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"TEZEPELUMAB: A COMPREHENSIVE REVIEW OF ITS MECHANISM, CLINICAL USE, SAFETY, ADVERSE EFFECTS, AND THERAPEUTIC ROLE IN SEVERE ASTHMA"

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ABSTRACT

Tezepelumab is a fully human IgG2 monoclonal antibody produced using recombinant DNA technology in Chinese hamster ovary (CHO) cells. It was approved by the U.S. Food and Drug Administration (FDA) in 2021 as an add-on maintenance therapy for patients with severe, uncontrolled asthma. The therapeutic action of Tezepelumab is based on the inhibition of thymic stromal lymphopoietin (TSLP), an epithelial-derived cytokine that plays a central role in initiating and sustaining airway inflammation. By blocking TSLP, Tezepelumab helps reduce multiple downstream inflammatory pathways involved in asthma pathogenesis, irrespective of eosinophil levels or allergic status. The drug is administered via the subcutaneous route using pre-filled syringes, with a recommended dose of 210 mg once every four weeks. Clinical trials have demonstrated a significant reduction in annualized asthma exacerbation rates compared to placebo, along with improvements in lung function and overall disease control. These outcomes highlight Tezepelumab as an effective therapeutic option for patients who do not achieve adequate symptom control with standard inhaled therapies. This activity aims to enhance clinicians' understanding of Tezepelumab by outlining its indications, mechanism of action, pharmacokinetic properties, dosing regimen, route of administration, and considerations for

special populations such as pregnant women and patients with comorbid conditions. Additionally, it reviews the potential adverse effects, contraindications, drug interactions, warnings, and toxicity concerns associated with its use. By providing comprehensive, evidence-based information, this activity supports informed clinical decision-making and promotes the safe and effective use of Tezepelumab. It also equips the interprofessional healthcare team with the knowledge required to optimize patient outcomes, improve asthma management, and ensure appropriate monitoring during therapy.

KEYWORDS: Tezepelumab, Thymic stromal lymphopoietin, Maintenance therapy, Uncontrolled asthma, Cytokine, Biologic therapy.

INTRODUCTION

Asthma is a long-standing airway inflammation disorder characterized by episodic airflow limitation, increased airway reactivity, and repeated occurrences of wheezing, shortness of breath, chest tightness, and persistent coughing. Asthma remains a major public health concern worldwide, affecting more than 300 million individuals across all age groups. Its prevalence continues to rise, particularly in developing nations, due to urbanization, pollution, lifestyle changes, and increased exposure to environmental triggers. Effective and timely treatment is therefore crucial—not only to prevent life-threatening episodes but also to improve long-term outcomes and reduce global disease burden. Despite the widespread availability of inhaled corticosteroids, bronchodilators, and combination therapies, a significant proportion of patients continue to experience poor symptom control and frequent exacerbations, placing them at risk for repeated hospitalizations and reduced quality of life. These limitations have driven the need for advanced targeted therapies, particularly for individuals with severe or treatment-refractory asthma.

In recent years, biologic therapies have transformed asthma management by targeting specific inflammatory pathways. However, many existing biologic therapies, such as anti-IL-5, anti-IL-4Rα, and anti-IgE agents, mainly benefit patients with allergic or eosinophilic asthma. This leaves a considerable subset of patients—especially those with low eosinophil counts or non-Type 2 inflammation—without effective biological treatment options.

Tezepelumab, a fully human monoclonal antibody, introduces a novel therapeutic approach by inhibiting thymic stromal lymphopoietin (TSLP), an upstream epithelial cytokine that is responsible for multiple inflammatory cascades. By inhibiting TSLP, Tezepelumab prevents

the early activation of inflammatory pathways, offering benefits across diverse asthma phenotypes and therapeutic benefits across a broader spectrum of patients. Clinical trials have shown substantial reductions in exacerbation rates, improved lung function, and enhanced symptom control, positioning Tezepelumab as a major advancement in the management of severe asthma.

OBJECTIVES

- Understanding the common indications for Tezepelumab therapy and comprehending the mechanism of action.
- To evaluate how patients respond to Tezepelumab therapy by monitoring disease activity, symptoms, and adverse effects.
- To consider the appropriate dosage and administration of Tezepelumab and to review its effect on specific populations.
- To review the warnings and precautions associated with the drug
- Enforce effective communication of the adverse drug reactions associated with Tezepelumab therapy amongst interdisciplinary healthcare team members to promote appropriate management, to provide comprehensive patient care, improve patient outcomes, and address complex patient needs.
- To establish a comprehensive monitoring and screening protocol for the safe and effective use of Tezepelumab.

INDICATIONS

FDA-Approved Indications

Tezepelumab is an FDA-approved drug indicated for the management of severe asthma. Tezepelumab is approved as a supplementary long-term therapy for the management of severe asthma. It is the only drug authorized to be used as a biologic for severe asthma, it is a versatile option extensive patient population with severe asthma because its effectiveness is not restricted by specific asthma phenotypes, including eosinophilic or allergic types.[1]

Tezepelumab is a monoclonal antibody that acts on thymic stromal lymphopoietin (TSLP) and does not allow its binding with the TSLP receptor. This action has an influence on both type 2 and non-type 2 inflammatory pathways, which include allergic inflammation, eosinophilic inflammation, and airway hyperresponsiveness.[2]

Tezepelumab is an anti-thymic stromal lymphopoietin (TSLP) monoclonal antibody that helps reduce exacerbations and improve the condition of asthma patients whose condition remains uncontrolled despite treatment with add- on controller drugs and corticosteroids.[3,4,5]

The efficacy of Tezepelumab has been demonstrated through significant reductions in annualized asthma exacerbation rates (AAERs) compared to placebo. It has been reported to enhance lung functions and control asthma symptoms across a broad population, including those with additional challenges such as nasal polyposis and perennial allergies.[6,7] Its broad-spectrum efficacy is evident as it reduces type 2 (T2) inflammatory biomarkers, commonly elevated in asthmatic patients.[8]

Off-Label Indications

Tezepelumab is primarily used as maintenance therapy in asthma; however, it is also being investigated for any other potential therapeutic indications. The use of Tezepelumab in treating conditions such as eosinophilic esophagitis, chronic rhinosinusitis along with nasal polyps, chronic spontaneous urticaria, and chronic obstructive pulmonary disease (COPD) is under evaluation.[1]

Tezepelumab is observed to significantly reduce the nasal polyp's size, nasal congestion, and symptoms associated with sinusitis. It has been observed that in adults suffering from severe chronic rhinosinusitis along with nasal polyps, the need for surgery of nasal-polyp and glucocorticoids is reduced when compared to placebo.[9]

MECHANISM OF ACTION

Asthma is a chronic airway condition characterized by airway narrowing, bronchial hyperresponsiveness, airway inflammation, and recurrent flare-ups. An estimated 300 million people have been diagnosed with this disease the global prevalence of asthma has risen significantly over recent decades.[10]

A lymphocyte-stimulating cytokine called Thymic Stromal Lymphopoietin (TSLP) was identified in mice in 1994. TSLP is primarily produced by epithelial cells that line barrier tissues, including the respiratory tract, skin, and gastrointestinal system. It is also produced by fibroblasts and dendritic cells. The pathophysiology of asthma revolves around an array of functions that TSLP performs.[11] When TSLP binds to its receptor, it forms a heterodimer with IL-7 receptor- α (IL7R α), which stimulates intracellular pro-inflammatory signaling by

activating the Janus kinase (JAK)-signal transducer and activation of transcription protein (STAT). The genes that encode Th2 cytokines, notably Interleukins- 4, 5, 9, and 13, are induced by the intracellular signaling network. In addition, dendritic cells, B and T lymphocytes, innate immune cells, and eosinophils are all impacted by TSLP. It enhances eosinophil survival, inhibits apoptotic processes, and stimulates the release of chemokines, interleukin-6, and eosinophil-derived toxins. Furthermore, through regulating the expression of ICAM1, CD18, and L-selectin on the surface, TSLP contributes to the promotion of eosinophil transmigration and tissue accumulation. Given its upstream position, TSLP plays a key role in controlling both Th1 and Th2 immune responses, which are central to airway inflammation in asthma. Severe asthmatic patients' airways have higher levels of ILC2, which is activated by TSLP, IL-25, and IL-33 produced by airway epithelial cells. This contributes to glucocorticoid resistance and ILC2-mediated immunological responses. Airway Th2 immune responses are stimulated by receptor activation, which additionally results in dendritic cell polarization and the stimulation of multiple immune cell types, among which are mast cells, basophils, eosinophils, and type 2 helper T cells (Th2).[10]

Blocking TSLP activity may interrupt several allergic inflammatory pathways, drawing interest as therapeutic target for asthma management.[11] Tezepelumab is a humanized monoclonal antibody designed to prevent TSLP from attaching to its receptor.

Clinical studies indicate that Tezepelumab acts on a broad range of inflammatory pathways, irrespective of the presence of eosinophilic inflammation, which can reduce exacerbations in asthmatic patients. A reduction in exacerbation rates has been observed across various seasons and baseline disease characteristics because of the use of Tezepelumab.[6] Furthermore, Tezepelumab significantly reduces several T2 inflammatory biomarkers, suggesting reduced airway inflammation and improved asthma control.[8]

In general, Tezepelumab is a potential treatment choice for patients with difficult-to-manage, persistent asthma, particularly those who do not respond to other mAb treatments.[12]

PHARMACOKINETICS

Absorption: Following subcutaneous administration, maximum blood concentrations of Tezepelumab are typically reached between 3 and 10 days after administration. Population pharmacokinetic analysis estimated the absolute bioavailability to be approximately 77%.[13]

Additionally, these pharmacokinetics studies suggest no requirement for weight-based or adolescent dosing adjustment, which is consistent with the phase 3 fixed-dose strategy of Tezepelumab.[3] The pharmacokinetic profile of Tezepelumab was similar across different delivery devices, such as an accessorized pre-filled syringe and an autoinjector, and was not subjected to any clinically relevant variability.[4]

Distribution: According to population pharmacokinetic analysis, on administering Tezepelumab, a 70 kg subject shows a central distribution volume of 3.9 L and a peripheral volume of 2.2 L.

Metabolism: Tezepelumab is metabolized by various proteolytic enzymes present ubiquitously in the body. It is not metabolized hepatically.

Elimination: Tezepelumab is cleared by intracellular degradation. Population Pharmacokinetic analysis suggested the estimated clearance of Tezepelumab in a 70 kg adult is approximately 0.17 liters per day.[27] The half-life following intravenous or subcutaneous injection ranged from approximately 19 to 25 days.[14]

ADMINISTRATION

Available Dosage Forms and Strengths

Tezepelumab is present as a subcutaneous injection in the form of a pre-filled syringe or autoinjector dosage form. Population pharmacokinetic (PK) and pharmacodynamic (PD) modelling has demonstrated that administering 210 mg of Tezepelumab subcutaneously every four weeks produces nearly 90% of the drug's maximal therapeutic response in reducing asthma exacerbation rates and fractional exhaled nitric oxide levels without significant additional benefit from higher doses.[3,4]

In clinical trials, different dosing strategies have been explored, such as 70 mg every four weeks or 280 mg every two weeks, but the 210 mg every four weeks dosage has shown significant efficacy in reducing asthma exacerbations. The long-term safety and efficacy of Tezepelumab are being evaluated in several phase 3 studies, which continue to support its current dosing recommendation.[5,15]

Test for functionality of the delivery devices that include an accessorized pre-filled syringe and an autoinjector is performed in both home and clinical settings; the result indicates reliable information.[4]

Specific Populations

Pregnancy: Clinical study on the effect of Tezepelumab in pregnancy has not been studied yet. Tezepelumab is a Monoclonal antibody; these get transported across the placenta during pregnancy;[30,31] therefore, during the 2nd and 3rd trimesters of pregnancy, potential effects on a foetus can be observed.[28] In a study examining maternal, embryo-foetal, and neonatal toxicity, pregnant cynomolgus monkeys received intravenous doses of Tezepelumab at either 50 or 300 mg/kg/week from the early stages of pregnancy until gestation. The results showed that Tezepelumab did not impact the health of the mothers, the outcomes of the pregnancies, the development of the embryos and foetuses, or the growth of the newborns up to 6.5 months old. However, the clinical studies do not provide enough data on pregnancy exposure to determine the drug-associated risk.[27]

In the confirmatory asthma exacerbation studies, a total of eleven pregnancies were reported-four in the PATHWAY study and seven in the NAVIGATOR study. In PATHWAY, all four pregnancies occurred during the on-treatment period, with two in the Tezepelumab 210 mg Q4W group and two in the 280 mg Q2W group. In NAVIGATOR, three pregnancies occurred in the Tezepelumab 210 mg Q4W group (two during treatment) and four in the placebo group (two during treatment).

The use of Tezepelumab in pregnant women is not advised unless the benefits to the mother are considered greater than the possible harm to the fetus.[28]

Lactation: The excretion of Tezepelumab in human milk is still uncertain. However, after the first few days of birth, human IgGs are excreted in breast milk; therefore, this poses a threat to breastfed child. A decision on the administration of Tezepelumab to breastfeeding women should be made considering the risk-to-benefit ratio.[29]

Paediatric population: 82 adolescent subjects aged 12–17 years were enrolled in the NAVIGATOR trial and randomized to receive either Tezepelumab 210 mg administered subcutaneously every four weeks or placebo. Relative to placebo, Tezepelumab treatment was associated with a reduction in the annualized asthma exacerbation rate and an improvement in lung function. The pharmacodynamic effects and safety outcomes observed in the adolescent subgroup were consistent with those reported in the overall study population. However, clinical data regarding the efficacy and safety of Tezepelumab in patients below 12 years of age are not currently available.[27]

Geriatric Use: Among the 665 patients with asthma who received Tezepelumab 210 mg subcutaneously every four weeks in the PATHWAY and NAVIGATOR studies, 119 participants were aged 65 years or older, including 32 individuals aged 75 years and above. The safety profile observed in these elderly subgroups was comparable to that of the overall study population. Consequently, no age-based dose adjustment of Tezepelumab is considered necessary.[29]

Age, Sex, and Race: Population pharmacokinetic analyses demonstrated that demographic factors including age (12–80 years), sex, and race (White, Black, Asian, and other ethnic groups) did not produce clinically meaningful effects on the pharmacokinetics of Tezepelumab.

Body Weight: Pharmacokinetic modeling suggests that increased body weight may be associated with reduced systemic exposure to Tezepelumab. However, this variation does not result in clinically relevant changes in therapeutic efficacy or safety outcomes. Therefore, dose modification based on body weight is not considered necessary.

Patients with Renal impairment: The population pharmacokinetic analysis examined the effect of Tezepelumab on patients with renal impairment. The clearance of Tezepelumab in patients with mild to moderate renal dysfunction was comparable to that observed in individuals with normal kidney function. The effect of Tezepelumab on patients with life-threatening renal impairment is still under study.

Patients with Hepatic impairment: Tezepelumab is metabolized by proteolytic enzymes and not hepatic-specific enzymes; therefore, hepatic impairment does not influence Tezepelumab clearance.[27]

ADVERSE EFFECTS

Tezepelumab is generally associated with a safe profile; however, certain non-serious adverse drug reactions were observed, such as nasopharyngitis, headache, and bronchitis.[32] Serious adverse reactions such as pneumonia, stroke, and Guillain-Barré syndrome have also occurred in subjects.[16]

Some adverse reactions, such as dyspnoea, body temperature, nocturnal paroxysmal dyspnoea, tongue itching, chest pain, and myalgia, not mentioned in the label, have also been

identified in various studies, this provides valuable evidence for further research and clinical practice of Tezepelumab.[17]

An evaluation of drug administration through autoinjectors reported an occurrence of injection site reaction in a small fraction of patients (5.7%); however, no such reactions were observed when the drug was administered through accessorized pre-filled syringes.[4]

AE associated with Tezepelumab in females was high when compared to men, in accordance with the higher prevalence of female asthma patients.[18]

The NAVIGATOR study shows that between Tezepelumab and placebo, the frequency of tumors remained the same. Reported cancer cases included melanoma in situ, basal cell carcinoma, prostate cancer, squamous cell carcinoma, endometrial cancer, and oral squamous cell carcinoma. No tumor cases were observed among patients treated with Tezepelumab in the CASCADE trial.[19]

The DESTINATION study indicates that over a 2-year observation period, patients receiving Tezepelumab showed a higher incidence of cardiac adverse events compared to those in the placebo group. however, rates of serious cardiac events and cardiovascular-related deaths were similar in both the Tezepelumab and placebo groups.[20]

Long-term safety and tolerability of Tezepelumab are still being evaluated in ongoing studies to ensure a comprehensive understanding and management of any potential adverse effects that may emerge with its extended use.[29]

Reports, however, suggest that adverse effects associated with Tezepelumab are not significantly different from placebo in many cases. This indicates that while patients may experience some side effects, the risk is comparable to other treatments, highlighting Tezepelumab's relative safety as an option for asthma management.[21,22] Besides, Tezepelumab reduces the need for the use of oral corticosteroids, which are associated with serious multiorgan adverse effects; this signifies the safer long-term option of Tezepelumab.[23]

Drug Interactions

Studies related to Tezepelumab's drug interactions have not been performed yet.

According to the population pharmacokinetic analysis, the concomitant use of asthma medications like leukotriene receptor antagonist, theophylline, corticosteroid does not have any clinically significant effect on Tezepelumab clearance.

Population pharmacokinetic analysis shows that treatment with Tezepelumab does not modulate pro-inflammatory cytokines in patients with asthma and therefore, no clinically significant TP-drug interactions are observed to affect the P450 enzymes.

The concurrent administration of live attenuated vaccine with Tezepelumab should be restricted as its safety is still under examination.[27]

CONTRAINDICATIONS

Tezepelumab administration is contraindicated in individuals with known hypersensitivity to the drug or any of its constituents.[24]

Warnings and precautions

Hypersensitivity Reactions: Hypersensitivity Reactions, such as rash and allergic conjunctivitis, can be observed in some people allergic to this drug; this reaction may occur within hours of administration or may occur within days i.e. delayed onset.

Acute Asthma Symptoms: Tezepelumab is not intended for managing sudden asthma symptoms or flare-ups. Tezepelumab should be avoided for immediate relief of bronchospasm or status asthmaticus.

Risk Associated with Abrupt Reduction of Corticosteroid Dosage: Upon administration of Tezepelumab, the systemic or inhaled corticosteroids should not be abruptly terminated.

Parasitic (Helminth) Infection: The immune response to certain helminth infections may involve thymic stromal lymphopoietin (TSLP). Therefore, this drug should be avoided in patients diagnosed with any helminthic infection.

Live Attenuated Vaccines: The use of live attenuated vaccines should be avoided in patients receiving Tezepelumab.[27]

TOXICITY

Signs and Symptoms of Toxicity

Single-dose toxicity: To evaluate the medication's safety, single-dose research was conducted on cynomolgus monkeys. There were no indications of Tezepelumab acute toxicity following a single intravenous dose of 300 mg/kg.

Repeat dosage toxicity: At the 300 mg/kg dose, blood cholesterol was only little to slightly reduced in the repeat-dose trials.[28]

Pregnancy and Fertility: Based on indirect evaluations of possible effects on fertility, Tezepelumab did not significantly affect either the male or female reproductive organs in repeat-dose toxicology experiments conducted in sexually mature cynomolgus monkeys for up to six months.

In several studies involving cynomolgus monkeys administered with Tezepelumab either intravenously or subcutaneously for a duration of up to six months, researchers found no signs of proliferative or preneoplastic lesions. Additionally, there were no adverse reproductive or developmental toxicities observed, nor were there any adverse effects on pregnant monkeys, their foetuses, or their offspring. Moreover, no detrimental effects of Tezepelumab were noted in the offspring over a period of 6.5 months.[25]

Carcinogenesis: Several mouse models of skin carcinogenesis have reported that the deletion of TSLP/TSLPR signalling can result in increased tumour formation. This possesses as a potential risk for Tezepelumab as its action involves binding to TSLP and its binding site for TSLPR and thereby inhibition of the TSLP - TSLPR interaction.[26]

Management of overdose

The recovery phases demonstrated that the effect on serum cholesterol was reversible.[28]
Tezepelumab overdose does not have any explicit treatment. In the event of an overdose, the patient must receive medical care and should be kept under observation.

MONITORING

To guarantee the safe and effective administration of Tezepelumab, it is essential to implement a thorough monitoring and screening protocol for patients receiving Tezepelumab treatment, as outlined below:

- The patient must be monitored for serious adverse drug effects like stroke, pneumonia, and Guillain-Barré syndrome.
- While administering the injection, care should be taken to avoid an injection site reaction.
- Patients receiving Tezepelumab must be tested for any malignancy that develops after administration of the drug.
- Monitoring of cardiac health is essential to evaluate any cardiac adverse effects associated with the long-term use of Tezepelumab.
- Tezepelumab can induce Hypersensitivity reactions in patients allergic to it; patients must be monitored for any signs or symptoms associated with hypersensitivity.
- Patients must be monitored for anaphylaxis.
- Care should be taken to discontinue Tezepelumab if the patient is diagnosed with any helminthic infection.
- Asthma in pregnant women should be consistently supervised and the therapy should be modified to ensure efficient control.
- Patients should be monitored for the development of any infections.

ENHANCING HEALTHCARE TEAM OUTCOMES

The efficacious administration of Tezepelumab, a human monoclonal antibody used as an add- on maintenance therapy for asthma, demands the implication and participation of an inter-related healthcare team. This healthcare team should possess extensive knowledge and practical experience to navigate these drugs and diseases.

The essential contemplations the healthcare team is responsible for are mentioned below:

- The healthcare team is responsible for making sure the medication is given correctly and in a sufficient dosage.
- The healthcare team must emphasize on ruling out any helminthic infections.
- Tezepelumab's impact on asthma flare ups should be evaluated by the medical team.
- The healthcare team should carefully monitor patients throughout their course of treatment to detect any adverse effects.
- It is the duty of the Healthcare team to counsel the patients about the possible adverse effects and drug interactions associated with Tezepelumab.
- The healthcare team must ensure that the drug is not administered under conditions in which it is contraindicated.

- The healthcare team should be on the lookout for the development of malignancy or the diagnosis of any cardiac adverse reaction.
- The Healthcare team should calculate the risk-to-benefit ratio before administering Tezepelumab to Pregnant or lactating women.

CONCLUSION

Tezepelumab represents a significant advancement in the management of severe asthma by inhibiting TSLP and the downstream inflammatory pathways it triggers. Its ability to benefit patients irrespective of eosinophil levels or IgE status distinguishes it from other available biologics. Evidence from clinical studies highlights its effectiveness in reducing exacerbation rates and improving respiratory outcomes, alongside a generally favorable safety profile.

Administered as a subcutaneous injection of 210 mg every four weeks, tezepelumab is convenient for long-term use. Most adverse effects are mild and manageable, and ongoing studies continue to evaluate its long-term safety and tolerability. The drug is contraindicated in patients with known hypersensitivity to its components and should be used cautiously in individuals with helminthic infections.

In summary, Tezepelumab offers a novel, broadly effective treatment option for patients with severe, uncontrolled asthma. Its unique mechanism, demonstrated efficacy, and manageable safety profile support its role as an add-on therapy, while further studies will continue to clarify its long-term benefits, safety, and cost-effectiveness.

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