucose and symptoms of hyperglycemia prior to infusion and continue to monitor while on treatment with TEPEZZA. Ensure patients with hyperglycemia or preexisting diabetes are under appropriate glycemic control before and while receiving TEPEZZA.

Hearing Impairment Including Hearing Loss: TEPEZZA may cause severe hearing impairment including hearing loss, which in some cases may be permanent. Assess patients' hearing before, during, and after treatment with TEPEZZA and consider the benefit-risk of treatment with patients.

ADVERSE REACTIONS

The most common adverse reactions (incidence ≥5% and greater than placebo) are muscle spasm, nausea, alopecia, diarrhea, fatigue, hyperglycemia, hearing impairment, dysgeusia, headache, dry skin, ear discomfort, weight decrease, nail disorders and menstrual disorders.

Please see Full Prescribing Information or visit TEPEZZAhcp.com for more information.

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.

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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References

*Based on 25,062 individual patients enrolled in Amgen By Your Side who received at least one dose of TEPEZZA from 02/05/2020 – 11/14/2025.

1 Smith TJ, et al. Teprotumumab for Thyroid-Associated Ophthalmopathy. 2017; N Engl J Med 2017; 376:1748-1761DOI: 10.1056/NEJMoa1614949.

2 Douglas RS, et al. Teprotumumab for the Treatment of Active Thyroid Eye Disease. N Engl J Med. 2020;382(4):341-352.

3 Barrio-Barrio J, et al. Graves' Ophthalmopathy: VISA versus EUGOGO Classification, Assessment, and Management. Journal of Ophthalmopathy. 2015;2015:249125.

4 Ponto KA, et al. Quality of life and occupational disability in endocrine orbitopathy. Dtsch Arztebl Int. 2009;106(17):283-289.

5 Weightman DR, et al. Autoantibodies to IGF-1 Binding Sites in Thyroid Associated Ophthalmopathy. Autoimmunity. 1993;16(4):251–257.

6 Pritchard J, et al. Immunoglobulin Activation of T Cell Chemoattractant Expression in Fibroblasts from Patients with Graves' Disease Is Mediated Through the Insulin-Like Growth Factor 1 Receptor Pathway. J Immunol. 2003;170:6348-6354.

7 McKeag D, et al. Clinical features of dysthyroid optic neuropathy: a European Group on Graves' Orbitopathy (EUGOGO) survey. Br J Ophthalmol. 2007;91:455-458.

8 Bartalena L, et al. The 2021 European Group on Graves' Orbitopathy (EUGOGO) Clinical Practice Guidelines for the Medical Management of Graves' Orbitopathy [published online ahead of print]. Eur J Endocrinol. 2021 Jul 1:EJE-21-0479.R1.

9 Data on file, Amgen; 2025.

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