HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use TEZSPIRE safely and effectively. See full prescribing information for TEZSPIRE.

TEZSPIRE™ (tezepelumab-ekko) injection, for subcutaneous use

Initial U.S. Approval: 2021

-------------------------- DOSAGE FORMS AND STRENGTHS-------------------------

Known hypersensitivity to tezepelumab-ekko or excipients. (1)

Revised: 12/2021

FULL PRESCRIBING INFORMATION: CONTENTS*

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*Sections or subsections omitted from the full prescribing information are not listed.
Administration Instructions for Single-Dose Pre-filled Syringe

Refer to Figure 1 to identify the pre-filled syringe components for use in the administration steps. Do not remove the needle cover until Step 2 of these instructions when you are ready to inject TEZSPIRE. Do not touch the needle guard activation clips to prevent premature activation of the needle safety guard.

Figure 1  TEZSPIRE Pre-filled Syringe Components

1. Grasp the syringe body to remove the pre-filled syringe from its tray. Do not grab the pre-filled syringe by the plunger.
   The pre-filled syringe may contain small air bubbles; this is normal. Do not expel the air bubbles prior to administration.

2. Do not remove the needle cover until ready to inject. Hold the syringe body and remove the needle cover by pulling straight off. Do not hold the plunger or plunger head while removing the needle cover. You may see a drop of liquid at the end of the needle. This is normal.

3. Gently pinch the skin and administer subcutaneously at approximately 45º angle into the recommended injection site (i.e., upper arm, thigh, or abdomen).

4. Inject all of the medication by pushing in the plunger all the way until the plunger head is completely between the needle guard activation clips. This is necessary to activate the needle guard.

5. After injection, maintain pressure on the plunger head and remove the needle from the skin. Release pressure on the plunger head to allow the needle guard to cover the needle. Do not re-cap the pre-filled syringe.

6. Discard the used syringe into a sharps container.

3 DOSAGE FORMS AND STRENGTHS

Injection: a clear to opalescent, colorless to light yellow solution available as:
- 210 mg/1.91 mL (110 mg/mL) solution in a single-dose glass vial.
- 210 mg/1.91 mL (110 mg/mL) solution in a single-dose pre-filled syringe.

4 CONTRAINDICATIONS

TEZSPIRE is contraindicated in patients who have known hypersensitivity to tezepelumab-ekko or any of its excipients [see Warnings and Precautions (5.1)].

5 WARNINGS AND PRECAUTIONS

5.1 Hypersensitivity Reactions

Hypersensitivity reactions (e.g., rash and allergic conjunctivitis) can occur following administration of TEZSPIRE [see Contraindications (4) and Adverse Reactions (6)]. 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.

5.2 Acute Asthma Symptoms or Deteriorating Disease

TEZSPIRE should not be used to treat acute asthma symptoms or acute exacerbations. Do not use TEZSPIRE to treat acute bronchospasm or status asthmaticus. Patients should seek medical advice if their asthma remains uncontrolled or worsens after initiation of treatment with TEZSPIRE.

5.3 Risk Associated with 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.

5.4 Parasitic (Helminth) Infection

Thymic stromal lymphopoietin (TSLP) may be involved in the immunological response to some helminth infections. Patients with known helminth infections were excluded from participation in clinical trials. 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 treatment with TEZSPIRE and do not respond to anti-helminth treatment, discontinue treatment with TEZSPIRE until infection resolves.

5.5 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.

6 ADVERSE REACTIONS

The following clinically significant adverse reactions are described elsewhere in the labeling:
- Hypersensitivity [see Warnings and Precautions (5.1)]

6.1 Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice.

The safety of TEZSPIRE was based on the pooled safety population from PATHWAY and NAVIGATOR, which consists of 665 adult and pediatric patients 12 years of age and older with severe asthma who received at least one dose of TEZSPIRE 210 mg subcutaneously once every 4 weeks. The two placebo-controlled clinical trials were of 52 weeks duration. In addition, a similar safety profile was seen in a trial that enrolled 150 adult patients with severe asthma who required treatment with daily oral corticosteroids [see Clinical Studies (14)].

Adverse reactions that occurred at an incidence greater than or equal to 3% and more common than in the placebo group from the pooled safety population (PATHWAY and NAVIGATOR) are shown in Table 1.

Table 1  Adverse Reactions with TEZSPIRE with Incidence Greater than or Equal to 3% and More Common than Placebo in Patients with Severe Asthma in the Pooled Safety Population (PATHWAY and NAVIGATOR)

<table>
<thead>
<tr>
<th>Adverse Reaction</th>
<th>TEZSPIRE N=665</th>
<th>Placebo N=669</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pharyngitis*</td>
<td>4</td>
<td>3</td>
</tr>
<tr>
<td>Arthralgia</td>
<td>4</td>
<td>3</td>
</tr>
<tr>
<td>Back pain</td>
<td>4</td>
<td>3</td>
</tr>
</tbody>
</table>

* Pharyngitis (including Pharyngitis, Pharyngitis bacterial, Pharyngitis streptococcal and Viral pharyngitis)
 Specifically, the estimated background risk of major birth defects and miscarriages for the indicated population is unknown. All pregnancies have a background risk of birth defect, loss, or other adverse outcomes. In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2% to 4% and 15% to 20%, respectively.

Clinical Considerations

Disease-associated maternal and/or embryo/fetal risk:

In women with poorly or moderately controlled asthma, evidence demonstrates that there is an increased risk of preclampsia in the mother and premature, low birth weight, and small for gestational age in the neonate. The level of asthma control should be closely monitored in pregnant women and treatment adjusted as necessary to maintain optimal control.

Data

Animal Data

In the ePPND study, pregnant cynomolgus monkeys received tezepelumab-ekko from GD20 to GD42 (depending on pregnancy determination), at the beginning of organogenesis, and once every 7 days until the end of gestation at doses that produced exposures up to 168 times that achieved with the MRHD (on an AUC basis with maternal intravenous doses up to 300 mg/kg/week). There were no tezepelumab-ekko related adverse effects on maternal health, pregnancy outcome, embryo-fetal development, or neonatal growth and development up to 6.5 months of age. Tezepelumab-ekko crossed the placenta in cynomolgus monkeys and tezepelumab-ekko serum concentrations were 0.5- to 6.7-fold higher in infants relative to maternal animals.

8.2 Lactation

Risk Summary

There is no information regarding the presence of tezepelumab-ekko in human milk, its effects on the breastfed infant, or its effects on milk production. However, tezepelumab-ekko is a human monoclonal antibody immunoglobulin G2a (IgG2a), and immunoglobulin G (IgG) is present in human milk in small amounts. Tezepelumab-ekko was present in the milk of cynomolgus monkeys postpartum following dosing during pregnancy [see Data]. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for TEZSPIRE and any potential adverse effects on the breastfed infant from TEZSPIRE or from the underlying maternal condition.

8.3 Pediatric Use

8.4 Pharmacokinetics

In a prenatal and postnatal development study in cynomolgus monkeys, tezepelumab-ekko concentrations in milk were up to 0.5% of the maternal serum concentrations after intravenous administration of tezepelumab-ekko up to 300 mg/kg/week (168 times the exposures based on AUC achieved at MRHD). The concentration of tezepelumab-ekko in animal milk does not necessarily predict the concentration of drug in human milk.

11 DESCRIPTION

Tezepelumab-ekko, a thymic stromal lymphopoietin (TSLP) blocker, is a human monoclonal antibody immunoglobulin G2a (IgG2a) produced in Chinese hamster ovary (CHO) cells by recombinant DNA technology. Tezepelumab-ekko has a molecular weight of approximately 147 kDa. TEZSPIRE (tezepelumab-ekko) injection is a sterile, preservative-free, clear to opalescent, colorless to light yellow solution for subcutaneous injection supplied in a single-dose vial or single-dose pre-filled syringe.

Each single-dose vial or pre-filled syringe delivers 1.91 mL containing 210 mg tezepelumab-ekko, glacial acetic acid (2.8 mg), L-proline (48 mg), polysorbate 80 (0.19 mg), sodium hydroxide, and water for injection. The pH is 5.2.

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

Tezepelumab-ekko is a thymic stromal lymphopoietin (TSLP) blocker, human monoclonal antibody IgG2a, that binds to human TSLP with a dissociation constant of 15.8 pM and blocks its interaction with the heterodimeric TSLP receptor. TSLP is a cytokine mainly derived from epithelial cells and occupies an upstream position in the asthma inflammatory cascade.

Airway inflammation is an important component in the pathogenesis of asthma. Multiple cell types (e.g., mast cells, eosinophils, neutrophils, macrophages, lymphocytes, ILC2 cells) and cytokines (e.g., histamine, eicosanoids, leukotrienes, cytokines) are involved in airway inflammation. Blocking TSLP with tezepelumab-ekko reduces biomarkers and cytokines associated with inflammation including blood eosinophils, airway submucosal eosinophils, IgE, FeNO, IL-5, and IL-13; however, the mechanism of tezepelumab-ekko action in asthma has not been definitively established.

12.2 Pharmacodynamics

In NAVIGATOR, administration of TEZSPIRE 210 mg subcutaneously every 4 weeks (n=528) reduced blood eosinophils counts, FeNO, IL-5 concentration and IL-13 concentration from baseline compared with placebo (n=531) with an onset of effect 2 weeks after initiation of treatment and sustained reduction on treatment to 52 weeks. TEZSPIRE caused a slow but progressive reduction in serum total IgE concentration throughout 52 weeks of treatment. Similar effects were seen in PATHWAY.

12.3 Pharmacokinetics

The pharmacokinetics of tezepelumab-ekko were dose-proportional following administration of a single subcutaneous dose over a dose range from 2.1 mg to 420 mg (0.01 to 2 times the recommended dose). With an every 4 weeks dosing regimen, tezepelumab-ekko achieves steady-state after 12 weeks and the accumulation ratio for Cmax is 1.86-fold.

Absorption

Following subcutaneous administration, the maximum serum concentration was reached in approximately 3 to 10 days. Based on population pharmacokinetic analysis, oral exposure and absolute bioavailability was approximately 77%. There was no clinically relevant difference in bioavailability when administered to different injection sites (abdomen, thigh, or upper arm).
**Distribution**
Based on population pharmacokinetic analysis, central and peripheral volume of distribution of tezepelumab-ekko were 3.9 L and 2.2 L, respectively, for a 70 kg individual.

**Elimination**
As a human monoclonal antibody, tezepelumab-ekko is eliminated by intracellular catabolism and there is no evidence of target-mediated clearance within the studied dose range. Based on population pharmacokinetic analysis, the estimated clearance for tezepelumab-ekko was 0.17 L/day for a 70 kg individual. The elimination half-life was approximately 26 days.

**Metabolism**
Tezepelumab-ekko is a human monoclonal antibody (IgG2κ) that is degraded by proteolytic enzymes widely distributed in the body and not metabolized by hepatic enzymes.

**Specific Populations**
**Age, Sex, Race**
Based on population pharmacokinetic analysis, age (12 to 80 years), sex and race (White, Black, Asian, Other) had no clinically meaningful effects on the pharmacokinetics of tezepelumab-ekko.

**Body Weight**
Based on population pharmacokinetic analysis, higher body weight was associated with lower exposure. However, the effect of body weight on exposure had no meaningful impact on efficacy or safety and does not require dose adjustment.

**Patients with Renal Impairment**
No formal clinical studies have been conducted to investigate the effect of renal impairment on tezepelumab-ekko. The population pharmacokinetic analysis included 320 (23%) subjects with mild renal impairment and 38 (3%) subjects with moderate renal impairment. Tezepelumab-ekko clearance was similar in patients with mild renal impairment (estimated creatinine clearance 60 to 89 mL/min), moderate renal impairment (estimated creatinine clearance 30 to 59 mL/min) and those with normal renal function (estimated creatinine clearance ≥ 90 mL/min). Tezepelumab-ekko has not been studied in patients with severe renal impairment (estimated creatinine clearance < 30 mL/min).

**Patients with Hepatic Impairment**
No formal clinical studies have been conducted to investigate the effect of hepatic impairment on tezepelumab-ekko. Since tezepelumab-ekko is degraded by proteolytic enzymes widely distributed in the body and not metabolized by hepatic-specific enzymes, change in hepatic function is not expected to influence tezepelumab-ekko clearance.

**Drug Interactions**
No formal drug interaction studies have been conducted with tezepelumab-ekko. Based on the population pharmacokinetic analysis, commonly co-administered asthma medications (leukotriene receptor antagonist, theophylline/aminophylline, oral and inhaled corticosteroid) had no clinically meaningful effect on tezepelumab-ekko clearance.

**13 Nonclinical Toxicology**

**13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility**
Animal studies have not been conducted to evaluate the carcinogenic potential of tezepelumab-ekko. The malignancy risk in humans from an antibody that blocks TSLP is currently unknown.

Male and female fertility was unaffected based upon no observed adverse histopathological findings in the reproductive organs and no changes in menstrual cycle or semen analysis in sexually mature cynomolgus monkeys that received tezepelumab-ekko for 26 weeks at subcutaneous doses up to 300 mg/kg/week (approximately 134 times the MRHD on an AUC basis).

**14 Clinical Studies**
The efficacy of TEZSPIRE was evaluated in two randomized, double-blind, parallel group, placebo-controlled clinical trials (PATHWAY NCT02054130) and NAVIGATOR (NCT03347279) of 52 weeks duration. The two trials enrolled a total of 1609 patients 12 years of age and older with severe asthma.

PATHWAY was a 52-week dose-ranging exacerbation trial that enrolled 550 adult patients with severe asthma who received treatment with tezepelumab-ekko 70 mg subcutaneously every 4 weeks, TEZSPIRE 210 mg subcutaneously every 4 weeks, tezepelumab-ekko 280 mg subcutaneously every 2 weeks, or placebo subcutaneously. Patients were required to have a history of 2 or more asthma exacerbations requiring oral or injectable corticosteroid treatment or 1 asthma exacerbation resulting in hospitalization in the past 12 months.

NAVIGATOR was a 52-week exacerbation trial that enrolled 1061 patients (adult and pediatric patients 12 years of age and older) with severe asthma who received treatment with TEZSPIRE 210 mg subcutaneously every 4 weeks or placebo subcutaneously every 4 weeks. Patients were required to have a history of 2 or more asthma exacerbations requiring oral or injectable corticosteroid treatment or resulting in hospitalization in the past 12 months.

In both PATHWAY and NAVIGATOR, patients were required to have an Asthma Control Questionnaire 6 (ACQ-6) score of 1.5 or more at screening and reduced lung function at baseline [pre-bronchodilator forced expiratory volume in 1 second (FEV1) below 80% predicted in adults, and below 90% predicted in adolescents]. Patients were required to have been on regular treatment with medium or high-dose inhaled corticosteroids (ICS) and at least one additional asthma controller, with or without oral corticosteroids (OCS). Patients continued background asthma therapy throughout the duration of the trials. In both trials, patients were enrolled without requiring a minimum baseline level of blood eosinophils or FeNO.

The demographics and baseline characteristics of PATHWAY and NAVIGATOR are provided in Table 2 below.

| Table 2 Demographics and Baseline Characteristics of Patients in PATHWAY and NAVIGATOR |
|-----------------------------------------------|-----------------------------------------------|
| PATHWAY N=550                                | NAVIGATOR N=1059                              |
| Mean age (year) (SD)                         | Mean age (year) (SD)                          |
| 52 (12)                                      | 50 (16)                                      |
| Female (%)                                   | Female (%)                                    |
| 66                                           | 64                                           |
| White (%)                                    | White (%)                                     |
| 92                                           | 62                                           |
| Black or African American (%)                | Black or African American (%)                 |
| 3                                            | 6                                            |
| Asian (%)                                    | Asian (%)                                     |
| 3                                            | 28                                           |
| Hispanic or Latino (%)                       | Hispanic or Latino (%)                        |
| 1                                            | 15                                           |
| Never smoked (%)                             | Never smoked (%)                              |
| 81                                           | 80                                           |
| High-dose ICS use (%)                        | High-dose ICS use (%)                         |
| 49                                           | 75                                           |
| OCS use (%)                                  | OCS use (%)                                   |
| 9                                            | 9                                            |
| Mean number of exacerbations in previous year (SD) | Mean number of exacerbations in previous year (SD) |
| 2.4 (1.2)                                    | 2.8 (1.4)                                    |
| Mean duration of asthma (years) (SD)         | Mean duration of asthma (years) (SD)          |
| 17 (12)                                      | 22 (16)                                      |
| Mean baseline % predicted FEV1 (SD)          | Mean baseline % predicted FEV1 (SD)          |
| 60 (13)                                      | 63 (18)                                      |
| Mean post-bronchodilator FEV1 reversibility (%) (SD) | Mean post-bronchodilator FEV1 reversibility (%) (SD) |
| 23 (20)                                      | 15 (15)                                      |
| Mean baseline blood EOS count (cells/µL) (SD) | Mean baseline blood EOS count (cells/µL) (SD) |
| 371 (353)                                    | 340 (403)                                    |
| Positive serum specific IgE to any perennial allergen (%) | Positive serum specific IgE to any perennial allergen (%) |
| 46                                           | 64                                           |
| Mean FeNO (ppb) (SD)                         | Mean FeNO (ppb) (SD)                         |
| 35 (39)                                      | 44 (41)                                      |

* In the FEIA panel

EOS, Eosinophils; FEIA, Fluorescent enzyme immunoassay; FeNO, Fractional exhaled nitric oxide; FEV1, Forced expiratory volume in one second; ICS, Inhaled corticosteroid; IgE, Immunoglobulin E; OCS, Oral corticosteroid; ppb, Parts per billion; SD, Standard deviation.

The results summarized below are for the recommended TEZSPIRE 210 mg subcutaneously every 4 weeks dosing regimen.

**Exacerbations**
The primary endpoint for PATHWAY and NAVIGATOR was the rate of clinically significant asthma exacerbations measured over 52 weeks. Clinically significant asthma exacerbations were defined as worsening of asthma requiring the use of or increase in oral or injectable corticosteroids for at least 3 days, or a single depo-injection of corticosteroids, and/or emergency department visits requiring use of oral or injectable corticosteroids and/or hospitalization.

In both PATHWAY and NAVIGATOR, patients receiving TEZSPIRE had significant reductions in the annualized rate of asthma exacerbations compared to placebo. There were also fewer exacerbations requiring emergency room visits and/or hospitalization in patients treated with TEZSPIRE compared with placebo (Table 3).
Table 3  Rate of Clinically Significant Exacerbations Over 52 Weeks in PATHWAY and NAVIGATOR

<table>
<thead>
<tr>
<th>Trial</th>
<th>Treatment</th>
<th>Exacerbations per year</th>
<th>Rate</th>
<th>Rate Ratio (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Annualized Asthma Exacerbation Rate</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PATHWAY</td>
<td>TEZSPIRE (N=137)</td>
<td>0.20</td>
<td>0.29</td>
<td>(0.16, 0.51)</td>
</tr>
<tr>
<td></td>
<td>Placebo (N=138)</td>
<td>0.72</td>
<td></td>
<td></td>
</tr>
<tr>
<td>NAVIGATOR</td>
<td>TEZSPIRE (N=528)</td>
<td>0.93</td>
<td>0.44</td>
<td>(0.37, 0.53)</td>
</tr>
<tr>
<td></td>
<td>Placebo (N=531)</td>
<td>2.10</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Exacerbations requiring emergency room visit/hospitalization</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PATHWAY</td>
<td>TEZSPIRE (N=137)</td>
<td>0.03</td>
<td>0.15</td>
<td>(0.04, 0.58)</td>
</tr>
<tr>
<td></td>
<td>Placebo (N=138)</td>
<td>0.18</td>
<td></td>
<td></td>
</tr>
<tr>
<td>NAVIGATOR</td>
<td>TEZSPIRE (N=528)</td>
<td>0.06</td>
<td>0.21</td>
<td>(0.12, 0.37)</td>
</tr>
<tr>
<td></td>
<td>Placebo (N=531)</td>
<td>0.28</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Exacerbations requiring hospitalization</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PATHWAY</td>
<td>TEZSPIRE (N=137)</td>
<td>0.02</td>
<td>0.14</td>
<td>(0.03, 0.71)</td>
</tr>
<tr>
<td></td>
<td>Placebo (N=138)</td>
<td>0.14</td>
<td></td>
<td></td>
</tr>
<tr>
<td>NAVIGATOR</td>
<td>TEZSPIRE (N=528)</td>
<td>0.03</td>
<td>0.15</td>
<td>(0.07, 0.22)</td>
</tr>
<tr>
<td></td>
<td>Placebo (N=531)</td>
<td>0.19</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Figure 3**  Kaplan-Meier Cumulative Incidence Curves for Time to First Exacerbation in NAVIGATOR

**Lung Function**

Change from baseline in FEV₁ was assessed as a secondary endpoint in PATHWAY and NAVIGATOR. Compared with placebo, TEZSPIRE provided clinically meaningful improvements in the mean change from baseline in FEV₁ in both trials (Table 4).

**Table 4**  Mean Change from Baseline in Pre-Bronchodilator FEV₁ at End of Trial in PATHWAY and NAVIGATOR*

<table>
<thead>
<tr>
<th>Trial</th>
<th>Treatment</th>
<th>LS Mean Change from Baseline (L)</th>
<th>Difference from Placebo (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>PATHWAY</td>
<td>TEZSPIRE (N=133)</td>
<td>0.08</td>
<td>0.13 (0.03, 0.23)</td>
</tr>
<tr>
<td></td>
<td>Placebo (N=138)</td>
<td>-0.06</td>
<td></td>
</tr>
<tr>
<td>NAVIGATOR</td>
<td>TEZSPIRE (N=527)</td>
<td>0.23</td>
<td>0.13 (0.08, 0.18)</td>
</tr>
<tr>
<td></td>
<td>Placebo (N=531)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* Week 52 in PATHWAY, Week 52 in NAVIGATOR

**Figure 4**  Mean Change (95% CI) from Baseline in Pre-Bronchodilator FEV₁ (L) in NAVIGATOR

In NAVIGATOR, patients receiving TEZSPIRE experienced fewer exacerbations than those receiving placebo regardless of baseline levels of blood eosinophils or FeNO (Figure 2). Similar results were seen in PATHWAY.

In NAVIGATOR, improvement in FEV₁ was seen as early as 2 weeks after initiation of treatment and was sustained through week 52 (Figure 4).

The time to first exacerbation was longer for the patients receiving TEZSPIRE compared with placebo in NAVIGATOR (Figure 3). Similar findings were seen in PATHWAY.
**17 PATIENT COUNSELING INFORMATION**

Advise the patient to read the FDA-approved patient labeling (Patient Information).

**Hypermnsensitivity Reactions**

Inform patients that hypersensitivity reactions (e.g., rash and allergic conjunctivitis) can occur following administration of TEZSPIRE [see Contraindications (4) and Adverse Reactions (6)]. These reactions can occur within hours of administration, but in some instances have a delayed onset (i.e., days). Instruct patients to contact their healthcare provider if they experience symptoms of an allergic reaction [see Warnings and Precautions (5.1)].

**Not for Acute Symptoms or Deteriorating Disease**

Inform patients that TEZSPIRE does not treat acute asthma symptoms or acute exacerbations. Inform patients to seek medical advice if their asthma remains uncontrolled or worsens after initiation of treatment with TEZSPIRE [see Warnings and Precautions (5.2)].

**Risk Associated with Abrupt Reduction of Corticosteroid Dosage**

Inform patients to not discontinue systemic or inhaled corticosteroids except under the direct supervision of a healthcare provider. Inform patients that reduction in corticosteroid dose may be associated with systemic withdrawal symptoms and/or unmask conditions previously suppressed by systemic corticosteroid therapy [see Warnings and Precautions (5.3)].

**Administration of Vaccines**

Instruct patients to inform the healthcare provider that they are taking TEZSPIRE prior to a potential vaccination [see Warnings and Precautions (5.5)].

Manufactured by: AstraZeneca AB, Sodertalje, Sweden SE-15185

US License No. 2059

At: Amgen Inc., One Amgen Center Drive, Thousand Oaks, CA 91320-1799

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12/2021 US-54600 12/21
PATIENT INFORMATION
TEZSPIRE™ (TEZ-SPY-ER)
tezepelumab-ekko
injection, for subcutaneous use

What is TEZSPIRE?
TEZSPIRE is a prescription medicine used with other asthma medicines for the maintenance treatment of severe asthma in people 12 years of age and older whose asthma is not controlled with their current asthma medicine. TEZSPIRE helps prevent severe asthma attacks (exacerbations) and can improve your breathing. TEZSPIRE is not used to treat sudden breathing problems. Tell your healthcare provider if your asthma does not get better or if it gets worse after you start treatment with TEZSPIRE. It is not known if TEZSPIRE is safe and effective in children under 12 years of age.

Do not receive TEZSPIRE if you:
• are allergic to tezepelumab or any of the ingredients in TEZSPIRE. See the end of this Patient Information leaflet for a complete list of ingredients in TEZSPIRE.

Before you receive TEZSPIRE, tell your healthcare provider about all of your medical conditions, including if you:
• have ever had a severe allergic reaction (hypersensitivity).
• have a parasitic (helminth) infection.
• have recently received or are scheduled to receive any live attenuated vaccinations. People who receive TEZSPIRE should not receive live attenuated vaccines.
• are pregnant, think you may be pregnant, or plan to become pregnant. It is not known if TEZSPIRE may harm your unborn baby.
• are breastfeeding or plan to breastfeed. It is not known if TEZSPIRE passes into your breast milk. Talk to your healthcare provider about the best way to feed your baby if you receive TEZSPIRE.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.
Do not change or stop your corticosteroid medicines or other asthma medicines unless your healthcare provider tells you to.

How will I receive TEZSPIRE?
• Your healthcare provider will give you TEZSPIRE in a healthcare setting.
• TEZSPIRE is injected under your skin (subcutaneously) 1 time every 4 weeks.
• If you miss an appointment, ask your healthcare provider when to schedule your next treatment.

What are the possible side effects of TEZSPIRE?
TEZSPIRE may cause serious side effects, including:
• severe allergic reactions. Call your healthcare provider or get emergency medical care if you get any of the following symptoms of allergic reaction:
  ○ rash
  ○ hives
  ○ breathing problems
  ○ red, itchy, swollen, or inflamed eyes

The most common side effects of TEZSPIRE include:
• sore throat (pharyngitis)
• joint pain (arthritis)
• back pain

These are not all of the possible side effects of TEZSPIRE.
Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.
General information about the safe and effective use of TEZSPIRE

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. You can ask your pharmacist or healthcare provider for information about TEZSPIRE that is written for health professionals.

What are the ingredients in TEZSPIRE?

**Active ingredient:** tezepelumab-ekko

**Inactive ingredients:** glacial acetic acid, L-proline, polysorbate 80, sodium hydroxide, and water for injection

Manufactured by:
AstraZeneca AB, Sodertalje, Sweden SE-15185
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