TEZSPIRE® DEMONSTRATES POSITIVE PHASE 3 RESULTS IN EOSINOPHILIC ESOPHAGITIS ACROSS BOTH CO-PRIMARY AND ALL KEY SECONDARY ENDPOINTS

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Statistically Significant and Clinically Meaningful Disease and Symptom Improvements Compared to Placebo Maintained Through Week 52

Efficacy in a Third Epithelial-Driven Inflammatory Disease Supports Broad Potential of TEZSPIRE

THOUSAND OAKS, Calif., Aug. 27, 2026 /PRNewswire/ -- Amgen (NASDAQ:AMGN) and AstraZeneca today announced positive top-line results from the Phase 3 CROSSING trial of TEZSPIRE® (tezepelumab-ekko) in patients living with eosinophilic esophagitis (EoE). TEZSPIRE demonstrated statistically significant and clinically meaningful improvements across co-primary and key secondary endpoints at week 24 which were sustained through week 52. The co-primary endpoints were histologic remission and the frequency and severity of dysphagia (difficulty swallowing). The safety profile of TEZSPIRE was generally consistent with its approved indications.

EoE is a chronic and progressive epithelial-driven inflammatory disorder of the esophagus affecting more than 470,000 people in the U.S., with the prevalence increasing five-fold since 2009.[1,2] Esophageal inflammation can lead to dysphagia, food impaction and esophageal narrowing.[2] For patients, the risk of food moving slowly or becoming stuck can make daily meals difficult and stressful.[3] Nearly half of patients, including adolescents, do not achieve adequate disease control with current first-line treatments, which include dietary restriction, swallowed topical corticosteroids and proton pump inhibitors.[4-6]

"We're pleased that TEZSPIRE showed efficacy in a third epithelial-driven inflammatory condition, eosinophilic esophagitis," said Jay Bradner, M.D., executive vice president of Research and Development, Artificial Intelligence and Data at Amgen. "In this Phase 3 trial, TEZSPIRE improved both the underlying inflammation and the swallowing difficulties that can make eosinophilic esophagitis so disruptive for patients. That combination is important for patients and builds confidence in TEZSPIRE as a potential new treatment for people struggling with EoE."

CROSSING is a randomized, double-blind trial that evaluated the efficacy and safety of TEZSPIRE at one of two doses administered subcutaneously every four weeks compared to placebo in adults and adolescents with symptomatic and uncontrolled EoE while on maintenance therapy. In the trial, the first co-primary endpoint, histologic remission, was defined as having a low count of peak eosinophils in the esophageal tissue. The second co-primary endpoint, the frequency and severity of dysphagia, was assessed using the patient-reported Dysphagia Symptom Questionnaire (DSQ) and measured as a mean change from baseline in DSQ score.[7]

"Despite the availability of first-line therapies or dietary interventions, many patients with eosinophilic esophagitis still experience substantial burden, including difficulty swallowing food and emotional and daily-life impacts of the disease," said Arjan Bredenoord, M.D., gastroenterologist and professor at the Amsterdam University Medical Center, Amsterdam, the Netherlands, and primary investigator in the trial. "The impressive results from the CROSSING trial sustained over 52 weeks demonstrate that tezepelumab, taken every four weeks, could provide a new approach to treating EoE, with the potential to help more patients achieve remission and symptom improvement."

Full results will be shared with regulatory authorities and the scientific community at an upcoming medical meeting.

TEZSPIRE® (tezepelumab-ekko) U.S. Indication

TEZSPIRE is indicated for:

- the add-on maintenance treatment of adult and pediatric patients aged 12 years and older with severe asthma. TEZSPIRE is not indicated for the relief of acute bronchospasm or status asthmaticus.
- the add-on maintenance treatment of adult and pediatric patients aged 12 years and older with inadequately controlled chronic rhinosinusitis with nasal polyps (CRSwNP).

TEZSPIRE® (tezepelumab-ekko) Important Safety Information

CONTRAINDICATIONS
Known hypersensitivity to tezepelumab-ekko or excipients.

WARNINGS AND PRECAUTIONS

Hypersensitivity Reactions
Hypersensitivity reactions were observed in the clinical trials (e.g., rash and allergic conjunctivitis) following the administration of TEZSPIRE. Postmarketing cases of anaphylaxis have been reported. These reactions can occur within hours of administration, but in some instances have a delayed onset (i.e., days). In the event of a hypersensitivity reaction, consider the benefits and risks for the individual patient to determine whether to continue or discontinue treatment with TEZSPIRE.

Acute Asthma Symptoms or Deteriorating Disease
TEZSPIRE should not be used to treat acute asthma symptoms, acute exacerbations, acute bronchospasm, or status asthmaticus.

Abrupt Reduction of Corticosteroid Dosage
Do not discontinue systemic or inhaled corticosteroids abruptly upon initiation of therapy with TEZSPIRE. Reductions in corticosteroid dose, if appropriate, should be gradual and performed under the direct supervision of a physician. Reduction in corticosteroid dose may be associated with systemic withdrawal symptoms and/or unmask conditions previously suppressed by systemic corticosteroid therapy.

Parasitic (Helminth) Infection
It is unknown if TEZSPIRE will influence a patient's response against helminth infections. Treat patients with pre-existing helminth infections before initiating therapy with TEZSPIRE. If patients become infected while receiving TEZSPIRE and do not respond to anti-helminth treatment, discontinue TEZSPIRE until infection resolves.

Live Attenuated Vaccines
The concomitant use of TEZSPIRE and live attenuated vaccines has not been evaluated. The use of live attenuated vaccines should be avoided in patients receiving TEZSPIRE.

ADVERSE REACTIONS
The most common adverse reactions (incidence ≥ 3%) are:

- **Asthma:** pharyngitis, arthralgia, and back pain.
- **Chronic rhinosinusitis with nasal polyps:** nasopharyngitis, upper respiratory tract infection, epistaxis, pharyngitis, back pain, influenza, injection site reaction and arthralgia.

USE IN SPECIFIC POPULATIONS
There are no available data on TEZSPIRE use in pregnant women to evaluate for any drug-associated risk of major birth defects, miscarriage, or other adverse maternal or fetal outcomes. Placental transfer of monoclonal antibodies such as tezepelumab-ekko is greater during the third trimester of pregnancy; therefore, potential effects on a fetus are likely to be greater during the third trimester of pregnancy.

Please see the full Prescribing Information including Patient Information and Instructions for Use.

You may report side effects related to AstraZeneca products by clicking here.

About TEZSPIRE® (tezepelumab-ekko)

TEZSPIRE is a first-in-class human monoclonal antibody that works on a primary source of inflammation: the airway and gut epithelia, which are the first points of contact for many viruses, allergens, pollutants and other environmental triggers and insults. Specifically, TEZSPIRE targets and blocks thymic stromal lymphopoietin (TSLP), a key epithelial cytokine that sits at the top of multiple inflammatory cascades and initiates an overreactive immune response to allergic, eosinophilic and other types of epithelial-driven inflammation associated with severe asthma, chronic rhinosinusitis with nasal polyps (CRSwNP), chronic obstructive pulmonary disease (COPD) and eosinophilic esophagitis (EoE).[7,8-11]

TSLP is released by the epithelium in response to inhaled or swallowed environmental inflammatory triggers. Across these disease states, the expression of TSLP is increased and correlates with disease severity.[8-12]

TEZSPIRE is currently approved for the treatment of severe asthma in the U.S., EU, China, Japan and more than 70 countries across the globe, and for the treatment of inadequately controlled CRSwNP in the U.S., EU, China and Japan.

Beyond severe asthma and CRSwNP, TEZSPIRE is also in development for other potential indications including COPD and EoE.[13-15]

About Eosinophilic Esophagitis (EoE)

EoE is a chronic and progressive epithelial-driven inflammatory disorder of the esophagus with prevalence growing across the world.[1,2] It is characterized by inflammation, remodeling and esophageal epithelial dysfunction. Epithelial dysfunction and inflammation are important characteristics of EoE and impede the ability of the epithelium to act as a physical and immunological barrier against the external environment.[2]

The most common symptoms of EoE include difficulty and pain swallowing, food becoming stuck in the esophagus (which may require emergency medical interventions), nausea and vomiting, abdominal or chest pain, poor appetite and difficulty sleeping.[2,16,17] Many patients, including adolescents, experience a substantial impact on their quality of life including significant anxiety related to swallowing and choking, depression and decreased work/school productivity.[18,19]

Patients are often treated with proton pump inhibitors or swallowed topical corticosteroids to manage inflammation.[2,4] Nearly half of patients with EoE will not respond to standard first-line therapies or dietary treatment.[5,6] Existing treatment options, including those targeting downstream mediators, may not fully address epithelial-driven inflammation.[20,21]

About the Phase 3 CROSSING Trial

CROSSING is a randomized, double-blind, placebo-controlled, multi-center, parallel-group, Phase 3 trial designed to evaluate the efficacy and safety of TEZSPIRE administered subcutaneously every four weeks, compared to placebo in patients aged 12-80 years with symptomatic and histologically active EoE. A total of 368 patients were randomized in a 1:1:1 ratio to receive either a low or high dose of TEZSPIRE or placebo.[7]

The co-primary endpoints analyzed at week 24 were the proportion of patients with histologic remission, defined as a peak esophageal eosinophil count less than or equal to six eosinophils per high-power field, and mean changes from baseline in the Dysphagia Symptom Questionnaire (DSQ). The peak eosinophil count is obtained when biopsies of the tissue of the esophagus are examined under a microscope. A count of 15 or more peak eosinophils per high power microscopic field measured by esophageal biopsy is often the cutoff used to diagnose EoE.[22,23] The DSQ captures the presence and severity of dysphagia symptoms in a daily diary with a four-item patient-reported questionnaire; the score is calculated over 14-day periods, ranging from zero to 84, with a higher score indicating more severe dysphagia. Key secondary endpoints assessed histologic remission and dysphagia symptoms at week 52; changes in endoscopic disease features (EoE-EREFS) and histologic severity and extent (EoE-HSS) at weeks 24 and 52, as well as endoscopic response, inflammatory remission and total endoscopic remission at week 52.[7]

In the trial, patients were allowed to remain on background medications for EoE, including proton pump inhibitors and swallowed topical corticosteroids, provided that they were stable prior to entry and during the treatment period.[7]

About the Amgen and AstraZeneca Collaboration

Amgen is in a collaboration with AstraZeneca for the development and commercialization of TEZSPIRE. Under the collaboration, both companies share global costs, profits and losses equally after payment by AstraZeneca of a mid-single-digit royalty to Amgen. AstraZeneca leads global development. In North America, Amgen, as the principal, recognizes product sales of TEZSPIRE in the United States, and AstraZeneca, as the principal, recognizes product sales of TEZSPIRE in Canada. AstraZeneca leads commercialization for TEZSPIRE outside North America. Amgen manufactures and supplies TEZSPIRE worldwide.

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, heart disease, inflammatory conditions, rare diseases 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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