ADVOCATE HEALTH

Overview of Biologics in the Treatment of Asthma and COPD

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Disclosures

The planners and speaker have indicated that there are no relevant financial relationships with any ineligible companies to disclose.

Abbreviation Key

- **AD**: Atopic dermatitis
- **BP**: Bullous pemphigoid
- **CAT**: COPD assessment test
- **COPD**: Chronic obstructive pulmonary disease
- **CRSwNP**: Chronic rhinosinusitis with nasal polyps
- **CSU**: Chronic spontaneous urticaria
- **EGPA**: Eosinophilic granulomatosis with polyangiitis
- **EoE**: Eosinophilic esophagitis
- **FeNO**: Fractional exhaled nitric oxide
- **FEV**: Forced expiratory volume
- **FVC**: Forced vital capacity
- **GINA**: Global Initiative for Asthma
- **GOLD**: Global Initiative for Chronic Obstructive Lung Disease
- **HES**: Hypereosinophilic syndrome
- **ICS**: Inhaled corticosteroid
- **IgE**: Immunoglobulin E
- **IL**: Interleukin
- **IV**: Intravenous
- **LABA**: Long-acting beta agonist
- **LAMA**: Long-acting muscarinic antagonist
- **mMRC**: Modified Medical Research Council dyspnea score
- **OCS**: Oral corticosteroid
- **PN**: Prurigo nodularis
- **QOL**: Quality of life
- **SABA**: Short-acting beta agonist
- **SQ**: Subcutaneous
- **TSLP**: Thymic stromal lymphopoietin
- **UTI**: Urinary tract infection

Learning Objectives

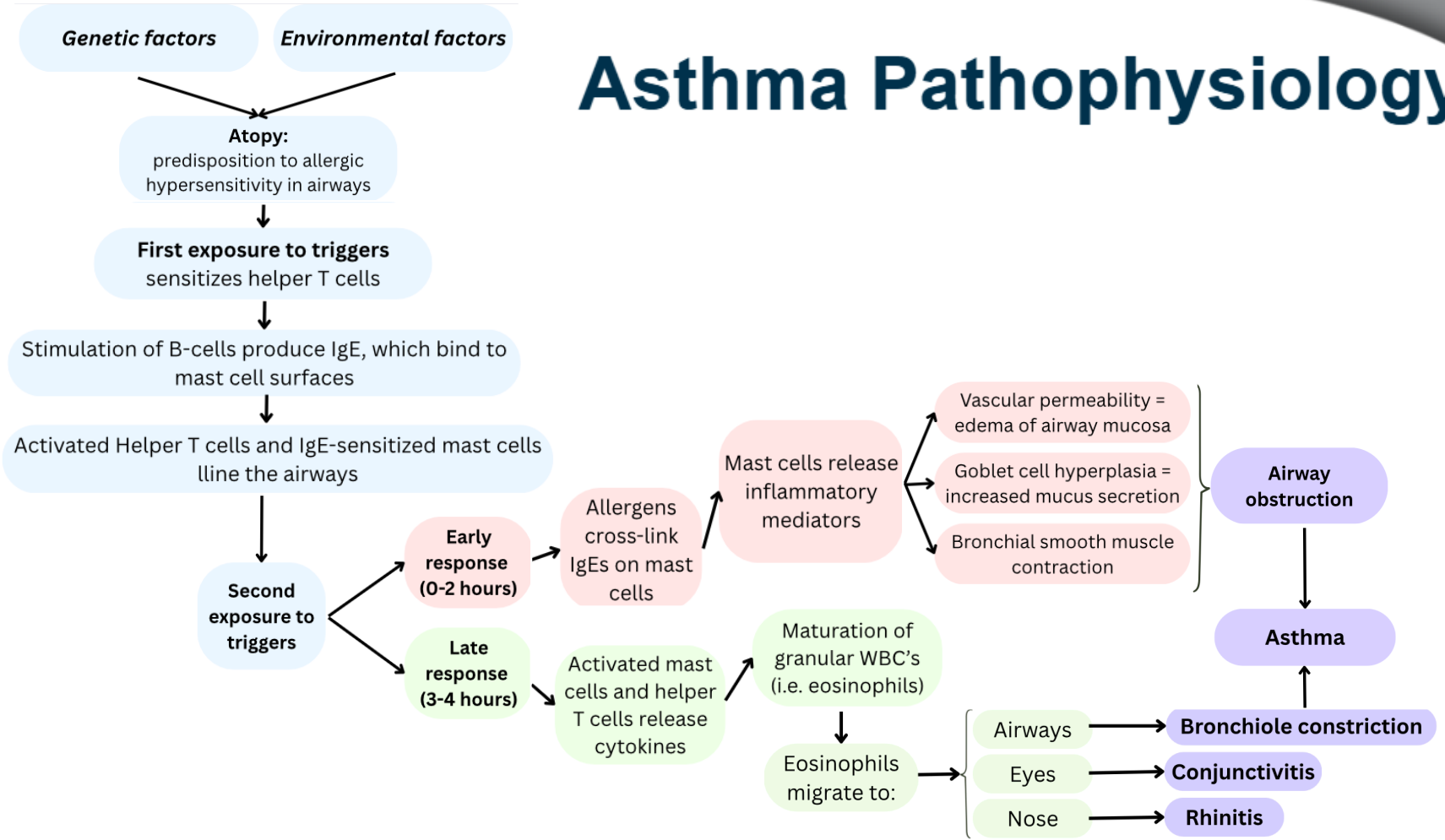
At the end of this session, learners should be able to:

1. RECOGNIZE THE PATHOPHYSIOLOGY OF ASTHMA AND COPD IN RELATION TO BIOLOGIC THERAPY.
2. OUTLINE CURRENT GUIDELINE RECOMMENDATIONS FOR BIOLOGIC USE IN ASTHMA AND COPD.
3. IDENTIFY BIOLOGIC TARGETS AND KEY CLINICAL DATA SUPPORTING THEIR USE.
4. COMPARE AVAILABLE BIOLOGIC THERAPIES BASED ON MECHANISM, INDICATION, AND EFFICACY.
5. SELECT APPROPRIATE BIOLOGIC TREATMENT STRATEGIES BASED ON PATIENT CASE SCENARIOS.

Objective 1:

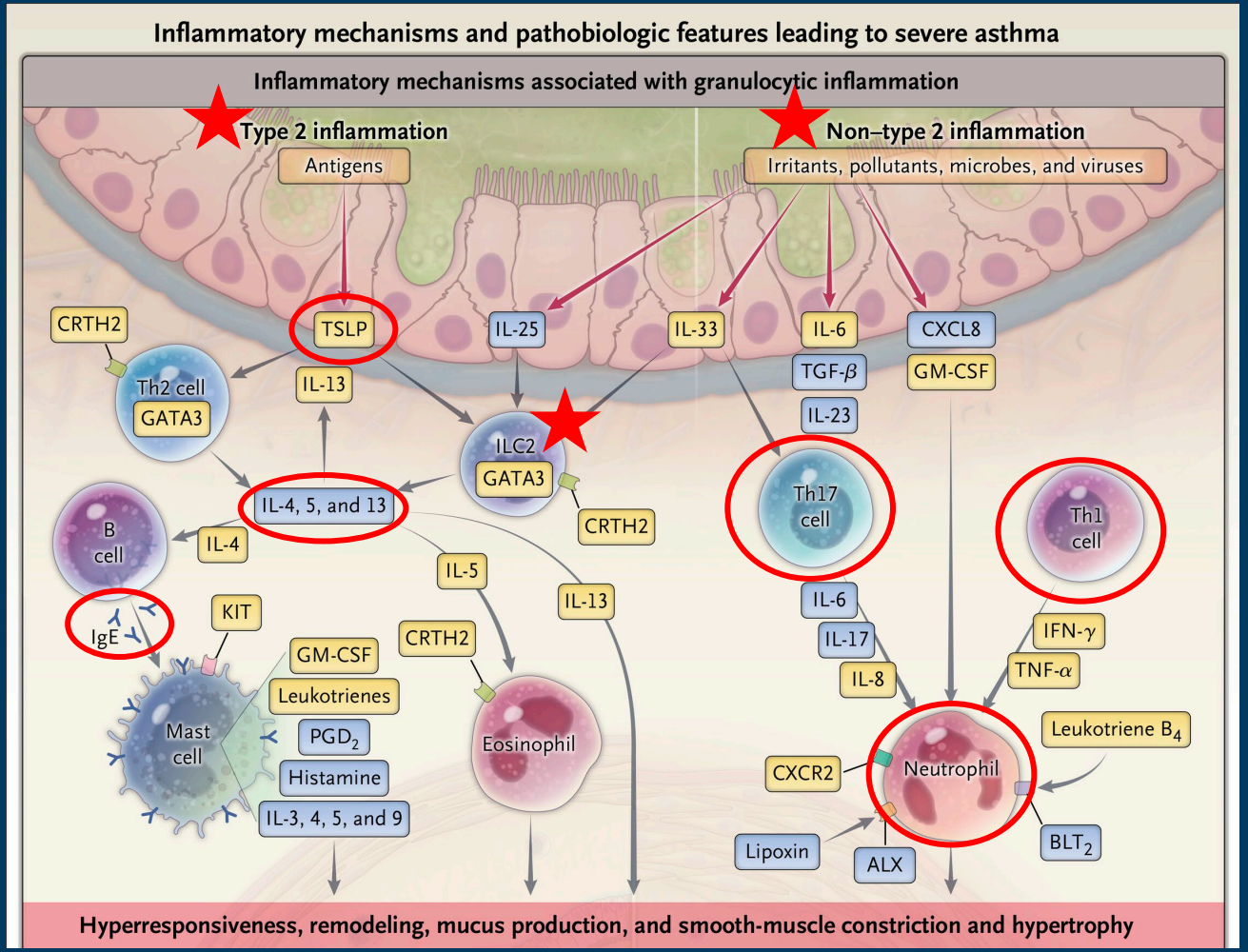
Recognize the pathophysiology of asthma and COPD in relation to biologic therapy.

Asthma Pathophysiology



Sinyor B, et al. Pathophysiology of Asthma. *NCBI*. 2023.

Asthma Inflammation



Israel E, et al. Severe and Difficult-to-Treat Asthma. *NIH.* 2017.

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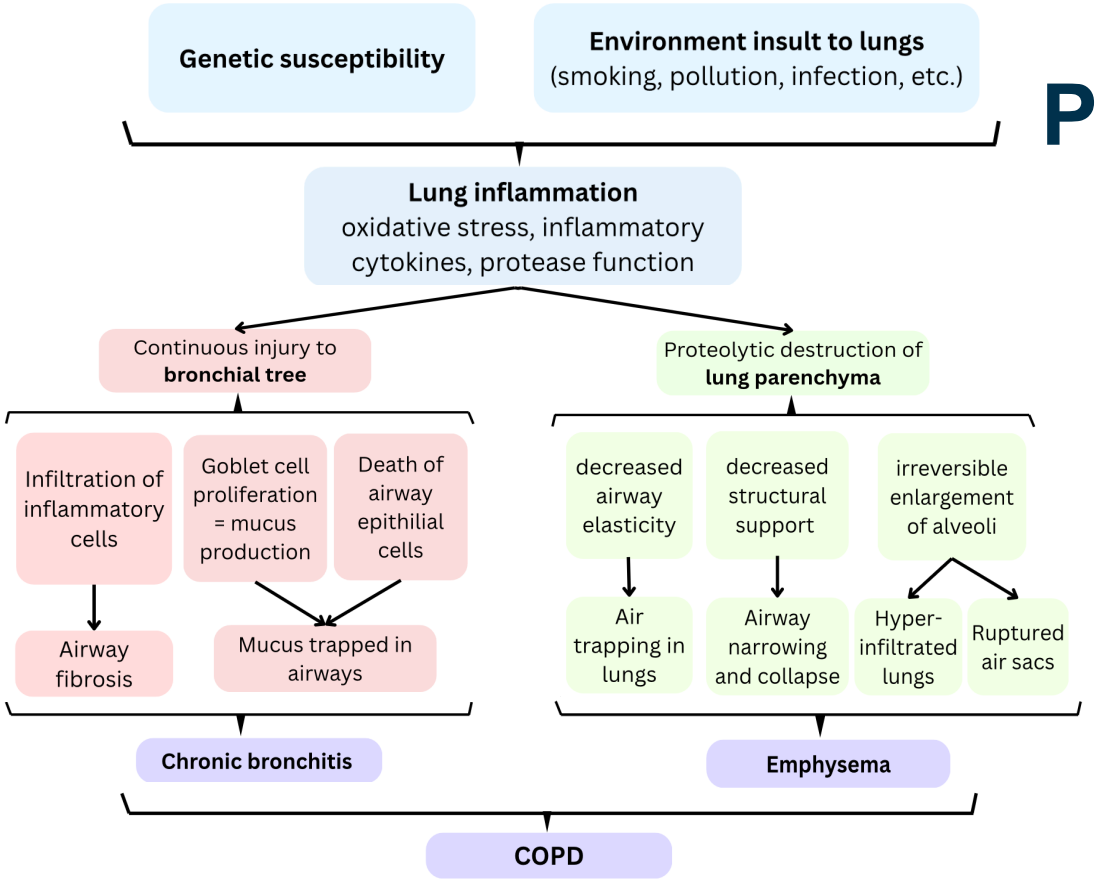
COPD Pathophysiology



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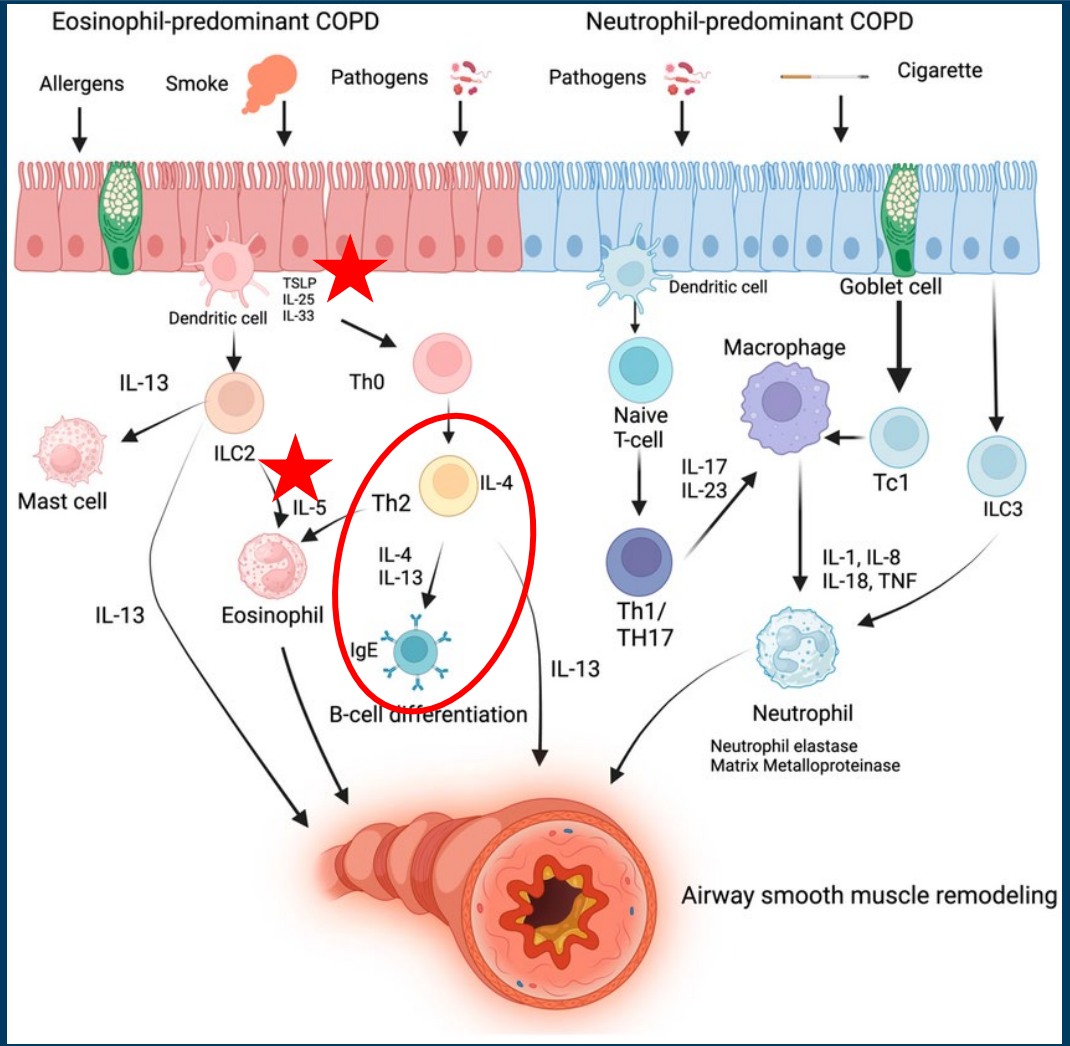
Curtis J, et al. Understanding COPD. *Respiratory Care*. 2023.

COPD Inflammation



Appleton L, et al. Personalized COPD Care. *JCM*. 2024.

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Asthma vs. COPD

FEATURE	ASTHMA	COPD
Onset	Often in childhood or early adulthood	Usually after age 40
Cause	Allergens, genetics, environmental triggers	Smoking, air pollution, occupational exposure
Inflammation Type	Eosinophilic, Type 2-high	Neutrophilic, Type 2-low
Reversibility of Airflow Limitation	Reversible with bronchodilators	Irreversible or partially reversible
Symptoms	Episodic wheezing, chest tightness, cough, dyspnea	Persistent cough, sputum production, dyspnea
Response to ICS	Good response	Limited response
Biomarkers	↑ Eosinophils, ↑ IgE, ↑ FeNO	↑ Neutrophils, normal IgE, ↓ FeNO
Imaging	Normal or hyperinflation	Emphysema, airway thickening

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Simmalee K, et al. Exploring the Pathogenesis and Clinical Implications of Asthma and COPD. *Frontiers in Medicine.* 2025.

Knowledge check #1

TJ, a 58-year-old man presents with shortness of breath and a chronic productive cough that has worsened over the past several years. He reports a 40-pack-year smoking history. On physical exam, you note prolonged expiratory phase and decreased breath sounds. Pulmonary function testing shows an FEV_1/FVC ratio of 0.60 that is not fully reversible after bronchodilator administration.

Which diagnosis best fits this patient's presentation?

A. Asthma

B. COPD

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Objective 2:

Outline current guideline recommendations for biologic use in asthma and COPD.

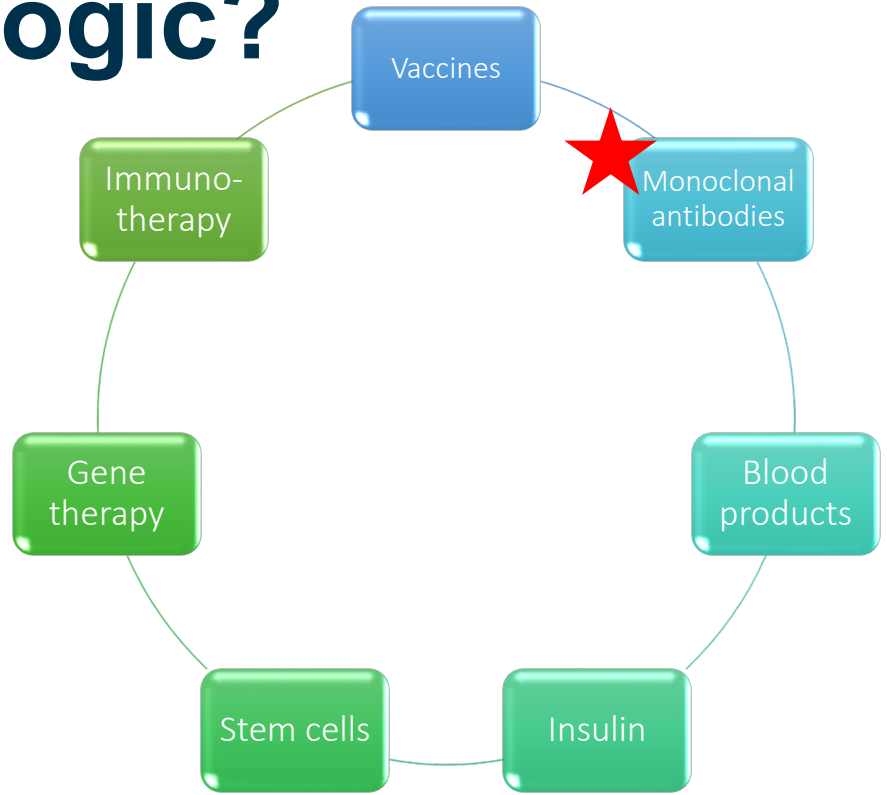
What is a biologic?

Biologics are medications derived from living organism cells

- Human
- Animal
- Microorganisms

Concerns

- Usually injectable only
- Cost $$$$
- Biosimilars
- Specialty pharmacies only



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Biologics. *Cleveland Clinic*. 2024.

GINA Guidelines

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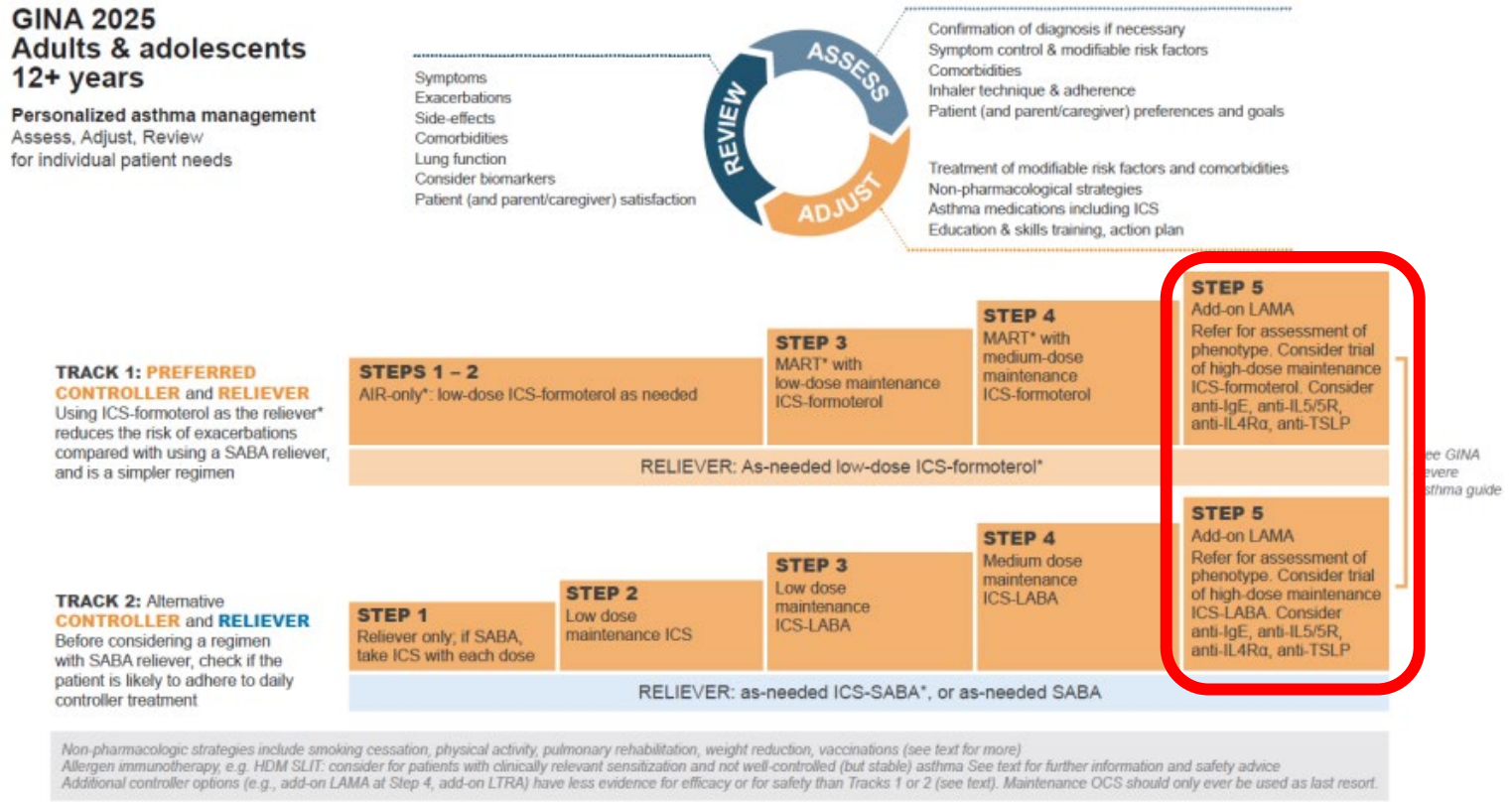

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2025 Global Strategy for Asthma Management and Prevention. *GINA*. 2025.

Severe and Uncontrolled Asthma

Severe asthma

- Require GINA level 5 medications for control or remain uncontrolled
  - High dose ICS with LABA ± LAMA

Uncontrolled asthma

- 2 or more exacerbations requiring OCS in last year
- Exacerbations requiring escalation of care
- Persistent FEV_1 <80% predicted

What is FEV_1 percent predicted?

"Forced expiratory volume per 1 second"

Reversible with bronchodilator: increase in FEV_1 by 12% or 0.2 L

Goal: > 80%

2025 Global Strategy for Asthma Management and Prevention. *GINA*. 2025.
Chhabra s, et al. Clinical Implication of Spirometry in Asthma. *Lung India. 2015.*

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Add-on Biologic Considerations

Phenotype/Endotype	Biomarkers	Labs	Biologic Targets
Type 2 Phenotype			
Allergic Asthma	IgE, IL-4, IL-5, and IL-13	**HIGH** IgE, FeNO positive allergy skin tests	IgE, TSLP
Eosinophilic Asthma	IL-4, IL-5, and IL-13	**HIGH** blood eosinophils, FeNO	IL-5, IL-5R, IL-4, TSLP
Type 2 Low Phenotype			
Neutrophilic Asthma	None identifiable	**LOW** eosinophils, and FeNO variable IgE	none
Paucigranulocytic Asthma	None identifiable	**LOW** eosinophils, and FeNO normal IgE	none

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2025 Global Strategy for Asthma Management and Prevention. *GINA*. 2025.

Add-on Biologic Considerations

Phenotype/Endotype	Biomarkers	Labs	Biologic Targets	Biologics
Type 2 Phenotype				
Allergic Asthma	IgE, IL-4, IL-5, and IL-13	**HIGH** IgE, FeNO positive allergy skin tests	IgE, TSLP	Omalizumab (Xolair®) Tezepelumab-ekko (Tezspire®)
Eosinophilic Asthma	IL-4, IL-5, and IL-13	**HIGH** blood eosinophils, FeNO	IL-5, IL-5R, IL-4, TSLP	Mepolizumab (Nucala®) Benralizumab (Fasenra®) Reslizumab (Cinqair®) Dupilumab (Dupixent®) Tezepelumab-ekko (Tezspire®)
Type 2 Low Phenotype				
Neutrophilic Asthma	None identifiable	**LOW** eosinophils, and FeNO variable IgE	none	none
Paucigranulocytic Asthma	None identifiable	**LOW** eosinophils, and FeNO normal IgE	none	none

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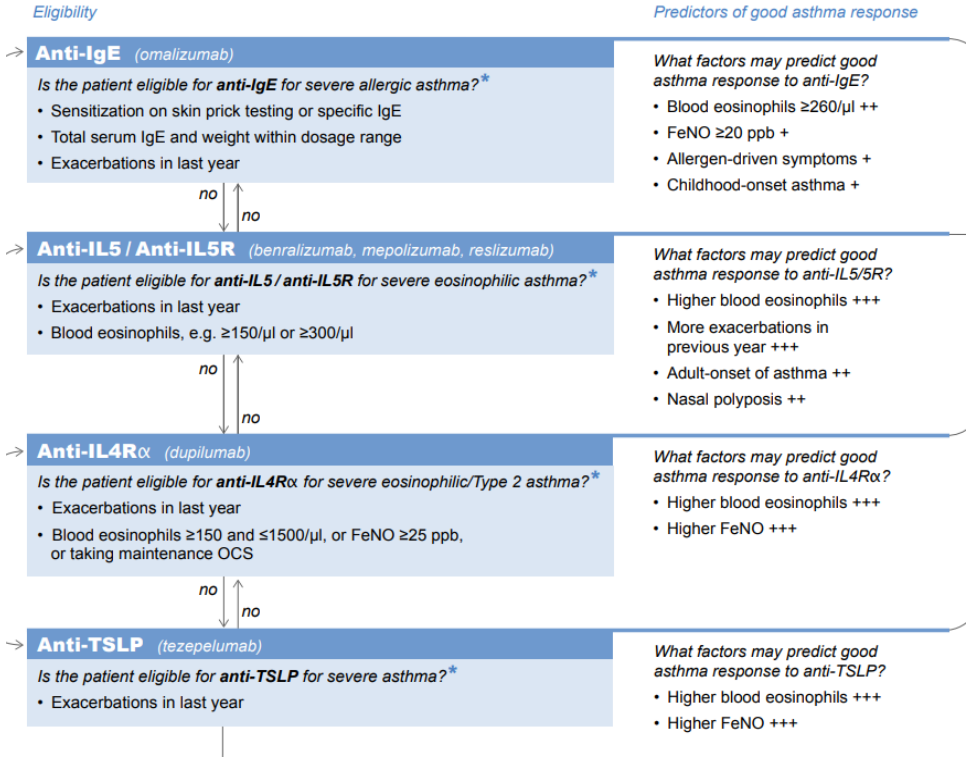
2025 Global Strategy for Asthma Management and Prevention. *GINA*. 2025.

Asthma Guideline Biologic Use



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2025 Global Strategy for Asthma Management and Prevention. *GINA*. 2025.

Knowledge check #2

AB, an 11-year-old patient with a 5-year history of asthma presents for follow-up due to persistent symptoms despite being on high-dose ICS-formoterol maintenance therapy. The patient reports frequent nighttime awakenings and daily use of rescue inhalers. The provider now wants to consider biologic therapy.

Laboratory findings:

Total IgE: 150 IU/mL
Allergy skin testing: Negative
Blood eosinophils: 320 cells/µL
FeNO: 32 ppb

Which asthma phenotype best fits this clinical presentation?

A. Allergic asthma

B. Eosinophilic asthma

C. Type 2-low asthma

D. Asthma-COPD overlap

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GOLD Guidelines

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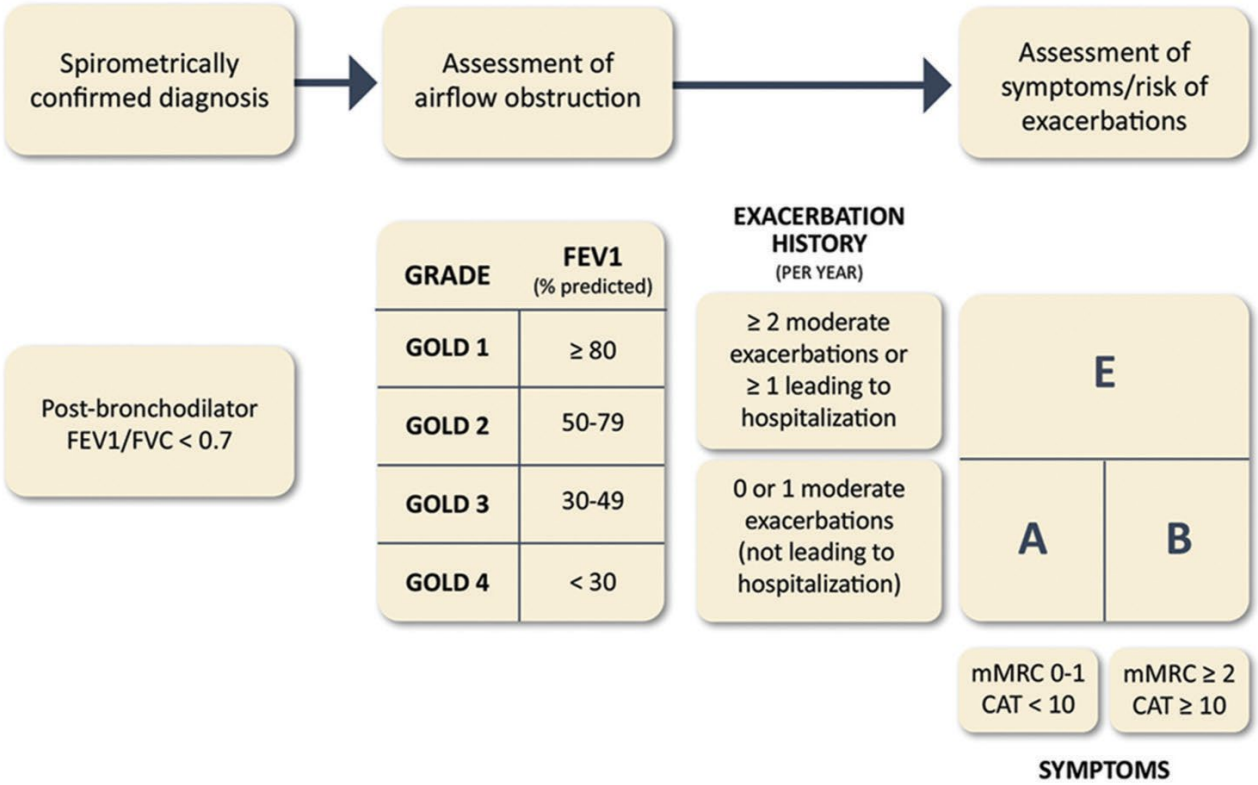
GOLD ABE Assessment Tool



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2025 Report Global Strategy for the Diagnosis, Management, and Prevention of COPD. *GOLD.* 2025.

Initial Pharmacological Treatment

≥ 2 moderate exacerbations or ≥ 1 leading to hospitalization

GROUP E

LABA + LAMA*

consider LABA+LAMA+ICS if blood eos ≥ 300*

0 or 1 moderate exacerbations (not leading to hospital admission)

GROUP A

A bronchodilator

mMRC 0-1, CAT < 10

GROUP B

LABA + LAMA*

mMRC ≥ 2, CAT ≥ 10

*single inhaler therapy may be more convenient and effective than multiple inhalers
Exacerbations refers to the number of exacerbations per year

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2025 Report Global Strategy for the Diagnosis, Management, and Prevention of COPD. *GOLD.* 2025.

GOLD Guideline Directed Biologic Use

Minimal guidance in 2025 report!

Anti IL-4/13 (dupilumab)

- COPD and chronic bronchitis
- 2 or more moderate or 1 severe exacerbations in the last year, despite triple therapy
- Eosinophils ≥ 300 cells/µL

Anti IL-5 (mepolizumab)

- 2 or more exacerbations in the last year
- Elevated eosinophils

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2025 Report Global Strategy for the Diagnosis, Management, and Prevention of COPD. *GOLD.* 2025.

Knowledge check #3

TJ, a 58-year-old man presents with COPD returns to clinic for a follow up after complaining of uncontrolled shortness of breath. He has had 2 exacerbations in the past year that required hospitalization and oral corticosteroids. He is currently on LABA-LAMA-ICS inhaled therapy. The physician has ordered labs to determine if TJ is a candidate for biologic treatment.

Laboratory findings:
Total IgE: 24 IU/mL
Blood eosinophils: 422 cells/μL

Is TJ a candidate for biologic treatment?

A. Yes

B. No

C. Not enough information

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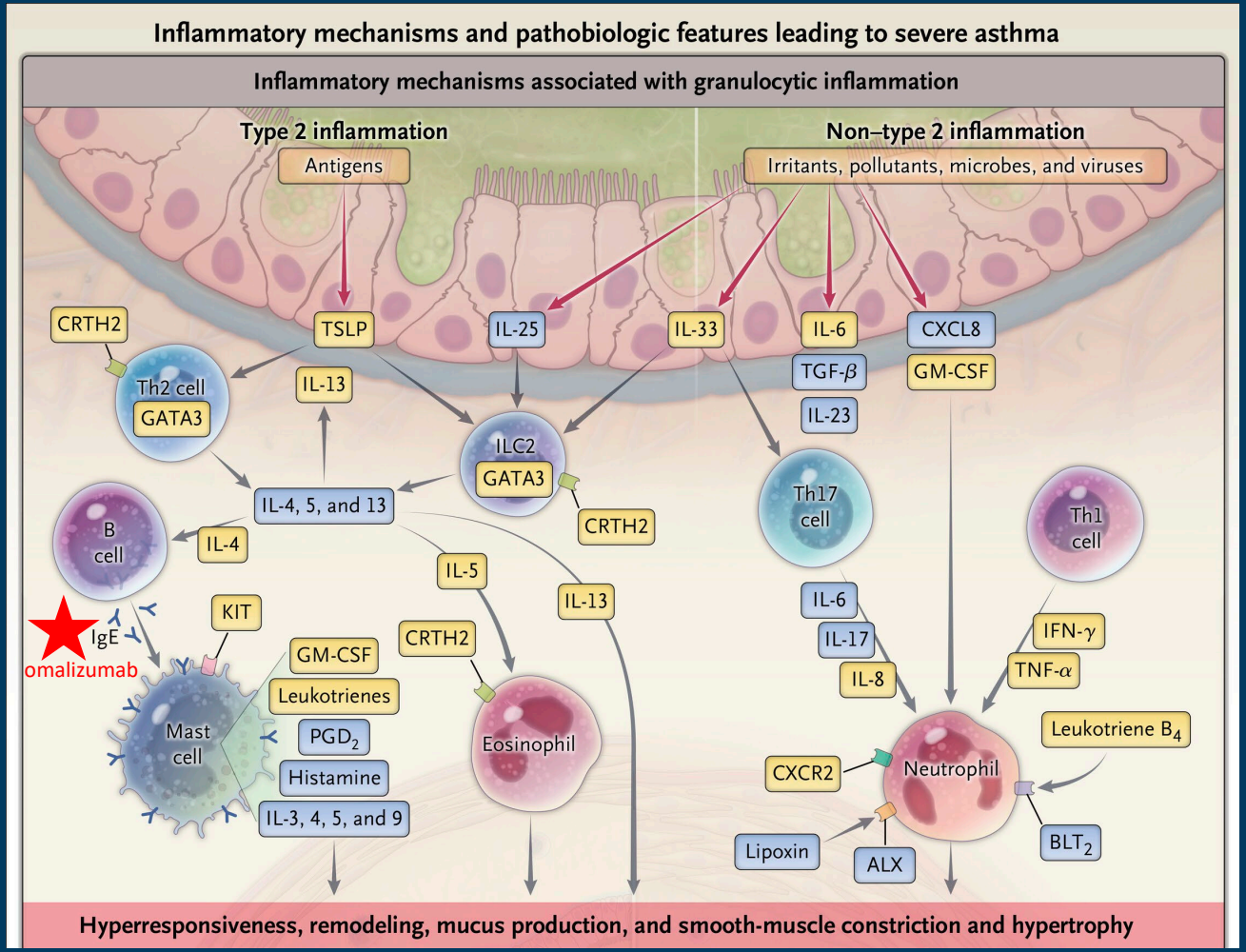
Objective 3:

Identify biologic targets and key clinical data supporting their use.



Omalizumab (Xolair®)

- Binds to free IgE and prevents it from binding to its receptor on mast cells and basophils

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Israel E, et al. Severe and Difficult-to-Treat Asthma. *NIH*. 2017.

Omalizumab (Xolair®) - Anti IgE

Mechanism	• Binds to **free IgE** and prevents it from binding to its receptor on mast cells and basophils • Reduces allergic inflammation and downregulates FcεRI receptor expression on effector cells
Indications	Moderate-to-severe persistent allergic asthma (≥6 years) • With positive skin or in vitro reactivity to perennial aeroallergens • Inadequately controlled with inhaled corticosteroids
Dosing	75–600 mg SQ every 2–4 weeks • Dose based on baseline serum IgE level and body weight
Pharmacokinetics	• Metabolism: Proteolytic degradation (not CYP-mediated) • Elimination Half-life: ~26 days
Warnings/Precautions	**Boxed Warning**: Anaphylaxis • Malignancy • Serum sickness • Helminth infections
Safety	**Common (1-10%)**: Injection site reactions, headache, arthralgia, fatigue, dizziness **Rare but serious**: Anaphylaxis, vasculitis, cardiovascular and cerebrovascular events
Pearls	• Refrigerate ➡ room temperature max 2 days • No routine lab monitoring needed • False elevation in serum IgE

Xolair (omalizumab) [package insert]. South San Francisco, CA; Gentech USA, Inc; Revised 02/2024.

Omalizumab Dosing ≥ 12 Years

Pre-treatment Serum IgE (IU/mL)	Dosing Frequency	Body Weight (lb/kg)			
		66-132 lb (30-60 kg)	>132-154 lb (>60-70 kg)	>154-198 lb (>70-90 kg)	>198-330 lb (>90-150 kg)
		Dose (mg)			
≥30-100	Every 4 weeks	150	150	150	300
>100-200		300	300	300	225
>200-300		300	225	225	300
>300-400	Every 2 weeks	225	225	300	Insufficient data to recommend a dose
>400-500		300	300	375	
>500-600		300	375		
>600-700		375			

Subcutaneous doses to be administered every 4 weeks Subcutaneous doses to be administered every 2 weeks

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Xolair (omalizumab) [package insert]. South San Francisco, CA; Gentech USA, Inc; Revised 02/2024.

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Xolair (omalizumab) [package insert]. South San Francisco, CA; Gentech USA, Inc; Revised 02/2024.

Soler M., et al. (2001)

Evaluate the efficacy, safety and corticosteroid-sparing effect of omalizumab administered subcutaneously in **allergic asthma**.

Intervention:	Population:	Results:	Safety:
• Omalizumab or placebo SQ every 2 or 4 weeks for 7 months • Based on body weight and serum IgE levels • Steroid phases: tapered to lowest effective dose after 16 weeks	• Mean age 40 • Baseline FEV_1 pred 70% • Baseline IgE 21-814 IU/mL (avg 215)	• Reduction in exacerbations (58% at week 16 and 52% at week 24), $p<0.001$ • Reduction in steroid requirement, $p<0.001$	• Similar compared to placebo • Headache • Injection site reactions

Conclusion: Omalizumab is efficacious in reducing exacerbations and steroid use in patients with allergic asthma.

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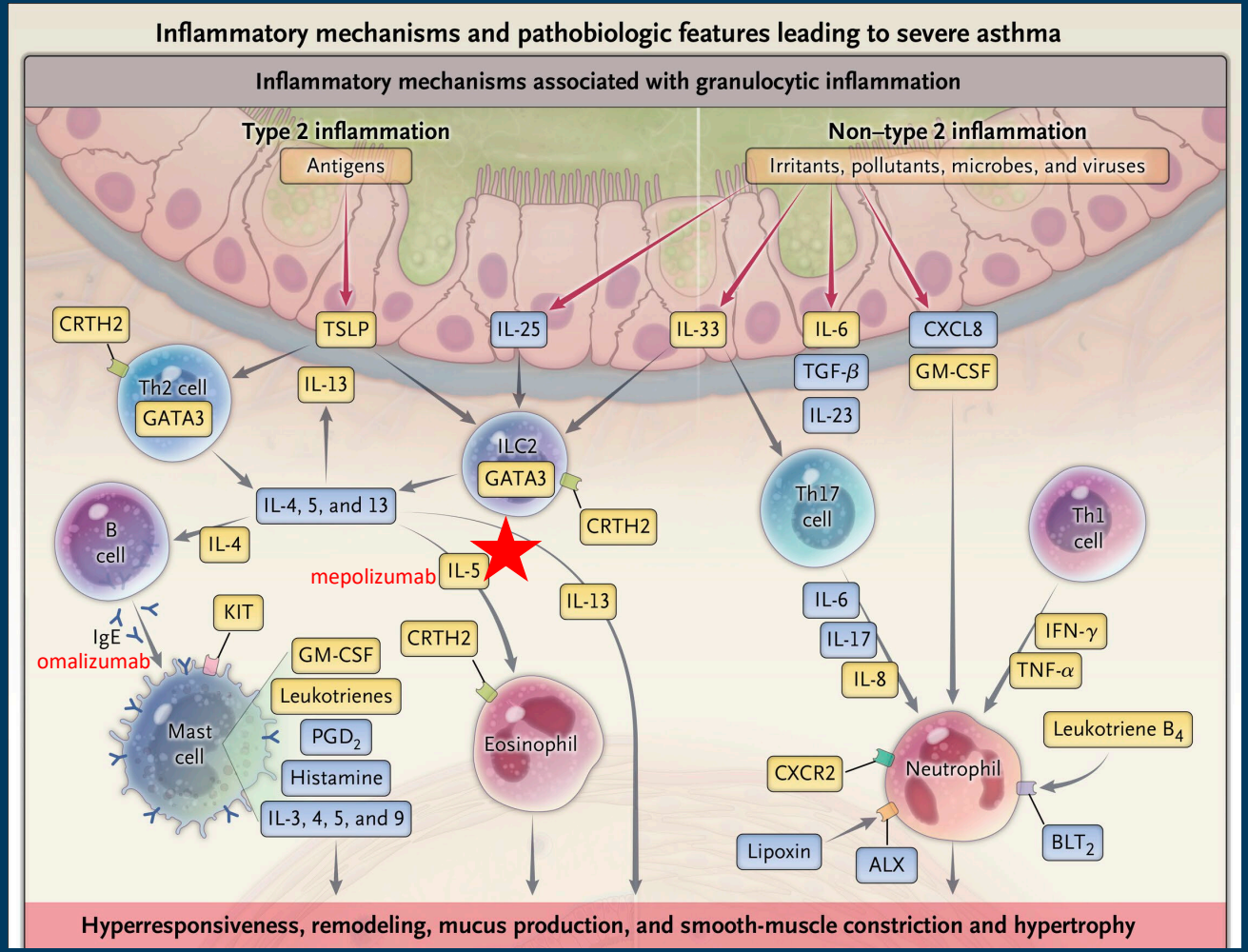
Soler M, et al. The Anti-IgE Antibody Omalizumab Reduces Exacerbations in Allergic Asthmatics. *ERJ*. 2001.



Mepolizumab (Nucala®)

- Binds to IL-5, which reduces eosinophil levels and inflammation

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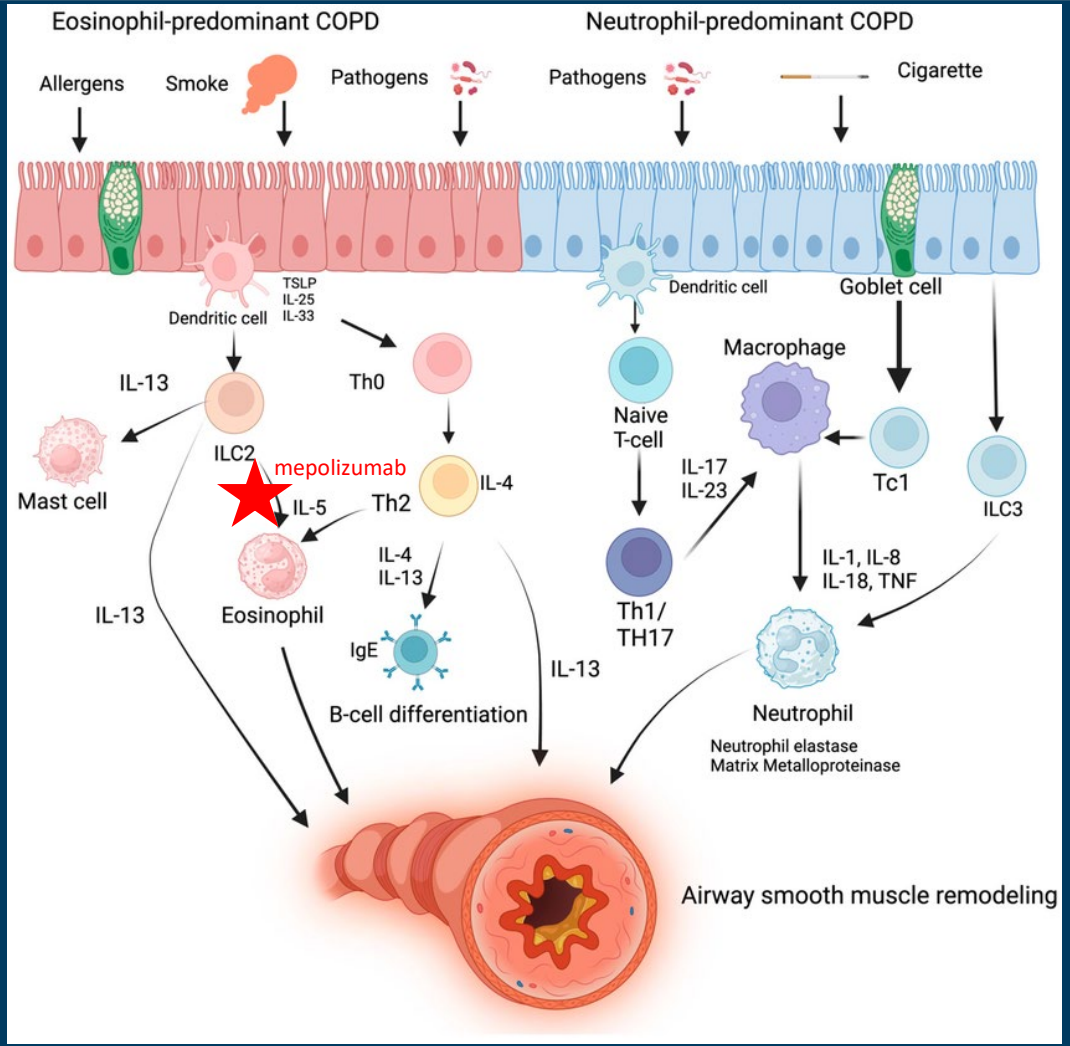
Israel E, et al. Severe and Difficult-to-Treat Asthma. *NIH.* 2017.



Mepolizumab (Nucala®)

- Binds to IL-5, which reduces eosinophil levels and inflammation

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Appleton L, et al. Personalized COPD Care. *JCM*. 2024.

Mepolizumab (Nucala®) - Anti IL-5

Mechanism	Binds to **IL-5**, which reduces eosinophil levels and inflammation
Indications	• Severe eosinophilic asthma (≥6 years) • COPD with eosinophilic phenotype
Dosing	6–11 years: 40 mg SQ every 4 weeks ≥12 years: 100 mg SQ every 4 weeks
Pharmacokinetics	Metabolism: Proteolytic degradation (not CYP-mediated) Elimination Half-life: ~20 days
Warnings/Precautions	• Hypersensitivity reactions • Herpes zoster infection
Safety	**Common (>10%)**: Headache, injection site reactions, back pain, fatigue, influenza, UTI **Rare but serious**: Hypersensitivity and herpes zoster
Pearls	• Refrigerate ➡ room temperature max 7 days • No routine lab monitoring

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Nucala (mepolizumab) [package insert]. Philadelphia, PA; GlaxoSmithKline LLC; Revised 08/2025.

MENSA Phase 3 study (2014)

Evaluate efficacy in minimizing exacerbations and safety of mepolizumab in patients with **severe eosinophilic asthma**.

Intervention:	Population:	Results:	Safety:
• Mepolizumab100 mg SQ or 75 mg IV vs placebo every 4 weeks for 32 weeks	• Age 12-82 • Baseline FEV_1 pred 60% • Baseline eosinophils ~300 cells/μL • Baseline IgE ~150 IU/mL • At least 2 exacerbations	• Exacerbations vs placebo, p<0.001: • 53% (SQ) • 47% (IV) • Improved asthma QOL scores, p<0.001	• Similar compared to placebo • Headache • Injection site reactions • Nasopharyngitis

Conclusion: Mepolizumab is efficacious in reducing exacerbations and improving quality of life in patients with eosinophilic asthma.

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Ortega H, et al. MENSA. *NEJM*. 2014.

MATINEE Phase 3 study (2025)

Evaluate the efficacy and safety of mepolizumab in patients with **COPD and eosinophilic inflammation** (≥300 cells/μL), receiving triple inhaled therapy.

Intervention:	Population:	Results:	Safety:
• Mepolizumab 100 mg SQ every 4 weeks or placebo for 52 to 104 weeks	• At least 2 moderate or 1 severe exacerbation in the last year • 72% smokers • Majority moderate to severe airway obstruction (FEV_1 30-80%) • Baseline eosinophils ~480 cells/μL	• Decreased exacerbations by 21%, p=0.01 • Increased time to first exacerbation by 98 days, p=0.009	• Similar compared to placebo • Headache • Nasopharyngitis

Conclusion: Mepolizumab is efficacious in reducing frequency and time to exacerbations and hospitalizations in COPD patients with eosinophils ≥300 cells/μL.

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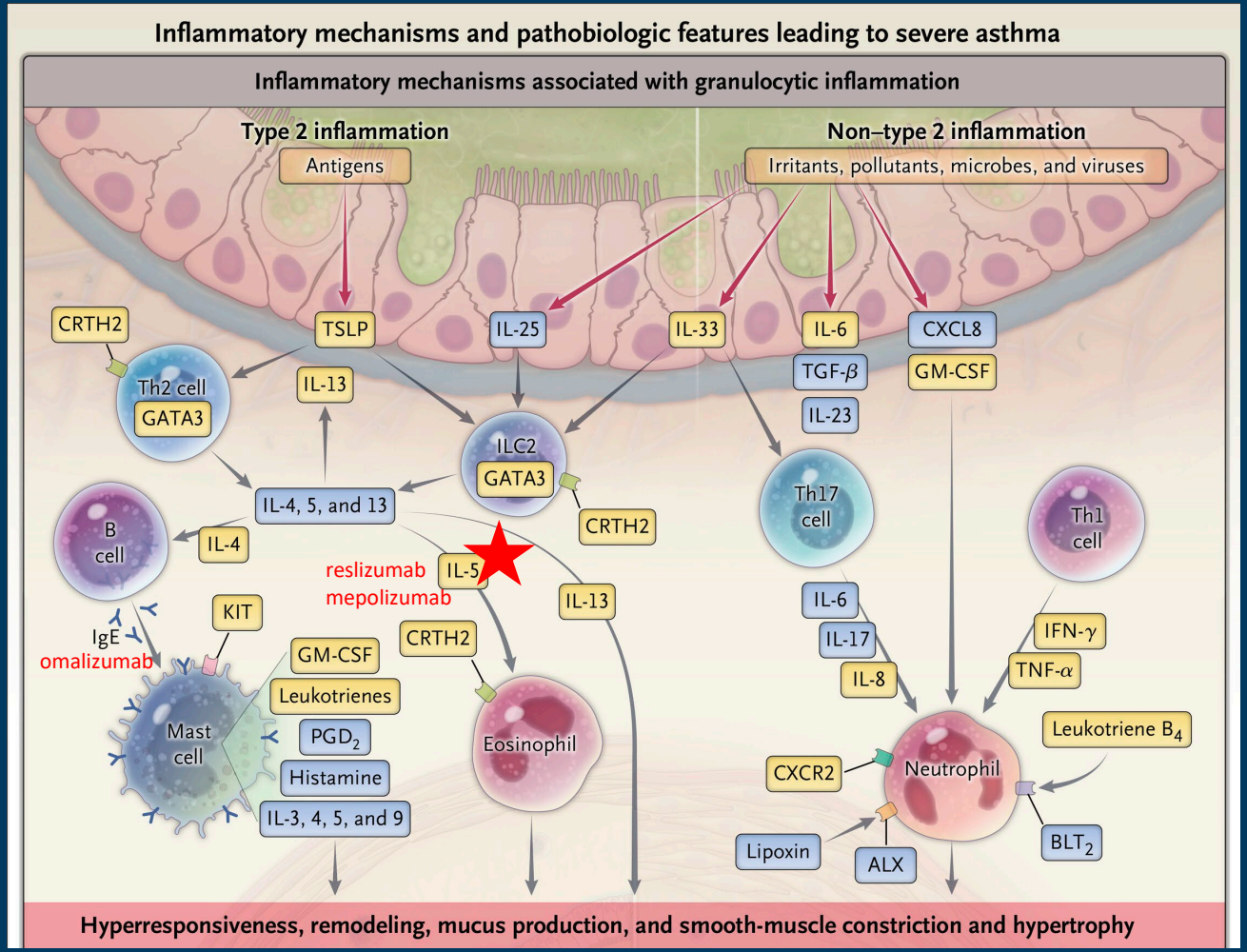
Sciurba F, et al. MATINEE. *NEJM*. 2025.



Reslizumab (Cinqair®)

- Binds to IL-5, which reduces eosinophil levels and inflammation

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Israel E, et al. Severe and Difficult-to-Treat Asthma. *NIH.* 2017.

Reslizumab (Cinqair®) - Anti IL-5

Mechanism	Binds to **IL-5**, which reduces eosinophil levels and inflammation
Indications	Asthma (≥18 years; eosinophilic)
Dosing	3 mg/kg IV infusion every 4 weeks (infuse over 20-50 minutes)
Pharmacokinetics	• Metabolism: Proteolytic degradation (not CYP-mediated) • Elimination Half-life: ~24 days
Warnings/Precautions	**Boxed Warning**: Anaphylaxis (0.3%) • Malignancy • Helminth infections
Safety	**Common (>2%)**: Oropharyngeal pain, elevated creatine phosphokinase (CPK), myalgias, musculoskeletal pain **Rare but serious**: Anaphylaxis, malignancy
Pearls	• Only IV infusion • Weight based dosing

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Cinqair (reslizumab) [package insert]. West Chester, PA; Teva Respiratory LLC; Revised 02/2020.

BREATH Phase 3 study (2016)

Characterize the effect of reslizumab on FEV_1 in **uncontrolled asthma** with eosinophils ≥400 cells/μL.

Intervention:	Population:	Results:	Safety:

• Reslizumab 0.3 or 3.0 mg/kg IV or placebo every 4 weeks for 16 weeks	• Age 12-75
	• Around 50% had exacerbation within last year
	• Baseline FEV_1 predicted 70%
	• Baseline eosinophils ~600 cells/μL
		• FEV_1 improvement vs placebo:
		  • 0.3 mg/kg: +0.115 L (p=0.0237)
		  • 3.0 mg/kg: +0.16 L (p=0.0018)
		• Improved QOL scores, p<0.05
		• Reduced SABA rescue use, p<0.02
			• Similar compared to placebo
			• Asthma worsening
			• Headache
			• Nasopharyngitis

Conclusion: Reslizumab is efficacious in improving lung function and quality of life in asthma patients with eosinophils ≥400 cells/μL.

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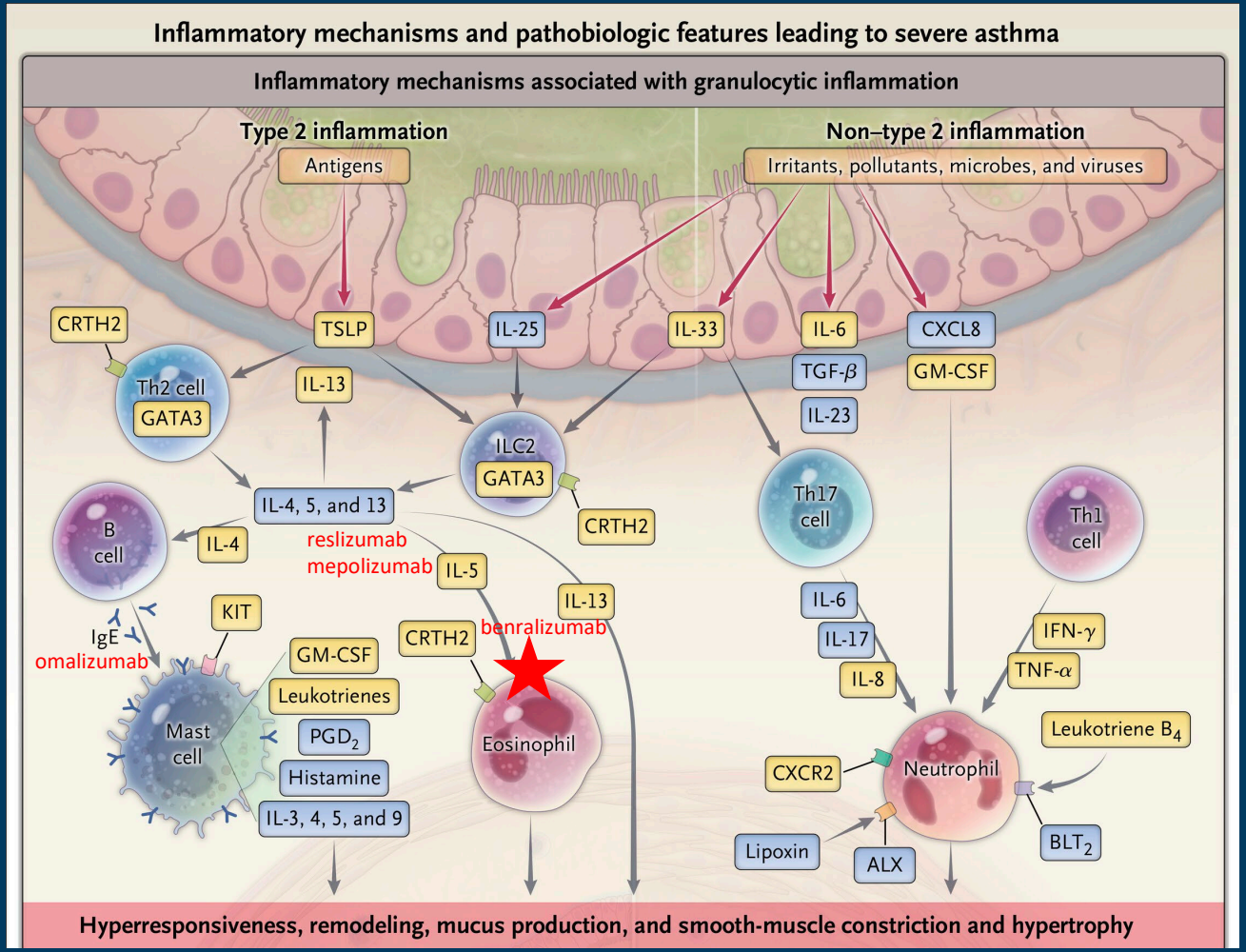
Bjermer L, et al. BREATH. *CHEST*. 2016.



Benralizumab (Fasenra®)

- Binds to IL-5 receptors, which reduces eosinophil levels and inflammation

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Israel E, et al. Severe and Difficult-to-Treat Asthma. *NIH*. 2017.

Benralizumab (Fasenra®)- Anti IL-5

Mechanism	Binds to **IL-5 receptor**, which reduces eosinophil levels and inflammation
Indications	Asthma (≥6 years; eosinophilic)
Dosing	6–11 years: <35 kg: 10 mg SQ every 4 weeks × 3 doses, then every 8 weeks ≥35 kg: 30 mg SQ every 4 weeks × 3 doses, then every 8 weeks ≥12 years: 30 mg SQ every 4 weeks × 3 doses, then every 8 weeks
Pharmacokinetics	• Metabolism: Proteolytic degradation (not CYP-mediated) • Elimination Half-life: ~15.5 days
Warnings/Precautions	• Hypersensitivity reactions: anaphylaxis, angioedema, urticaria, rash • Helminth infections
Safety	**Common (1-10%)**: headache, fever, pharyngitis **Rare but serious**: hypersensitivity and helminth
Pearls	• Refrigerate ➡ room temp max 14 days • No routine lab monitoring

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Fasenra (benralizumab) [package insert]. Södertälje, Sweden. AstraZeneca AB; Revised 09/2024.

SIROCCO Phase 3 study (2016)

Evaluate the efficacy and safety of benralizumab in patients with **severe asthma**, uncontrolled on high-dose ICS and LABA.

Intervention:	Population:	Results:	Safety:

• Benralizumab 30 mg SQ every 4 or 8 weeks vs placebo for 48 weeks	• Age 12-75
	• Medium-high dose ICS for ≥1 year
	• Baseline FEV_1 predicted ~56%
	• Average 3 exacerbations per year
		• Reduced annual exacerbations vs placebo, p<0.0001:
		  • Every 4 weeks: 45%
		  • Every 8 weeks: 51%
		• Improved FEV_1 up to +0.159 L (p=0.0018)
			• Similar compared to placebo
			• Similar between both dosing schedules
			• Arthritis
			• Upper respiratory infection, sinusitis
			• Headache

Conclusion: Benralizumab every 4 or 8 weeks is efficacious in reducing annual exacerbations and improving lung function in patients with severe uncontrolled asthma.

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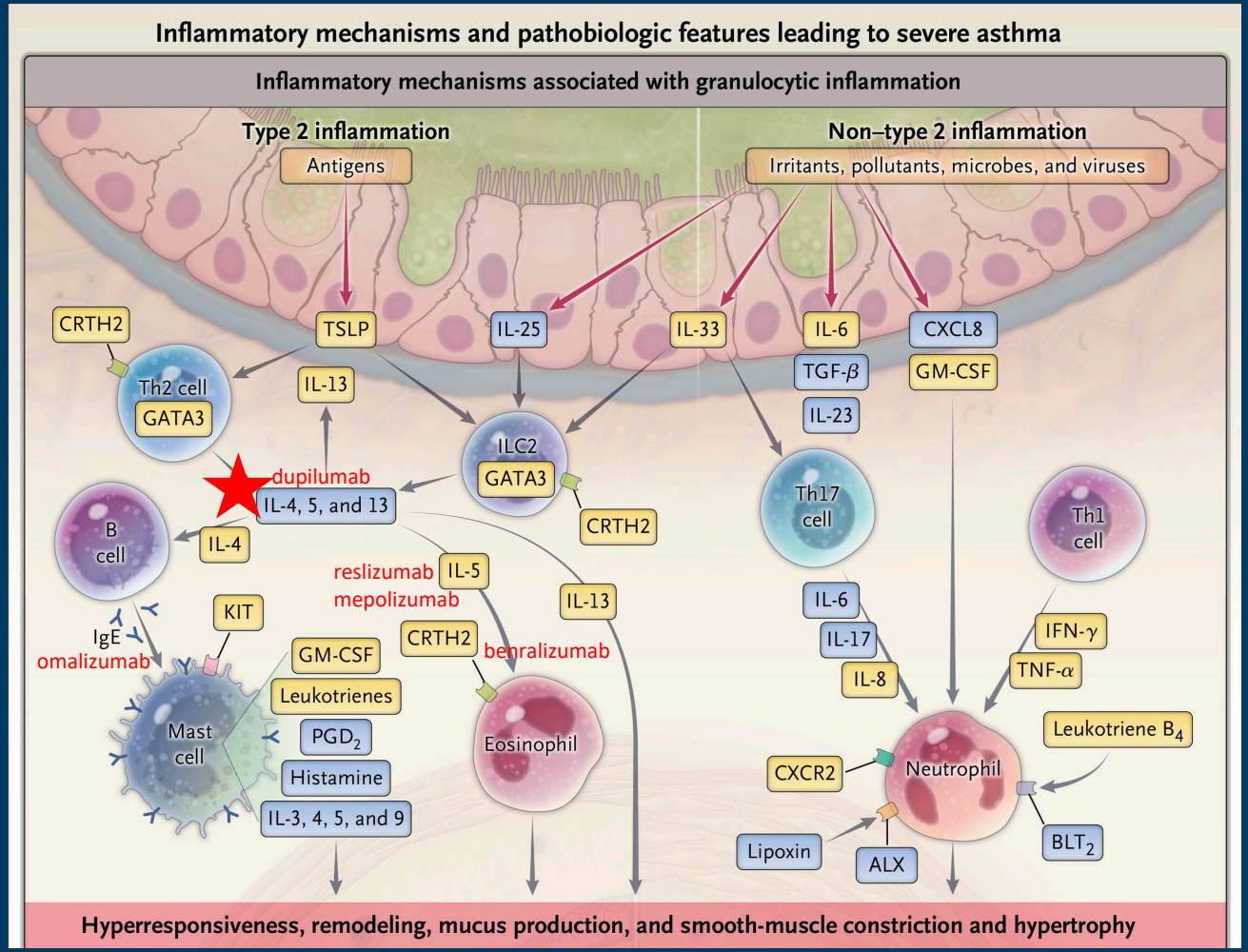
Bleecker E, et al. SIROCCO. *The Lancet*. 2016.



Dupilumab (Dupixent®)

- Binds to the IL-4 receptor alpha (IL-4Rα), blocking signaling from both IL-4 and IL-13

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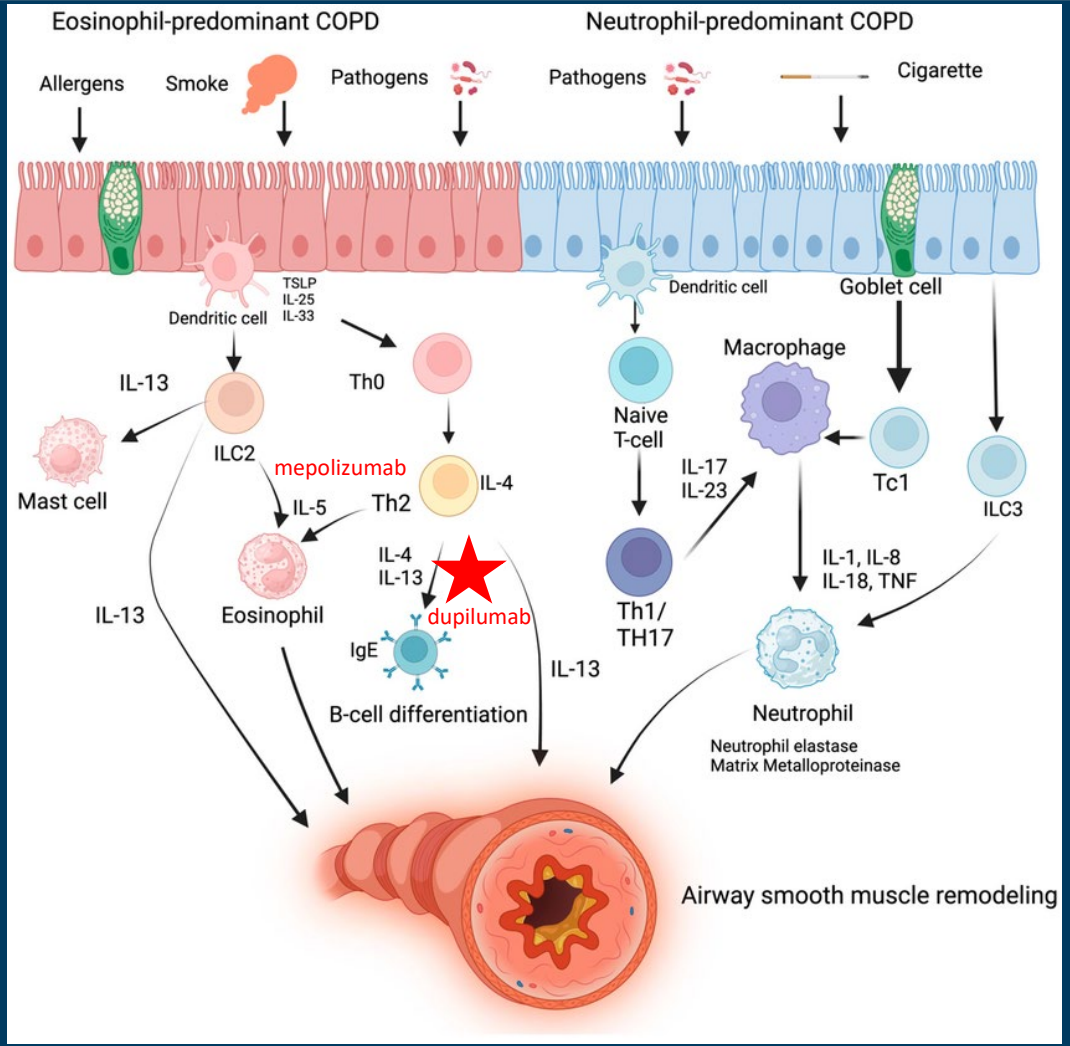
Israel E, et al. Severe and Difficult-to-Treat Asthma. *NIH.* 2017.



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Appleton L, et al. Personalized COPD Care. *JCM*. 2024.

Dupilumab (Dupixent®)- Anti IL-4/13

Mechanism	• Binds to the **IL-4 receptor alpha** (IL-4Rα), blocking signaling from both IL-4 and IL-13 • Reduces IgE production, eosinophil recruitment, and inflammatory cytokine release
Indications	• Asthma (≥6 years; eosinophilic or steroid-dependent) • COPD with Type 2 Inflammation
Dosing	**Children <12 years**: 300 mg SQ every 4 weeks (<30kg), 200 mg SQ every other week (>30 kg) **Ages 12 and up:** 400 mg SQ load, then 200 mg SQ every other week **OR** 600 mg SQ load, then 300 mg SQ every other week
Pharmacokinetics	Metabolism: Proteolytic degradation (not CYP-mediated) Elimination Half-life: ~21–25 days
Warnings/Precautions	• Live vaccines • Helminth infections • Hypersensitivity • Conjunctivitis and keratitis • New onset psoriasis, eosinophilic conditions, arthritis
Safety	**Common (>10%)**: eosinophilia, viral infections, injection site reaction, upper respiratory infection **Rare but serious**: hypersensitivity reactions
Pearls	• Refrigerate ➡ room temperature max 14 days • No routine lab monitoring • Many FDA indications

Dupixent (dupilumab) [package insert]. Tarrytown, NY; Regeneron Pharmaceuticals, Inc; Revised 06/2025.

LIBERTY ASTHMA QUEST Phase 3 study (2018)

Evaluate the efficacy and safety of dupilumab, in patients with **uncontrolled asthma**.

Intervention:	Population:	Results:	Safety:

• Dupilumab 200 or 300 mg SQ every 2 weeks or placebo for 52 weeks	• ≥ 12 years old
	• Baseline FEV_1 predicted 58%
	• 50% using high dose ICS
	• Baseline eosinophils ~370 cells/µL
	• High exhaled nitric oxide (avg 35)
		• Reduced exacerbations vs placebo, p<0.001:
		  • 200 mg: 47.7%
		  • 300 mg: 46%
		• Improved FEV_1 +0.32 L at week 12 (200 mg), p<0.001
			• Similar compared to placebo
			• Similar between 200 mg and 300 mg
			• Injection site reaction
			• Headache
			• Nasopharyngitis
			• No difference in conjunctivitis compared to placebo

Conclusion: Dupilumab 200 mg and 300 mg every 2 weeks is efficacious in reducing exacerbations and improving lung function in patients with uncontrolled asthma.

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Castro M, et al. LIBERTY ASTHMA QUEST. *NEJM*. 2018.

BOREAS Phase 3 study (2023)

Evaluate the efficacy and safety of dupilumab in patients with **COPD** and suspected type 2 inflammation, indicated by blood eosinophils ≥300 cells/μL on inhaled triple therapy.

Intervention:	Population:	Results:	Safety:
• Dupilumab 300 mg SQ every 2 weeks or placebo for 52 weeks	• Average age 65 • 70% former smokers • Baseline eosinophils ~400 cells/μL • Baseline FEV_1 ~50% • ~2 exacerbations in the last year	• Reduced exacerbations by 30%, p<0.001 • Improved FEV_1 +0.160 L at week 12, p<0.001 • Improved QOL (p=0.002) and symptoms scores (p=0.001)	• Similar compared to placebo • Injection site reaction • Headache • Upper respiratory infections

Conclusion: Dupilumab is efficacious in reducing exacerbations and improving lung function and quality of life in patients with COPD and eosinophils ≥300 cells/μL.

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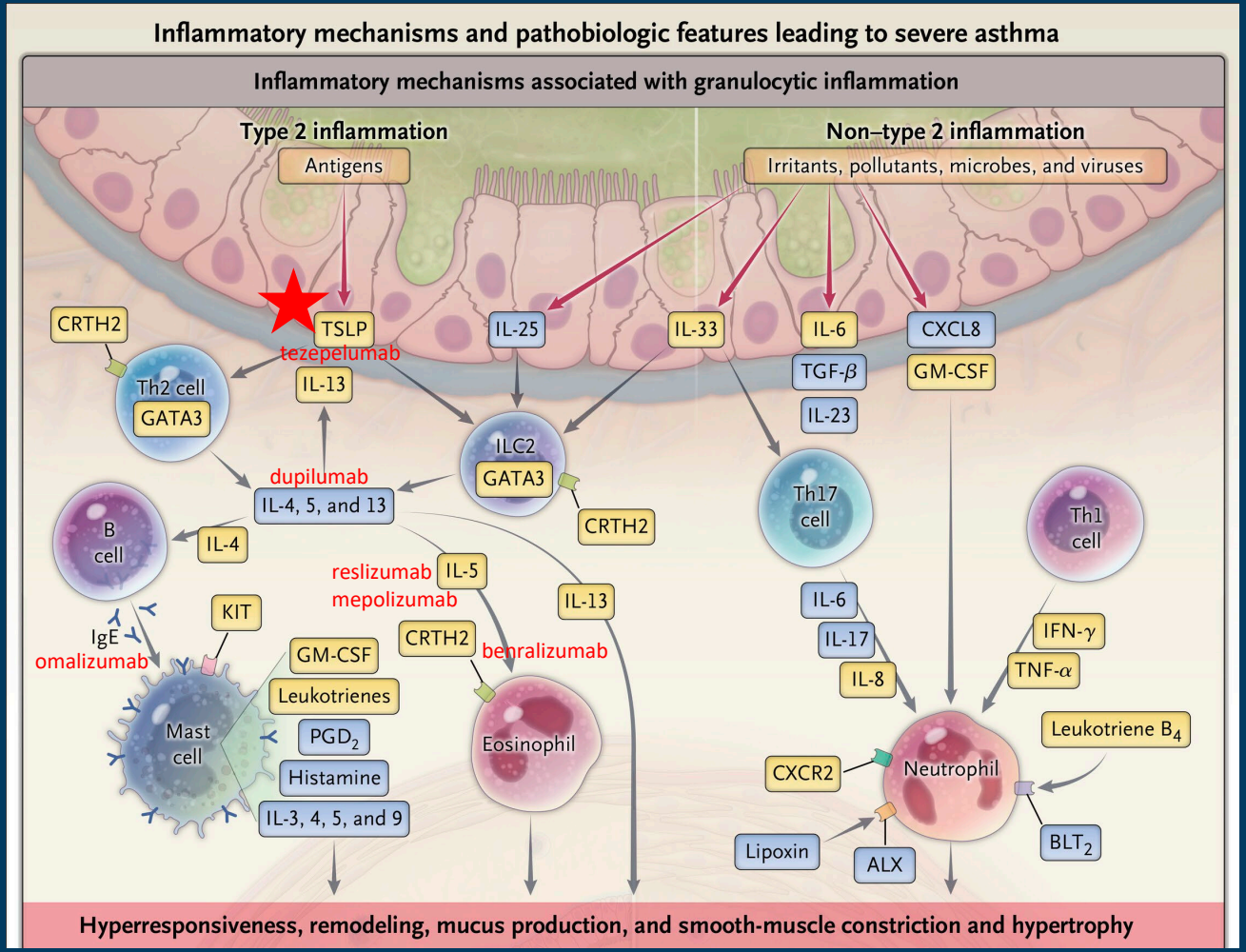
Bhatt S, et al. BOREAS. *NEJM*. 2023.



Tezepelumab-ekko (Tezspire®)

- Blocks TSLP, prevents activation of multiple inflammatory pathways, including eosinophilic, neutrophilic, and non-type 2 inflammation

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Israel E, et al. Severe and Difficult-to-Treat Asthma. *NIH.* 2017.

Tezepelumab-ekko (Tezspire®) - Anti TSLP

Mechanism	Blocks thymic stromal lymphopoietin (**TSLP**), prevents activation multiple inflammatory pathways, including eosinophilic, neutrophilic, and non-type 2 inflammation
Indications	Severe asthma (≥12 years)
Dosing	210 mg SQ every 4 weeks
Pharmacokinetics	• Metabolism: Proteolytic degradation (not CYP-mediated) • Elimination Half-life: ~26 days
Warnings/Precautions	• Live vaccines • Helminth infections • Hypersensitivity reactions: Rash, allergic conjunctivitis, and rare anaphylaxis
Safety	**Common (>3%)**: pharyngitis, arthralgia, back pain, injection site reaction **Rare but serious**: hypersensitivity reactions
Pearls	• Refrigerate ➡ room temperature max 30 days • No routine lab monitoring

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Tezspire (tezepelumab-ekko) [package insert]. Södertälje, Sweden. AstraZeneca AB; Revised 05/2023.

NAVIGATOR Phase 3 study (2021)

Evaluate the efficacy and safety of tezepelumab in adults and adolescents with severe, **uncontrolled asthma**.

Intervention:	Population:	Results:	Safety:
• Tezepelumab 210 mg SQ every 4 weeks or placebo for 52 weeks	• Ages 12-80 years • 75% on high dose ICS • Baseline FEV_1 predicted 62% • 59% had exhaled nitric oxide >25 ppb • Variable baseline eosinophils and IgE	• Improved FEV_1 by +0.13 L, $p<0.001$ • Reduced exacerbations by 56%, $p<0.001$ • Improved QOL and asthma symptom scores, $p<0.001$	• Similar compared to placebo • Upper respiratory infection • Injection site reactions • Headache

Conclusion: Tezepelumab is efficacious in reducing exacerbations and improving lung function and quality of life in patients with uncontrolled asthma independent of eosinophils.

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Menzies-Gow A, et al. NAVIGATOR. *NEJM*. 2021.

Objective 4:

Compare available biologic therapies based on mechanism, indication, and efficacy.

Biologics – Counseling Points

- Remove from fridge at least 30 minutes before injection
- Administer SQ - inject into thigh, abdomen, or back of upper arm
- Injection angle
  - Pen ➡ 90 degrees
  - Syringe ➡ 45 degrees
- When to hold biologic treatment
  - Live vaccines (dupilumab and tezepelumab)
- 3 - 6 months for optimal improvement

Comparing Biologics

	Omalizumab (Xolair®)	Mepolizumab (Nucala®)	Benralizumab (Fasenra®)	Reslizumab (Cinqair®)	Dupilumab (Dupixent®)	Tezepelumab-ekko (Tezspire®)
Target	Anti IgE	Anti IL-5	Anti IL-5 receptor	Anti IL-5	Anti IL-4 receptor (IL-4/13)	Anti TSLP
FDA age approval for asthma (years)	≥6	≥6	≥6	≥18	≥6	≥12
Asthma/COPD indication	Moderate-severe persistent and allergic asthma	Severe eosinophilic asthma, eosinophilic COPD	Severe eosinophilic asthma	Severe eosinophilic asthma	Severe eosinophilic or steroid-dependent asthma, COPD with Type 2 inflammation	Severe asthma
Biomarkers for asthma	Ige 30-1500 IU/mL FeNO ≥ 20 ppb	Eos ≥ 150 cells/µL	Eos ≥ 300 cells/µL	Eos ≥ 150 cells/µL	Eos 150-1500 cells/µL FeNO ≥ 25 ppb	None
Formulations	75 mg/0.5 mL: pen, syringe 150 mg/mL: pen, syringe, vial* 300 mg/2 mL: pen, syringe	100 mg/mL: pen, syringe, vial* 40 mg/0.4 mL: syringe	10 mg/0.5 mL: syringe* 30 mg/mL: syringe*, pen	100 mg/10 mL: vial*	200 mg/1.14 mL: pen, syringe 300 mg/2 mL: pen, syringe	210 mg/1.91 mL: pen, syringe*, vial*
Administration	SQ	SQ	SQ	IV (clinic only)	SQ	SQ
Other indications	Food Allergy (IgE) CRSwNP CSU	HES CRSwNP EGPA	EGPA	None	AD CRSwNP EoE PN CSU BP	None

*vials and pre-filled syringes should be prepped and administered by HCP only

Xolair (omalizumab) [package insert]. South San Francisco, CA; Gentech USA, Inc; Revised 02/2024.
Nucala (mepolizumab) [package insert]. Philadelphia, PA; GlaxoSmithKline LLC; Revised 08/2025.
Fasenra (benralizumab) [package insert]. Södertälje, Sweden. AstraZeneca AB; Revised 09/2024.
Cinqair (reslizumab) [package insert]. West Chester, PA; Teva Respiratory LLC; Revised 02/2020.
Dupixent (dupilumab) [package insert]. Tarrytown, NY; Regeneron Pharmaceuticals, Inc; Revised 06/2025.
Tezspire (tezepelumab-ekko) [package insert]. Södertälje, Sweden. AstraZeneca AB; Revised 05/2023.

Knowledge check #4

AB, an 11-year-old patient with a 5-year history of asthma presents for follow-up due to persistent symptoms despite being on high-dose ICS-formoterol maintenance therapy. The patient reports frequent nighttime awakenings and daily use of rescue inhalers. The provider now wants to consider biologic therapy.

Laboratory findings:

Total IgE: 150 IU/mL
Allergy skin testing: Negative
Blood eosinophils: 320 cells/µL
FeNO: 32 ppb
Weight: 37 kg

For this patient, which of the following would be appropriate biologics? (select all that apply)

A. Omalizumab (Xolair®)

B. Dupilumab (Dupixent®)

C. Tezepelumab-ekko (Tezspire®)

D. Benralizumab (Fasenra®)

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Questions?

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CE Learning Platform
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Remember to create/update your profile on the CE platform, complete an evaluation, then claim credit

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Overview of Biologics in the Treatment of Asthma and COPD

November 13, 2025

Taylor Eustice, PharmD

PGY1 Specialty Pharmacy Resident