AMGEN HIGHLIGHTS NEW COPD, ASTHMA AND VASCULITIS RESEARCH AT ATS 2024

May 1, 2024

Findings From Tezspire® (tezepelumab-ekko) Phase 2a COURSE COPD Study

Phase 1 Study on AMG104/AZD8630 (Inhaled Anti-TSLP) in Moderate to Severe Asthma

New TAVNEOS® (avacopan) Data in Adults With Severe Active ANCA-Associated Vasculitis With Lung Involvement

THOUSAND OAKS, Calif., May 1, 2024 /PRNewswire/ -- Amgen (NASDAQ:AMGN) today announced the presentation of new respiratory data at the American Thoracic Society (ATS) 2024 International Conference taking place May 12-22 in San Diego. Thirteen abstracts supporting two approved medicines and one investigational treatment will be presented.

"We look forward to presenting encouraging data from our Phase 2a COURSE trial in COPD with Tezspire and our Phase 1 investigational study of asthma with AMG104/AZD8630, an inhaled anti-TSLP therapy," said Jay Bradner, M.D., executive vice president of Research and Development and chief scientific officer at Amgen. "Our efforts underscore Amgen's commitment to pioneering new treatments for respiratory diseases with currently limited treatment options."

Data from the COURSE trial will be presented within the Clinical Trials Symposium. COURSE was a proof-of-concept, Phase 2a study evaluating the safety and efficacy of Tezspire® (tezepelumab-ekko) in patients with moderate to very severe chronic obstructive pulmonary disease (COPD), irrespective of inflammatory drivers, blood eosinophil count (BEC), emphysema, chronic bronchitis and smoking status.

Other research highlights include late-breaking data from the Phase 1 study of AMG104/AZD8630, an investigational inhaled anti-TSLP therapy being evaluated in patients with poorly controlled asthma, as well as a post-hoc analysis from the Phase 3 ADVOCATE trial, which assessed the efficacy and safety of TAVNEOS® (avacopan) in patients with severe active ANCA-associated vasculitis (GPA or MPA) with lung involvement.

Abstracts and Presentation Times:

TEZSPIRE

- **Tezepelumab in Adults with Moderate to Very Severe Chronic Obstructive Pulmonary Disease (COPD): Efficacy and Safety from the Phase 2a COURSE Study**
  Scientific Symposium Session B13, May 20, 9:50 a.m. – 10:05 a.m. PDT

- **Tezepelumab in Adults with Moderate to Very Severe Chronic Obstructive Pulmonary Disease (COPD): Efficacy and Safety from the Phase 2a COURSE Study**
  Poster Discussion Session A101, Room 30C-E, May 19, 2:15 p.m. – 4:15 p.m. PDT

- **Clinical Responses to Tezepelumab in Patients with Severe, Uncontrolled Asthma and a History of Nasal Polyps from the NAVIGATOR Study**
  Thematic Poster Session C31, Hall A-B2, May 21, 11:30 a.m. – 1:15 p.m. PDT

- **A Phase 4, Single-Arm, Open-Label Study to Evaluate the Effectiveness and Safety of Tezepelumab in Patients with Severe Asthma, Including Underrepresented Racial and Clinical Groups: Initial Baseline Demographics and Clinical Characteristics from the PASSAGE Study**
  Thematic Poster Session C34, Hall A-B2, May 21, 11:30 a.m. – 1:15 p.m. PDT

- **Effect of Biologics on Biomarkers of Type 2 Inflammation in Asthma: A Review of the Literature**
  Thematic Poster Session C34, Hall A-B2, May 21, 11:30 a.m. – 1:15 p.m. PDT

- **Efficacy of Biologics for Reducing Exacerbations Requiring Hospitalization or an Emergency Department Visit in Patients with Moderate to Severe, Uncontrolled Asthma**
  Thematic Poster Session C34, Hall A-B2, May 21, 11:30 a.m. – 1:15 p.m. PDT

- **Efficacy of Tezepelumab in Black or African American Patients: A Pooled Analysis of the PATHWAY and NAVIGATOR Studies**
  Thematic Poster Session C34, Hall A-B2, May 21, 11:30 a.m. – 1:15 p.m. PDT

- **Effect of Tezepelumab on Exercise Tolerance in Patients with Severe, Uncontrolled Asthma from the NAVIGATOR Study**
  Thematic Poster Session C34, Hall A-B2, May 21, 11:30 a.m. – 1:15 p.m. PDT

- **Patient Characteristics and Treatment Patterns with Tezepelumab in the United States: An Early Claims Data Study**
  Thematic Poster Session A35, Hall A-B2, May 21, 11:30 a.m. – 1:15 p.m. PDT

- **Asthma Exacerbation Rates as a Function of Biomarker Levels 4 Weeks After Initiation of Tezepelumab Treatment: An Analysis of the NAVIGATOR Study**
  RAPiD Poster Discussion Session C102, Room 28C-E, May 21, 2:15 p.m. – 4:15 p.m. PDT

- **Reduced Mucus Plugging with Tezepelumab is Spatially Associated with Reduced Air Trapping in a Broad Population of Patients with Moderate to Severe Asthma**
  RAPiD Poster Discussion Session C102, Room 28C-E, May 21, 2:15 p.m. – 4:15 p.m. PDT

SEVERE ASTHMA DISEASE BURDEN

- **Greater Exacerbation Reductions with Earlier Biologic Initiation After Severe Asthma Onset: Results from the CHRONICLE Study**
  RAPiD Poster Discussion Session C102, Room 28C-E, May 19, 2:15 p.m. – 4:15 p.m. PDT

AMG104/AZD8630 (iTSLP)

- **Phase 1 Safety and Efficacy of AZD8630/AMG104 Inhaled Anti-TSLP in Healthy Volunteers and Patients with Asthma on Medium-High Dose Inhaled Corticosteroid (ICS) and Long-Acting Beta-Agonist (LABA) with Elevated Baseline Fractional Exhaled Nitric Oxide (FeNO)**
  Thematic Poster Session A34, Hall A-B2, May 19, 2:15 p.m. – 4:15 p.m. PDT

TAVNEOS

- **Efficacy and Safety of Avacopan Versus Prednisone Taper in Patients with ANCA-Associated Vasculitis with Lung Involvement: A Post Hoc Analysis of the ADVOCATE Trial**
  Poster Discussion Session A26, Room 30C-E, May 19, 9:15 a.m. – 11:15 a.m. PDT

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 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 airway inflammation associated with severe asthma.[1,2] TSLP is released in response to multiple triggers associated with asthma exacerbations, including allergens, viruses and other airborne particles.[1,2]

Expression of TSLP is increased in the airways of patients with asthma and has been correlated with disease severity.[1,3] Blocking TSLP may prevent the release of pro-inflammatory cytokines by immune cells, resulting in the prevention of asthma exacerbations and improved asthma control.[1,3] 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.[1,3]

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 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 AstraZeneca recording its share of U.S. profits as Collaboration Revenue. Outside of the U.S., AstraZeneca will record product sales, with Amgen recording profit share as Other/Collaboration revenue.

In addition, we are also collaborating with AstraZeneca on AMG104/AZD8630, an inhaled anti-TSLP compound currently in development for asthma. In November 2021, Amgen and AstraZeneca agreed to include AMG104/AZD8630 in the existing collaboration agreement. The companies share both costs and income, with no inventor royalty. AstraZeneca will be the development, manufacturing and commercial lead. AstraZeneca and Amgen will jointly commercialize AMG104/AZD8630 in North America, and AstraZeneca will distribute the product and book sales globally, including for the U.S.

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.

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 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 full Prescribing Information including Patient Information and Instructions for Use.

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

About TAVNEOS® (avacopan)
TAVNEOS (avacopan), approved by the FDA as an adjunctive treatment of ANCA-associated vasculitis, is a first-in-class, orally administered small molecule that employs a novel, highly targeted mode of action in complement-driven autoimmune and inflammatory diseases. While the precise mechanism in ANCA vasculitis has not been definitively established, TAVNEOS, by blocking the complement 5a receptor (C5aR) for the pro-inflammatory complement system fragment known as C5a on destructive inflammatory cells such as blood neutrophils, is presumed to arrest the ability of those cells to do damage in response to C5a activation, which is known to be the driver of ANCA vasculitis. TAVNEOS's selective inhibition of only the C5aR leaves the beneficial C5a pathway through the C5L2 receptor functioning normally.

TAVNEOS® (avacopan) U.S. Indication

TAVNEOS is indicated as an adjunctive treatment of adult patients with severe active anti-neutrophil cytoplasmic autoantibody (ANCA)-associated vasculitis (granulomatosis with polyangiitis [GPA] and microscopic polyangiitis [MPA]) in combination with standard therapy including glucocorticoids. TAVNEOS does not eliminate glucocorticoid use.

TAVNEOS® (avacopan) Important Safety Information

CONTRAINDICATIONS

Serious hypersensitivity to avacopan or to any of the excipients

WARNINGS AND PRECAUTIONS

Hepatotoxicity

Serious cases of hepatic injury have been observed in patients taking TAVNEOS, including life-threatening events. Obtain liver test panel before initiating TAVNEOS, every 4 weeks after start of therapy for six months and as clinically indicated thereafter. Monitor patients closely for hepatic adverse reactions, and consider pausing or discontinuing treatment as clinically indicated (refer to section 5.1 of the Prescribing Information). TAVNEOS is not recommended for patients with active, untreated and/or uncontrolled chronic liver disease (e.g., chronic active hepatitis B, untreated hepatitis C, uncontrolled autoimmune hepatitis) and cirrhosis. Consider the risk and benefit before administering this drug to a patient with liver disease.

Serious Hypersensitivity Reactions

Cases of angioedema occurred in a clinical trial, including one serious event requiring hospitalization. Discontinue immediately if angioedema occurs and manage accordingly. TAVNEOS must not be re-administered unless another cause has been established.

Hepatitis B Virus (HBV) Reactivation

Hepatitis B reactivation, including life threatening hepatitis B, was observed in the clinical program. Screen patients for HBV. For patients with evidence of prior infection, consult with physicians with expertise in HBV and monitor during TAVNEOS therapy and for six months following. If patients develop HBV reactivation, immediately discontinue TAVNEOS and concomitant therapies associated with HBV reactivation, and consult with experts before resuming.

Serious Infections

Serious infections, including fatal infections, have been reported in patients receiving TAVNEOS. The most common serious infections reported in TAVNEOS group were pneumonia and urinary tract infections. Avoid use of TAVNEOS in patients with active, serious infection, including localized infections. Consider the risks and benefits before initiating TAVNEOS in patients with chronic infection, at increased risk of infection or who have been to places where certain infections are common.

ADVERSE REACTIONS

The most common adverse reactions (≥5% of patients and higher in the TAVNEOS group vs. prednisone group) were: nausea, headache, hypertension, diarrhea, vomiting, rash, fatigue, upper abdominal pain, dizziness, blood creatinine increased, and paresthesia.

DRUG INTERACTIONS

Avoid coadministration of TAVNEOS with strong and moderate CYP3A4 enzyme inducers. Reduce TAVNEOS dose when co-administered with strong CYP3A4 enzyme inhibitors to 30 mg once daily. Monitor for adverse reactions and consider dose reduction of certain sensitive CYP3A4 substrates.

Please see Full Prescribing Information and Medication Guide.

About Amgen
Amgen discovers, develops, manufactures and delivers innovative medicines to help millions of patients in their fight against some of the world's toughest diseases. More than 40 years ago, Amgen helped to establish the biotechnology industry and remains on the cutting-edge of innovation, using technology and human genetic data to push beyond what's known today. Amgen is advancing a broad and deep pipeline that builds on its existing portfolio of medicines to treat cancer, heart disease, osteoporosis, inflammatory diseases and rare diseases.

In 2024, Amgen was named one of the "World's Most Innovative Companies" by Fast Company and one of "America's Best Large Employers" by Forbes, among other external recognitions. 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, 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, any potential strategic benefits, synergies or opportunities expected as a result of such acquisition, and any projected impacts from the Horizon acquisition on our acquisition-related expenses going forward), 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.

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1. Menzies-Gow A, *et al*. Tezepelumab in Adults and Adolescents with Severe, Uncontrolled Asthma. *N Engl J Med*. 2021;384:1800-1809. DOI: 10.1056/NEJMoa2034975.
2. Varricchi G, et al. Thymic Stromal Lymphopoietin Isoforms, Inflammatory Disorders, and Cancer. *Front Immunol.* 2018; 9: 1595.
3. Li Y, et al. Elevated Expression of IL-33 and TSLP in the Airways of Human Asthmatics In Vivo: A Potential Biomarker of Severe Refractory Disease. *J Immunol*. 2018; 200: 2253–2262.

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