FDA APPROVES TEZSPIRE™ (TEZEPELUMAB-EKKO) IN THE U.S. FOR SEVERE ASTHMA

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First and Only Biologic to Consistently and Significantly Reduce Exacerbations in a Broad Population of Severe Asthma Patients

Only Biologic for Severe Asthma Approved With no Phenotype or Biomarker Limitations

THOUSAND OAKS, Calif., Dec. 17, 2021 /PRNewswire/ -- Amgen (NASDAQ:AMGN) today announced that the U.S. Food and Drug Administration (FDA) has approved Amgen and AstraZeneca's *Tezspire* ™ (tezepelumab-ekko) for the add-on maintenance treatment of adult and pediatric patients aged 12 years and older with severe asthma.[1]

To view the Multimedia News Release, please visit: https://www.multivu.com/players/English/8812852-amgen-fda-approval-tezepelumab-severe-asthma-inflammation/

Tezspire was approved following a Priority Review by the FDA and based on results from the PATHFINDER clinical trial program. The application included results from the pivotal NAVIGATOR Phase 3 trial in which *Tezspire* demonstrated superiority across every primary and key secondary endpoint in patients with severe asthma, compared to placebo, when added to standard therapy.[2]

"Today's approval by the FDA marks the first time patients and their physicians will have a biologic option for severe asthma without phenotypic limitations and irrespective of biomarker levels," said David M. Reese, M.D., executive vice president of Research and Development at Amgen. "Asthma is a complex and chronic inflammatory disease that affects everyone differently. By working at the top of the inflammation cascade, *Tezspire* helps stop the inflammation that causes asthma attacks at the source and has the potential to treat a broad population of people with severe asthma, including those who have historically lacked effective treatment options."

Tezspire is a first-in-class biologic for severe asthma that acts at the top of the inflammatory cascade by targeting thymic stromal lymphopoietin (TSLP), an epithelial cytokine.[3] It is the first and only biologic to consistently and significantly reduce asthma exacerbations across Phase 2 and 3 clinical trials, which included a broad population of severe asthma patients irrespective of key biomarkers, including blood eosinophil counts, allergic status and fractional exhaled nitric oxide (FeNO).[2,3] *Tezspire* is the first and only biologic for severe asthma that does not have a phenotype —eosinophilic or allergic—or biomarker limitation within its approved label.[4-11]

"Due to the complex and heterogeneous nature of severe asthma and despite recent advances, many patients continue to experience frequent exacerbations, an increased risk of hospitalization and a significantly reduced quality of life," said Professor Andrew Menzies-Gow, director of the Lung Division, Royal Brompton Hospital, London, UK, and the principal investigator of the NAVIGATOR trial. "*Tezspire* represents a much-needed new treatment for the many patients who remain underserved and continue to struggle with severe, uncontrolled asthma."

"Severe asthma continues to have a debilitating impact on many of the 34 million people living with the disease worldwide, affecting their breathing and limiting aspects of day-to-day life. The approval of *Tezspire* is long-awaited positive news for the asthma community," said Tonya Winders, president and chief executive officer at the Allergy & Asthma Network (AAN) and president of the Global Allergy and Airways Patient Platform (GAAPP). "For the first time, many people living with severe asthma have the opportunity to receive treatment regardless of the cause of their inflammation."

Results from the NAVIGATOR Phase 3 trial were published in *The New England Journal of Medicine* in May 2021.[2] In clinical studies of *Tezspire*, the most common adverse reactions were nasopharyngitis, upper respiratory tract infection and headache.[2]

Tezspire is under regulatory review in the EU, Japan and several other countries around the world.

Commitment to Patient Support

Amgen and AstraZeneca are committed to providing appropriate patients who are prescribed *Tezspire* with affordable access to the medicine. Patients, caregivers and physicians who need support or resources can contact the Tezspire Together program starting on Monday, Dec. 20 at 8:00 a.m. ET by calling 1-888-TZSPIRE (1-888-897-7473).

***Tezspire* ™ (tezepelumab-ekko) U.S. Indication**

Tezspire is a first-in-class medicine 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.

***Tezspire* ™ (tezepelumab-ekko) Important Safety Information**

CONTRAINDICATIONS

Known hypersensitivity to tezepelumab-ekko or excipients.

WARNINGS AND PRECAUTIONS

Hypersensitivity Reactions

Hypersensitivity reactions (e.g., rash and allergic conjunctivitis) can occur following administration of TEZSPIRE. 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, initiate appropriate treatment as clinically indicated and then 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 pharyngitis, arthralgia, and back pain.

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 *Tezspire* full Prescribing Information.

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

About the NAVIGATOR and the PATHFINDER Clinical Trial Program
In addition to the Phase 2b PATHWAY trial, the Phase 3 PATHFINDER program included two trials, NAVIGATOR and SOURCE. [2,12-14] The program includes additional mechanistic and long-term safety trials.[15]

NAVIGATOR is a Phase 3, randomized, double-blinded, placebo-controlled trial in adults (18–80 years old) and adolescents (12–17 years old) with severe, uncontrolled asthma, who were receiving standard of care (SoC). SoC was treatment with medium- or high-dose inhaled corticosteroids (ICS) plus at least one additional controller medication with or without daily oral corticosteroid treatment. The trial population included approximately equal proportions of patients with high (≥300 cells per microliter) and low (<300 cells per microliter) blood eosinophil counts. The trial comprised a five-to-six-week screening period, a 52-week treatment period and a 12-week post-treatment follow-up period. All patients received their prescribed controller medications without change throughout the trial.[2]

The primary efficacy endpoint was the AAER during the 52-week treatment period. Key secondary endpoints included the effect of *Tezspire* on lung function, asthma control and health-related quality of life.[3]

As part of prespecified analyses, the AAER over 52 weeks was also assessed in patients grouped by baseline blood eosinophil count, FeNO level and serum specific immunoglobin E (IgE) status (perennial aeroallergen sensitivity positive or negative).[3] These are inflammatory biomarkers used by clinicians to inform treatment options and involve tests analyzing a patient's blood (eosinophils/IgE) and exhaled air (FeNO).

The most frequently reported adverse events for *Tezspire* were nasopharyngitis, upper respiratory tract infection and headache.[2]

NAVIGATOR is the first Phase 3 trial to show benefit in severe asthma irrespective of eosinophils by targeting TSLP.[2] These results support the U.S. Food and Drug Administration Breakthrough Therapy Designation granted to *Tezspire* in September 2018 for patients with severe asthma, without an eosinophilic phenotype. In July 2021, *Tezspire* was the first and only biologic to be granted Priority Review in the U.S. for the treatment of asthma by the FDA.

Patients who participated in our Phase 3 clinical trials were eligible to continue in DESTINATION, a Phase 3 extension trial assessing long-term safety and efficacy.[16]

About *Tezspire* ™ (tezepelumab-ekko)
Tezspire is a first-in-class human monoclonal antibody that works on the primary source of inflammation: the airway epithelium, which is the first point of contact for viruses, allergens, pollutants and other environmental insults. Specifically, *Tezspire* targets and blocks 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 airway inflammation associated with severe asthma.[3,17] TSLP is released in response to multiple triggers associated with asthma exacerbations, including allergens, viruses and other airborne particles.[3,17] Expression of TSLP is increased in the airways of patients with asthma and has been correlated with disease severity.[3,18] Blocking TSLP may prevent the release of pro-inflammatory cytokines by immune cells, resulting in the prevention of asthma exacerbations and improved asthma control.[3,18] By working at the top of the cascade, *Tezspire* helps stop inflammation at the source and has the potential to treat a broad population of severe asthma patients.[3,18]

Tezspire is also in development for other potential indications including chronic obstructive pulmonary disease, chronic rhinosinusitis with nasal polyps, chronic spontaneous urticaria and eosinophilic esophagitis (EoE). In October 2021, tezepelumab was granted Orphan Drug Designation by the FDA for the treatment of EoE.

About Severe Asthma
Globally, there are approximately 2.5 million patients with severe asthma who are uncontrolled or biologic eligible, with approximately 1 million in the U.S. Many patients with severe asthma have an inadequate response to currently available biologics and oral corticosteroids and thus fail to

achieve asthma control.[19-24] Uncontrolled asthma occurs when symptoms persist despite treatment. Severe, uncontrolled asthma is debilitating with patients experiencing frequent exacerbations, significant limitations on lung function and a reduced quality of life.[20-22] Patients with severe uncontrolled asthma have twice the risk of asthma-related hospitalizations.[25,26] There is also a significant socio-economic burden with these severe uncontrolled asthma patients accounting for 50% of asthma-related costs.[28]

Multiple inflammatory pathways are involved in the pathogenesis of asthma.[27-29] Eosinophilic asthma, and more broadly, T2 inflammation-driven asthma, accounts for about two-thirds of patients with severe asthma.[29] These patients are typically characterized as having elevated levels of inflammatory biomarkers, including blood eosinophils, serum IgE and FeNO.[30,31] However, many patients do not fit the criteria for eosinophilic or allergic asthma, may have unclear or multiple drivers of inflammation, and may not qualify for or respond well to a current biologic medicine.[31]

About the Amgen and AstraZeneca Collaboration
In 2020, Amgen and AstraZeneca updated the 2012 collaboration agreement for *Tezspire*. Both companies will continue to share costs and profits equally after payment by AstraZeneca of a mid-single-digit royalty to Amgen. AstraZeneca continues to lead development and Amgen continues to lead manufacturing. All aspects of the collaboration are under the oversight of joint governing bodies. Under the amended agreement, Amgen and AstraZeneca will jointly commercialize *Tezspire* in North America. Amgen will record product sales in the U.S., with AZ recording its share of US profits as Collaboration Revenue. Outside of the U.S., AstraZeneca will record product sales, with Amgen recording profit share as Other/Collaboration revenue.

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 2021, Amgen was named one of the 25 World's Best Workplaces™ by Fortune and Great Place to Work™ and one of the 100 most sustainable companies in the world by Barron's.

For more information, visit www.amgen.com and follow us on www.twitter.com/amgen.

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., Kyowa Kirin Co., Ltd., or any collaboration to manufacture therapeutic antibodies against COVID-19), the performance of Otezla® (apremilast) (including anticipated Otezla sales growth and the timing of non-GAAP EPS accretion), the Five Prime Therapeutics, Inc. acquisition, or the Teneobio, Inc. 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 such as the ongoing COVID-19 pandemic on Amgen's business, 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 its 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 Amgen projects. 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 Amgen to complete clinical trials and obtain regulatory approval for product marketing has in the past varied and Amgen expects similar variability in the future. Even when clinical trials are successful, regulatory authorities may question the sufficiency for approval of the trial endpoints Amgen has selected. Amgen develops 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 Amgen may have believed at the time of entering into such relationship. Also, Amgen or others could identify safety, side effects or manufacturing problems with its products, including its devices, after they are on the market.

Amgen's results may be affected by its 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 its products and global economic conditions. In addition, sales of Amgen's 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, Amgen's research, testing, pricing, marketing and other operations are subject to extensive regulation by domestic and foreign government regulatory authorities. Amgen's business may be impacted by government investigations, litigation and product liability claims. In addition, Amgen's business may be impacted by the adoption of new tax legislation or exposure to additional tax liabilities. If Amgen fails to meet the compliance obligations in the corporate integrity agreement between Amgen and the U.S. government, Amgen could become subject to significant sanctions. Further, while Amgen routinely obtains patents for its products and technology, the protection offered by its patents and patent applications may be challenged, invalidated or circumvented by its competitors, or Amgen may fail to prevail in present and future intellectual property litigation. Amgen performs a substantial amount of its commercial manufacturing activities at a few key facilities, including in Puerto Rico, and also depends on third parties for a portion of its manufacturing activities,

and limits on supply may constrain sales of certain of its 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 Amgen's manufacturing activities, the distribution of Amgen's products, the commercialization of Amgen's product candidates, and Amgen's clinical trial operations, and any such events may have a material adverse effect on Amgen's product development, product sales, business and results of operations. Amgen relies on collaborations with third parties for the development of some of its product candidates and for the commercialization and sales of some of its commercial products. In addition, Amgen competes with other companies with respect to many of its marketed products as well as for the discovery and development of new products. Further, some raw materials, medical devices and component parts for Amgen's products are supplied by sole third-party suppliers. Certain of Amgen's distributors, customers and payers have substantial purchasing leverage in their dealings with Amgen. The discovery of significant problems with a product similar to one of Amgen's products that implicate an entire class of products could have a material adverse effect on sales of the affected products and on its business and results of operations. Amgen's 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 Amgen has acquired, may not be successful. A breakdown, cyberattack or information security breach could compromise the confidentiality, integrity and availability of Amgen's systems and Amgen's data. Amgen's stock price may be volatile and may be affected by a number of events. Global economic conditions may magnify certain risks that affect our business. Amgen's business performance could affect or limit the ability of the Amgen Board of Directors to declare a dividend or its ability to pay a dividend or repurchase its common stock. Amgen may not be able to access the capital and credit markets on terms that are favorable to it, or at all.

The scientific information discussed in this news release related to Amgen's 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 Amgen's 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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