TEZSPIRE™
(tezepelumab-ekko) Subcutaneous Injection 210 mg

The Discovery and Development Journey of *Tezspire*™

Tezspire™ is the first and only biologic approved for severe asthma without phenotypic or biomarker limitations.

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.

CONTRAINDICTIONS
Known hypersensitivity to tezepelumab-ekko or excipients.
Please see additional Important Safety Information on the next page.

1990s

Thymic stromal lymphopoietin (TSLP) first discovered as having a connection to inflammation

2002

Amgen discovered blocking TSLP may help reduce the number of asthma attacks experienced by patients

2006

Team advanced lead antibody AMG 157, now known as *Tezspire*™

2017

PATHWAY: Phase 2b*

This trial tested the efficacy and safety of *Tezspire*™ in adults with severe asthma, and demonstrated that when added to SOC† *Tezspire*™ (n=137) significantly reduced asthma exacerbations vs placebo (n=138).**

2018

U.S. FDA granted *Tezspire*™ Breakthrough Therapy Designation

NOV 2020

NAVIGATOR: Phase 3*

This trial tested the efficacy and safety of *Tezspire*™ in adults and adolescents with severe asthma. When added to SOC† patients who received *Tezspire*™ (n=529) vs placebo (n=532) had a significant reduction in asthma exacerbations, and greater improvements in lung function and patient-reported outcomes.**

JULY 2021

U.S. FDA accepted Biologics License Application submission and granted priority review to *Tezspire*™

– the first ever priority review granted for an asthma biologic

JAN 2022

U.S. FDA Approval and Commercial Launch

* Results published in the *New England Journal of Medicine (NEJM)*
** p<0.001
† SOC: standard of care

SEVERE ASTHMA FAST FACTS

1 MILLION People in the U.S. -and- **2.5 MILLION** People globally

LIVE WITH SEVERE ASTHMA THAT IS UNCONTROLLED OR BIOLOGIC ELIGIBLE[1-6]

THE NUMBER OF AMERICANS WITH ASTHMA IS ANTICIPATED TO GROW, THOUGHT TO BE DUE TO INCREASED URBANIZATION, LIFESTYLE CHANGES AND RATES OF OBESITY[7]

10% BY 2039

~60%

OF AMERICANS WITH SEVERE ASTHMA ARE NOT GETTING SPECIALIZED CARE[8]

2x AS MANY ASTHMA-RELATED HOSPITALIZATIONS ARE EXPERIENCED BY PATIENTS WITH SEVERE ASTHMA[5]

$300 BILLION THE PROJECTED COST TO THE U.S. HEALTH SYSTEM ATTRIBUTED TO UNCONTROLLED ASTHMA[7]

50% OF COSTS RELATED TO ASTHMA ARE ASSOCIATED WITH SEVERE ASTHMA[9]

AMGEN® AstraZeneca USA-157-80216

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INDICATION

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IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

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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.

Full Prescribing Information including Patient Information

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

REFERENCES

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