



AMGEN TO PRESENT TEZSPIRE® PHASE 2A COPD DATA AT ATS 2024

April 16, 2024

Planning Underway for Phase 3 Development of Tezepelumab in COPD

THOUSAND OAKS, Calif., April 16, 2024 /PRNewswire/ -- Amgen (NASDAQ:AMGN) today provided an update regarding the results of the Phase 2a COURSE trial for TEZSPIRE® (tezepelumab-ekko) in chronic obstructive pulmonary disease (COPD), which were accepted for presentation in the Clinical Trials Symposium at The American Thoracic Society (ATS) 2024 International Conference on Monday, May 20, from 9:15-11:15 a.m. PDT.

We are encouraged by the results of the COURSE Phase 2a proof-of-concept trial, which investigated tezepelumab in moderate to very severe COPD patients, across a broad range of eosinophil levels, irrespective of inflammatory drivers, emphysema, chronic bronchitis and smoking status. This study did not exclude any patients based on their baseline eosinophil count (BEC) and intentionally enrolled patients with a broad range of BECs. Overall, tezepelumab numerically reduced the annualized rate of moderate or severe COPD exacerbations versus placebo by 17% (90% CI: -6, 36; p=0.1042). Of note, more reductions were observed in a subgroup of patients with BEC ≥ 150 cells/ μ L (37% [95% CI: 7, 57]). The trend in reduction was greater in a small number of subjects with BEC ≥ 300 cells/ μ L.

"We are excited by these data and optimistic about the potential tezepelumab has for patients with COPD, a condition that continues to have a significant unmet medical need," said James Bradner, M.D., executive vice president of Research and Development and chief scientific officer at Amgen.

We look forward to presenting the full data set at the congress and based on these findings, we are actively planning for the Phase 3 development of tezepelumab in COPD.

TEZSPIRE is a registered trademark of Amgen Inc. and AstraZeneca.

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 $\geq 3\%$) 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](#).

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 2023, Amgen was named one of "America's Greatest Workplaces" by Newsweek, one of "America's Climate Leaders" by USA Today and one of the "World's Best Companies" by TIME.

For more information, visit [Amgen.com](https://www.amgen.com) and follow us on [X](#) (formerly known as Twitter), [LinkedIn](#), [Instagram](#), [TikTok](#), [YouTube](#) and [Threads](#).

Amgen Forward-Looking Statements

This communication 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. 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 communication 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.

Any scientific information discussed in this 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 release, and no conclusions can or should be drawn regarding the safety or effectiveness of the products for these uses.

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