TEZSPIRE™ (tezepelumab-ekko) Subcutaneous Injection 210 mg

TSLP in Severe Asthma

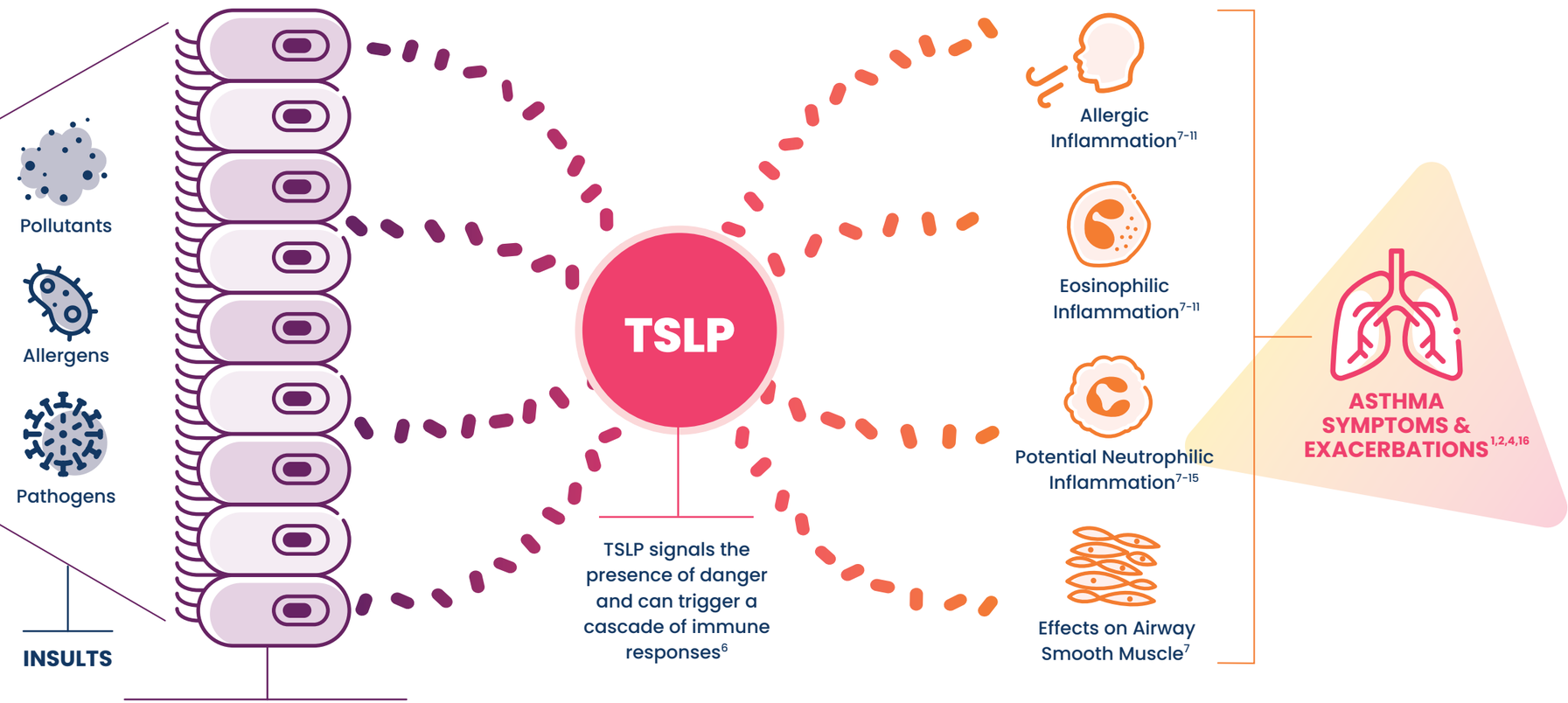
Severe asthma can be uncontrolled despite treatment because **not all severe asthma is the same.**[1,2] Various insults or triggers can activate a range of inflammatory pathways, which can differ between patients.[3] Recent research in asthma pathophysiology has implicated a cytokine called **thymic stromal lymphopoietin (TSLP)** as a key instigator of asthma inflammation.[4,5]

INDICATION

TEZSPIRE is indicated for the add-on maintenance treatment of patients with severe asthma aged 12 years and older. TEZSPIRE is not indicated for the relief of acute bronchospasm or status asthmaticus.

CONTRAINDICATION

Known hypersensitivity to Tezepelumab or excipients.



In asthma, an epithelial cytokine called TSLP contributes to an overreactive immune response that may lead to different types of airway inflammation and structural changes.[2,7,13,16,19] Airway inflammation can drive increased asthma symptoms and exacerbations.[1,2,4,16]

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TSLP in Severe Asthma

Important Safety Information

CONTRAINDICATIONS
Known hypersensitivity to Tezepelumab or excipients.

WARNINGS AND PRECAUTIONS
Hypersensitivity Reactions
Hypersensitivity reactions (eg, rash) can occur after 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.

Acute Asthma Symptoms or Deteriorating Disease
TEZSPIRE should not be used to treat acute asthma symptoms, acute exacerbations, or acute bronchospasm.

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.

ADVERSE REACTIONS
The most common adverse reactions (incidence ≥ 3%) include Pharyngitis, Arthralgia, Bacterial bronchitis bacterial, Back pain, Viral upper respiratory tract Infection.

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 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

INDICATION
TEZPIRE is indicated for the add-on maintenance treatment of patients with severe asthma aged 12 years and older.
TEZPIRE is not indicated for the relief of acute bronchospasm or status asthmaticus.

Please see here for Full Prescribing Information including Patient Information.

You may report side effects to TEZSPIRE by clicking here [or calling 800-236-9933]

REFERENCES

1. Corren J. *J Allergy Clin Immunol Pract*. 2019;7(5):1394-1403.
2. Lambrecht BN, et al. *Nat Immunol*. 2015;16(1):45-56.
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TEZSPIRE™ (tezepelumab-ekko) Subcutaneous Injection 210 mg

PATHFINDER

Comprehensive Clinical Development Program for TEZSPIRE™ (tezepelumab-ekko) in Severe Asthma

The PATHFINDER Clinical Trial Program represents a growing body of research in a broad population of severe asthma patients across ages, asthma phenotypes, and geographies, and includes mechanistic and long-term safety trials.[1-3]

TEZSPIRE™ is a first-in-class human monoclonal antibody designed to target and block thymic stromal lymphopoietin (TSLP).[2,4]
TEZSPIRE™ is an FDA-approved product.[4]

4 key studies[3]

1300+ patients[3]

21 countries[5-8]

INDICATION

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CONTRAINDICATION

Known hypersensitivity to Tezepelumab or excipients.

KEY PATHFINDER STUDIES*

Study	NAVIGATOR[3,5]	SOURCE[3,6,9]	CASCADE[3,7,10]	DESTINATION[3,8,11]
Phase	3	3	2	3
Completion	Nov. 2020	Sept. 2020	Nov. 2020	May 2022
Study objectives	Exacerbations, lung function, asthma control	Oral corticosteroid reduction	Airway inflammation and remodeling	Long-term extension
Patients	N=1061	N=150	N=116	N=951
Duration	52 weeks	48 weeks	28 weeks	Variable
Design	Multicenter, randomized, double-blind, placebo-controlled, parallel group TEZSPIRE™ vs placebo + SoC	Multicenter, randomized, double-blind, placebo-controlled TEZSPIRE™ vs placebo + SoC	Multicenter, randomized, double-blind, placebo-controlled, parallel group TEZSPIRE™ vs placebo + SoC	Multicenter, randomized, double-blind, placebo-controlled, parallel group TEZSPIRE™ vs placebo + SoC

*The PATHFINDER clinical development program for TEZSPIRE™ includes a total of 10 Phase 1-3 trials (PATH-BRIDGE, DIRECTION, PATHWAY, CASCADE, PATH-HOME, SOURCE, NAVIGATOR, DESTINATION, DIRECTION, and NOZOMI).

AMGEN AstraZeneca

Updated 11/21

TEZSPIRE™ (tezepelumab-ekko) Subcutaneous Injection 210 mg

PATHFINDER

Comprehensive Clinical Development Program for TEZSPIRE™ (tezepelumab-ekko) in Severe Asthma

Important Safety Information

CONTRAINDICATIONS
Known hypersensitivity to Tezepelumab or excipients.

WARNINGS AND PRECAUTIONS
Hypersensitivity Reactions
Hypersensitivity reactions (eg, rash) can occur after 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.

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Abrupt Reduction of Corticosteroid Dosage
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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.

ADVERSE REACTIONS
The most common adverse reactions (incidence ≥ 3%) include Pharyngitis, Arthralgia, Bacterial bronchitis bacterial, Back pain, Viral upper respiratory tract Infection.

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 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

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Please see here for Full Prescribing Information including Patient Information.

You may report side effects to TEZSPIRE by clicking here [or calling 800-236-9933]

ABBREVIATIONS

SoC standard of care

REFERENCES

1. AstraZeneca Press Release. December 22, 2020. https://bit.ly/36b7pp2. Accessed November 10, 2021.
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3. Menzies-Gow A, et al. *Respir Res.* 2020;21(1):266.
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NAVIGATOR Study

Studying a Spectrum of Severe Uncontrolled Asthma Patients

TEZSPIRE™ (tezepelumab-ekko), an anti-TSLP antibody, was studied in NAVIGATOR, a Phase 3, multicenter, randomized, double-blind, placebo-controlled study that builds on the results seen in the Phase 2b PATHWAY trial.[1,2] NAVIGATOR data show TEZSPIRE™ has potential in a broad population of severe uncontrolled asthma patients.[1]

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18 COUNTRIES[1]

1061 PATIENTS RANDOMIZED[1]

52 WEEKS[1]

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CONTRAINDICATION

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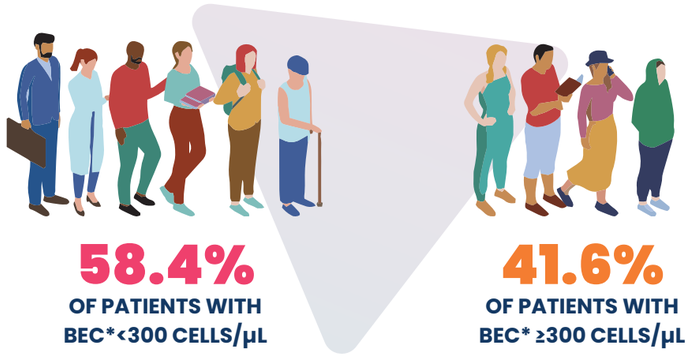
STUDY POPULATION [1]

- 12–80 years
- Severe, uncontrolled asthma
- Medium- or high-dose ICS + ≥1 additional asthma controller medication with or without OCS
- ≥2 exacerbations in last 12 months

*Blood Eosinophil Count



58.4%
OF PATIENTS WITH BEC*<300 CELLS/µL

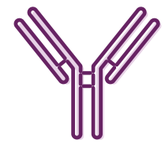
41.6%
OF PATIENTS WITH BEC* ≥300 CELLS/µL

TREATMENT ARMS [1]

TEZSPIRE™
210 mg + SoC
(n=528)

PLACEBO + SoC
(n=531)

Administered subcutaneously every 4 weeks for 52 weeks



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CLINICAL TRIAL RESULTS

- Statistically significant reductions in annualized asthma exacerbation rate[1,4]
- Increased proportion of exacerbation-free patients regardless of exacerbation history[5a]

OVERALL POPULATION
56% [b]
REDUCTION IN EXACERBATIONS

PATIENTS WITH BEC <300 CELLS/µL
41% [b]
REDUCTION IN EXACERBATIONS

PATIENTS WITH NASAL POLYPS
86% [c]
REDUCTIONS IN EXACERBATIONS

a Exploratory analysis: overall: OR: 1.93 (95% CI: 1.51, 2.47), 2 prior exacerbations OR: 1.61 (95% CI: 1.17, 2.21), ≥3 prior exacerbations OR: 2.58 (95% CI: 1.72, 3.86), vs placebo
b Primary outcome: $p<0.001$ vs placebo
c Exploratory analysis: 95% CI: 70, 93, vs placebo

SIGNIFICANT IMPROVEMENTS IN: [1]

Lung function [d] • Asthma control [d] • Quality of life [d]

MOST COMMON ADVERSE EVENTS	TEZSPIRE™ (n=528)	PLACEBO (n=531)
Nasopharyngitis	21.4%	21.5%
Upper respiratory tract infection	11.2%	16.4%
Headache	8.1%	8.5%
Asthma	5.1%	11.1%

d Secondary outcome: $p<0.001$ vs placebo

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NAVIGATOR Study

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ABBREVIATIONS

ICS inhaled corticosteroid

OCS oral corticosteroid

SoC standard of care (medium- or high-dose inhaled corticosteroids + ≥1 additional asthma controller medication with or without oral corticosteroids)

REFERENCES

1. Menzies-Gow A, et al. *N Engl J Med*. 2021;384(19):1800-1809.
2. Corren J, et al. *N Engl J Med*. 2017;377(10):936-946.
3. TEZSPIRE™ [package insert]. (full citation TK)
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