Biologics in Asthma: Targeted Therapy and Personalized Care

고려대구로병원
호흡기내과 김상혁

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Currently available biologics and consideration

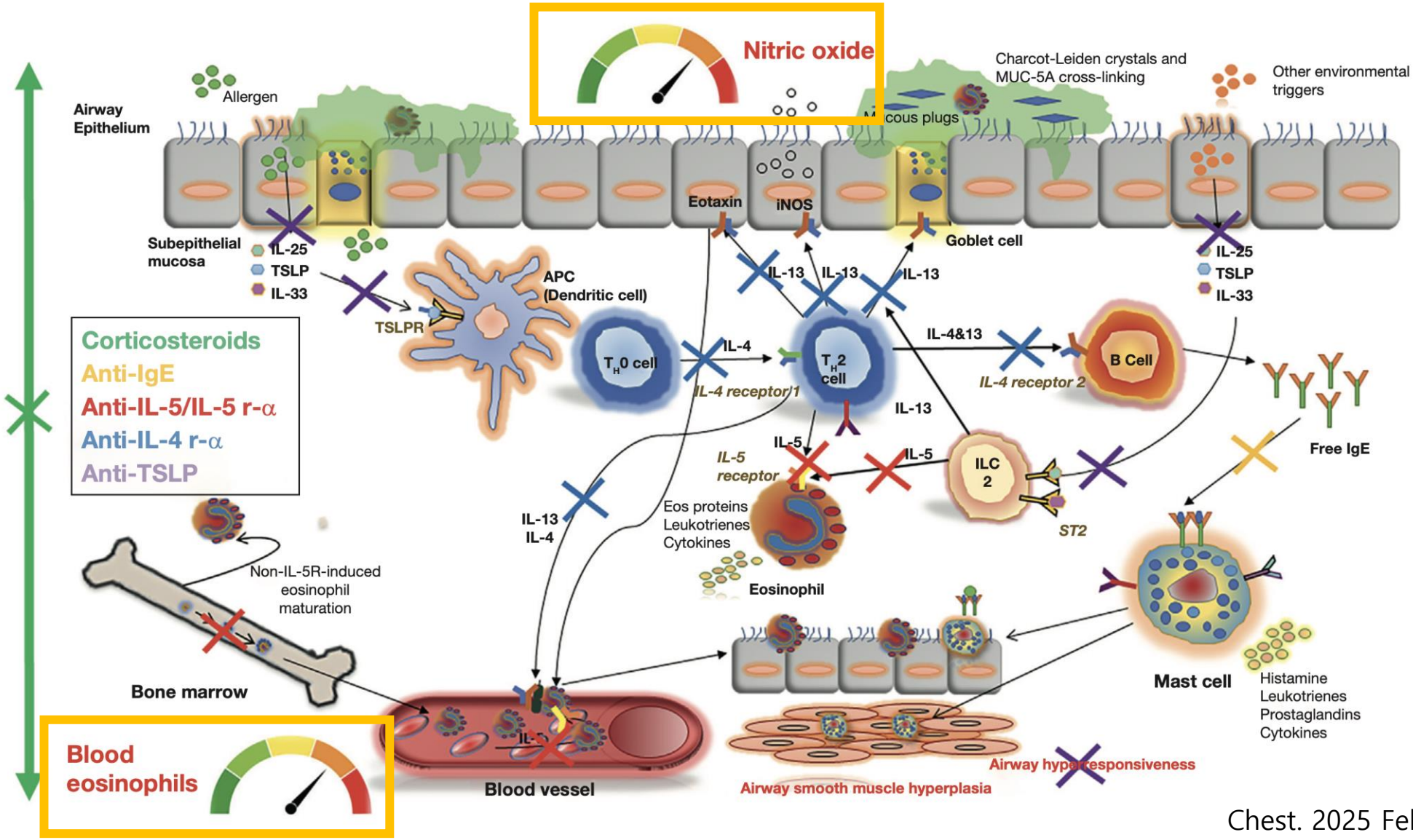
Future of Biologic Therapy for Asthma

Currently available biological agents for severe asthma

Biologics	Eligible patients	Predictors of favorable treatment reponse	Pathway	Usage	Precaution	FDA approval
Omalizumab	Severe allergic asthma, chronic idiopathic urticaria	Childhood-onset asthma, clinical history suggesting allergen-driven symptoms	Anti-IgE	Dosage depends on the patient's body weight and serum IgE level, SC, every 2–4 wk	Anaphylaxis, injection site reaction	Yes
Mepolizumab	Severe eosinophilic asthma, EGPA, hypereosinophilic syndrome, OCS-dependent asthma	Higher blood eosinophils, frequent number of severe exacerbation, adult-onset asthma, nasal polyposis	Anti-IL-5	100 mg, SC, every 4 wk	Hypersensitivity, herpes zoster, parasite infections	Yes
Reslizumab	Severe eosinophilic asthma, OCS-dependent asthma		Anti-IL-5	3 mg/kg, IV, every 4 wk	Hypersensitivity	Yes
Benralizumab	Severe eosinophilic asthma, OCS-dependent asthma		Anti-IL-5R	30 mg, SC every 4 wk for 3 doses, and thereafter every 8 wk	Hypersensitivity	Yes
Dupilumab	Severe eosinophilic asthma, severe T2 high asthma, OCS-dependent asthma, CRS with nasal polyposis, moderate-to-severe atopic dermatitis	Higher blood eosinophils, higher FeNO	Anti-IL-4Rα (blocking IL-4/IL-13)	Loading dose: 400–600 mg, SC Maintenance dose: 200–300 mg SC, every 2 wk	Injection site reaction, transient blood eosinophilia	Yes
Tezepelumab	Severe asthma (T2-high and T2-low), OCS-dependent asthma	Higher blood eosinophils, higher FeNO	Anti-TSLP	210 mg, SC, every 4 wk	Nasopharyngitis, upper respiratory infection	Yes

Tuberc Respir Dis (Seoul). 2024 Jan;87(1):12-21.

T2 inflammation cascade and effect of anti-inflammatory therapies



Chest. 2025 Feb;167(2):330-342.

CHEST

Choosing the Right Biologic for the Right Patient With Severe Asthma

Simon Couillard, MD, FRCPC; David J. Jackson, MD, PhD; Ian D. Pavord, DM; and Michael E. Wechsler, MD

Case 1 2722275

65/M

2025 3회 AE로 입원

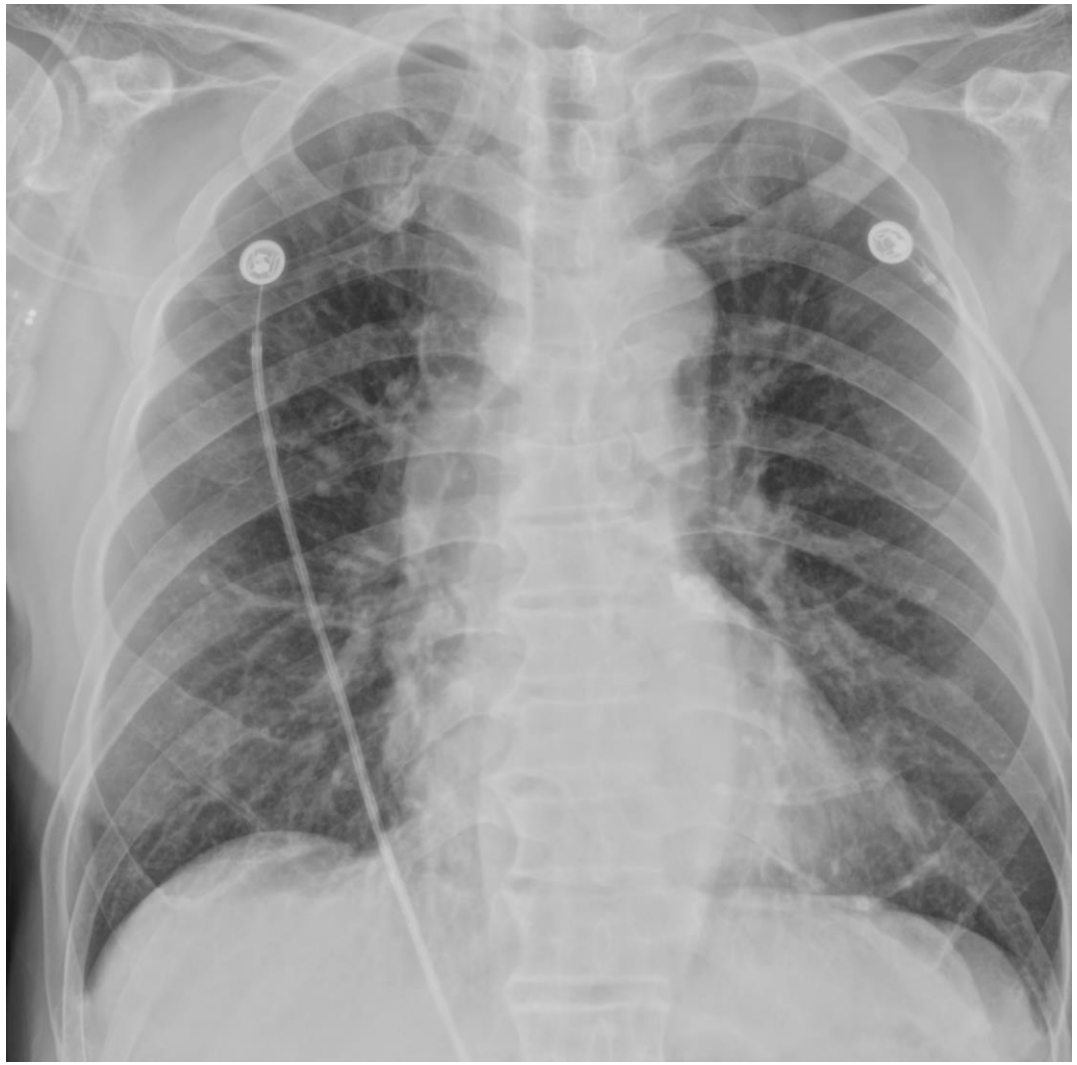
Beclometasone/Formoterol/Glycopyrronium 사용 중

타원 진단명 천식

Ex-smoker, 20갑년

PFT: FEV1 2.7L (87%pred), FVC 4.25L (100%pred), FEV1/FVC 64%, BDR 8%

IgE 859 (skin test -), BEC 386 cells/microL, FeNO 71ppb



Asthma management checklist

- [ ] Asthma diagnosis confirmed
- [ ] Asthma is uncontrolled
- [ ] Environmental trigger optimized
- [ ] Adherence and inhaler technique
- [ ] Comorbidities reviewed
- [ ] Phenotyped **(T1/T2, allergic, OCS dependent)**
- [ ] Biomarkers **(IgE, FeNO, blood EOS)**
- [ ] Physiologic features, imaging reviewed

Options	Features	Comments
Omalizumab	• Young woman of child-bearing age • Fits prescription criteria • Allergic / childhood onset	• Most data in pregnancy • IgE↑, sensitised • Modest effect on attacks
Dupilumab or tezepelumab	• Eos and FENO raised • Spirometry results obstuctive • History of severe asthma attacks • Childhood onset	• Only mAbs to ↓↓ FENO and ↑↑ FEV_1 • Large effect on attacks • First choice here if no plans for children
Mepolizumab or benralizumab	• Eos raised • History of severe asthma attacks	• Large effect on attacks
Reslizumab	• Eos raised	• Intravenous therapy, no • subcutaneous option

Chest. 2025 Feb;167(2):330-342.

생물학적 제제 투여기준 (급여기준)

투여대상 (다음 중 하나)

[기본조건] 고용량 ICS-LABA와 LAMA 사용에도 조절되지 않는 성인 환자로:

① 최근 1년 내 혈중 EOS ≥ 300 cells/μL

급성악화 ≥ 4회 (전신 스테로이드 필요), **또는** 최근 6개월간 지속적 경구 스테로이드 (≥ 프레드니솔론 5mg/day) 복용

② 최근 1년 내 혈중 EOS ≥ 400 cells/μL

급성악화 ≥ 3회 (전신 스테로이드 필요)

투여 지속 평가 기준 *(매년 평가, 필요시 조기 평가 가능)*

급성악화 빈도 **50% 이상 감소**

경구 스테로이드 용량 **50% 이상 감소** *(필요 환자만 해당)*

병용 및 교체투여 기준

생물학적 제제 간 **병용투여 불가**

생물학적 제제 간 **교체투여 원칙적 불가** *(단, omalizumab → 다른 약제 교체는 예외적 인정 가능)*

omalizumab → 타 약제 교체 조건:

omalizumab 3-6개월 사용 후 효과 부족, 부작용 또는 복약 순응도 개선 필요

교체 후 투여대상 기준 만족

Case 2

27/F

2025 local 천식 진단

High dose ICS 에 호전 없어 의뢰

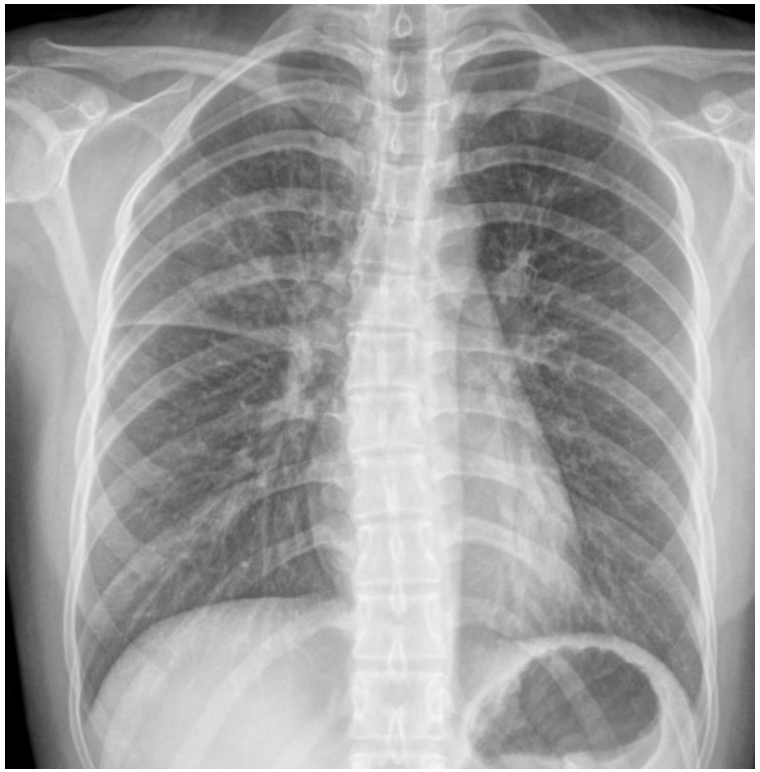
Budesonide/Formoterol/Tiotropium사용 중

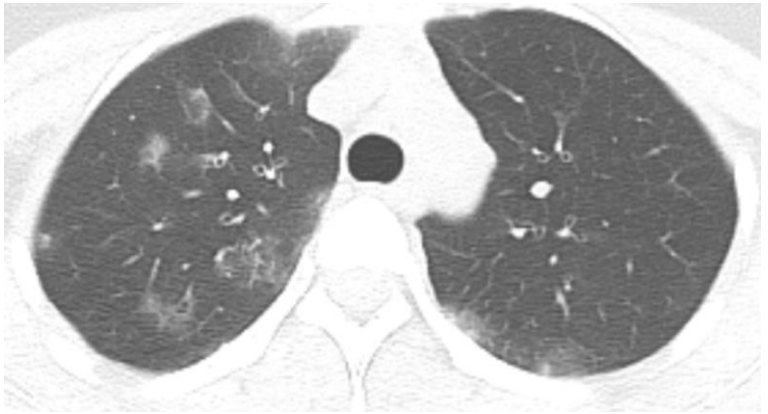
3제 사용 후에도 기침 악화, 발열

Never smoker

PFT: FEV1 2.23L (71%pred), FVC 2.59L (74%pred), FEV1/FVC 86%, BDR 2%

IgE 395 (skin test 집먼지 진드기+), BEC 2502 cells/microL, FeNO 82ppb





Hypereosinophilia w/u

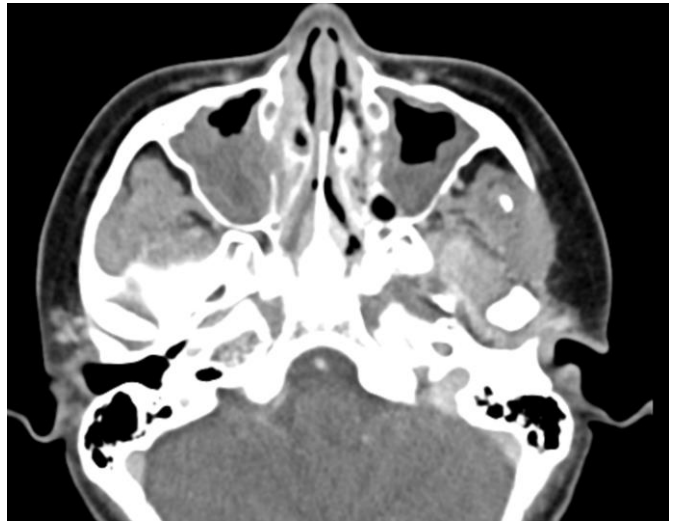
Parasite (-)

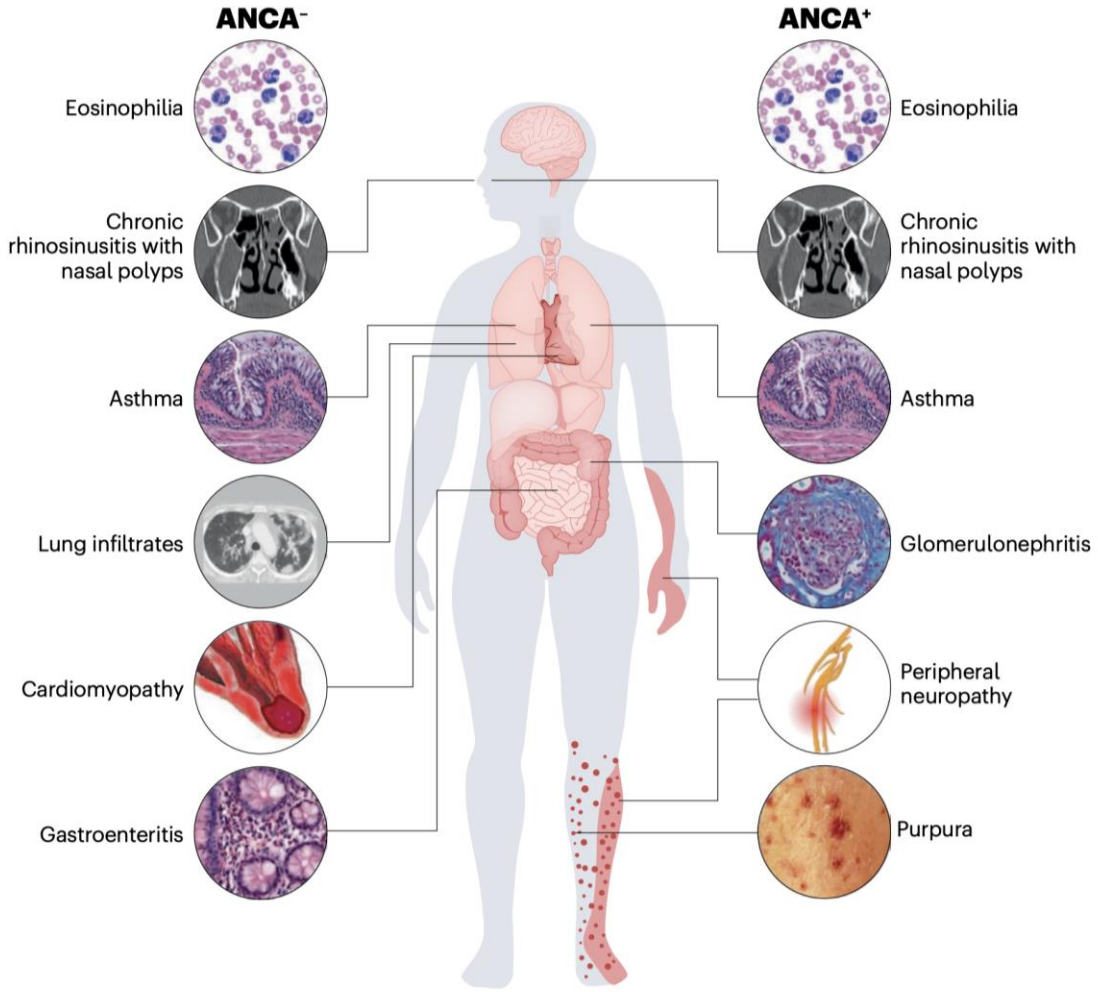
Neurologic involvement (-)

Skin lesions (-)

ANCA (-)

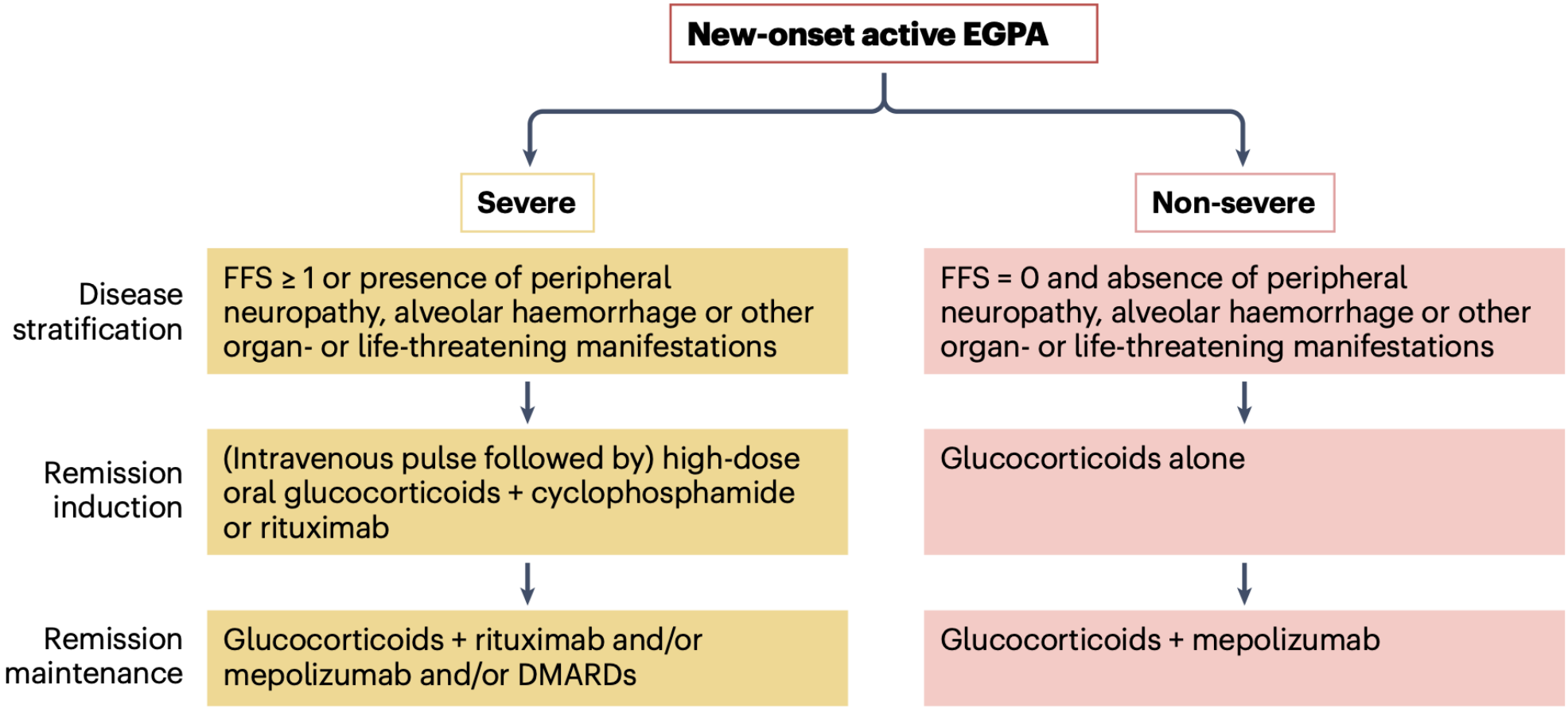
CRS (+)





Nat Rev Rheumatol. 2023 Jun;19(6):378-393.

EGPA management

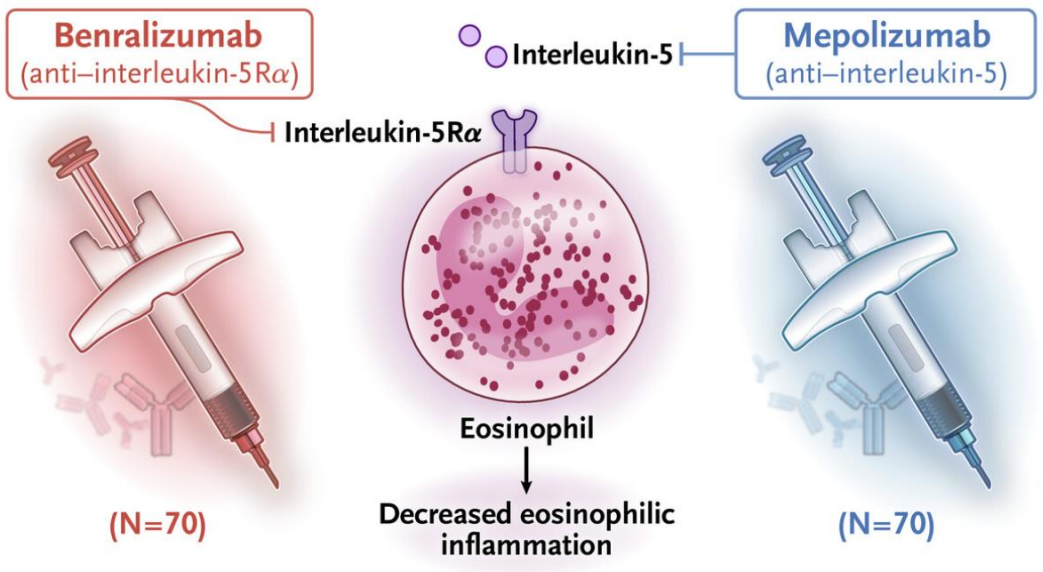


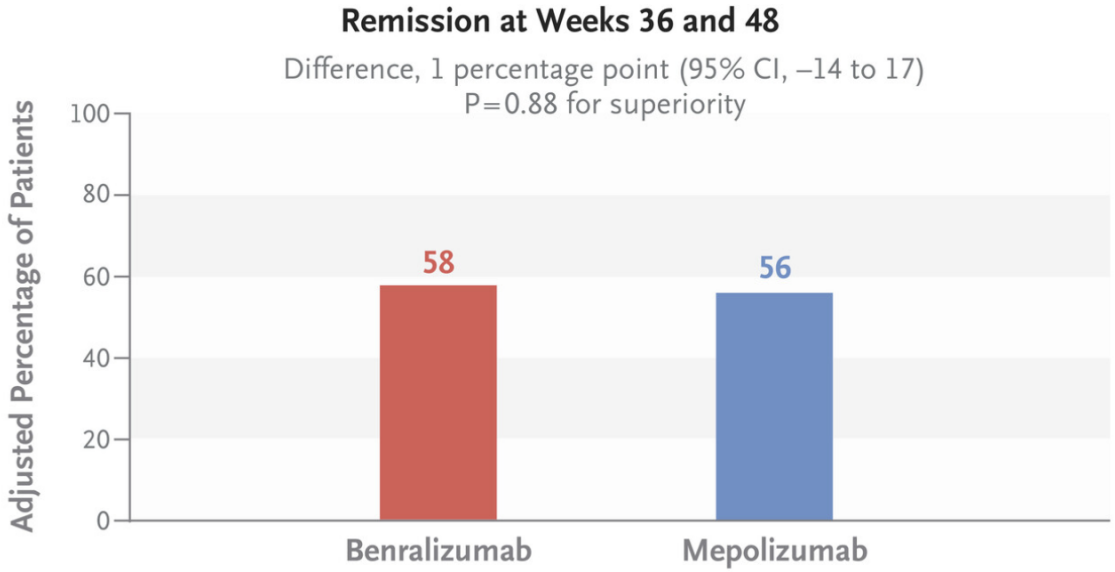
Nat Rev Rheumatol. 2023 Jun;19(6):378-393.

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Benralizumab versus Mepolizumab for Eosinophilic Granulomatosis with Polyangiitis





N Engl J Med 2024;390:911-921

Case 2

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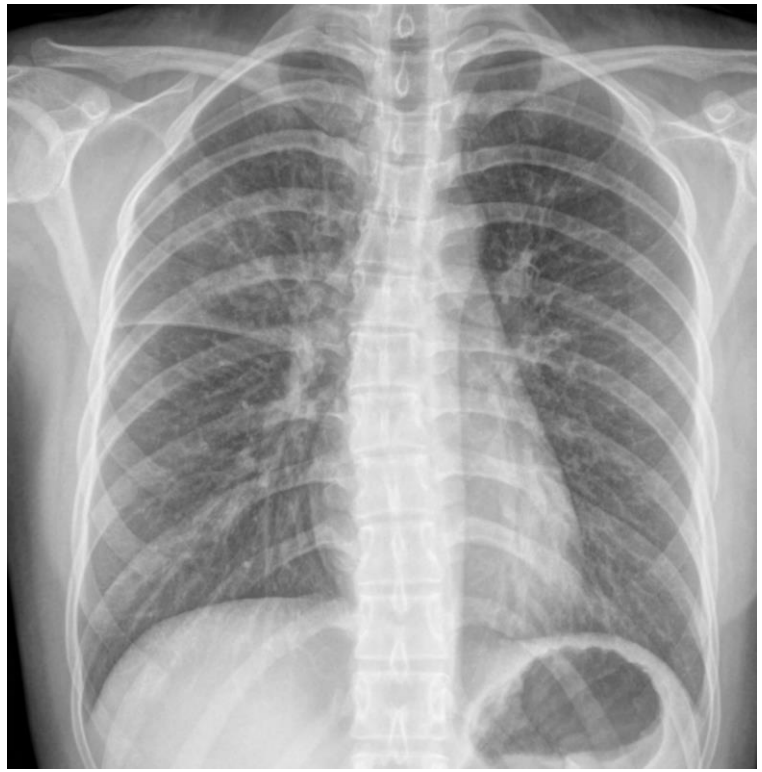
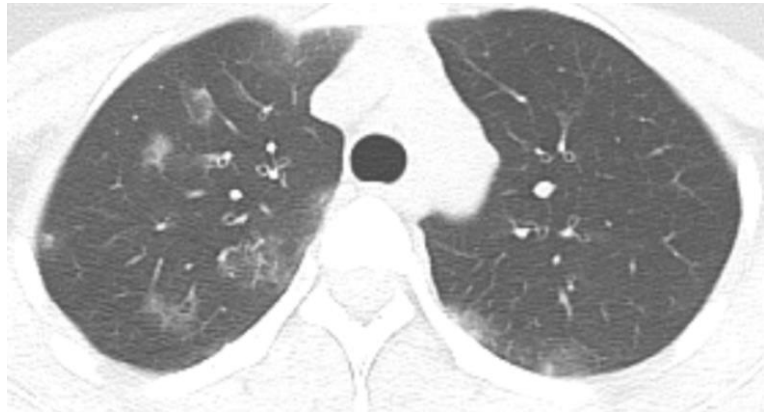




Biologics Safety in Pregnancy

Biologic	Human Pregnancy Data	Live Births Reported	Congenital Malformations	Preterm Births	Recommendation During Pregnancy
Omalizumab	Yes (EXPECT registry, case reports)	Yes (multiple, 233 in EXPECT registry)	No significant increase; ~8.1% (similar to background rate)	15%	Continue if benefits outweigh risks; not started newly
Mepolizumab	Yes (2 case reports)	Yes (1, another terminated)	None reported	1 reported	Data insufficient, 1 ongoing registry
Benralizumab	Yes (2 case reports)	Yes (1, no info for another)	None reported	1 reported	Data insufficient, 1 ongoing registry
Reslizumab	No	N/A	No data	No data	Avoid due to lack of data
Dupilumab	Yes (7 case reports)	Yes (7)	1 case with low birth weight, no malformations	1 preterm	Caution, observational studies ongoing
Tezepelumab	No	N/A	No data	No data	Avoid due to lack of data

J Allergy Clin Immunol Pract. 2022 Dec;10(12):3149-3155

Case 3 (가상)

56/W

40세 천식 진단

Never smoker

IgE 18 (skin test -), BEC 100 cells/microL, FeNO 15ppb

Are there factors masking T2 phenotype?

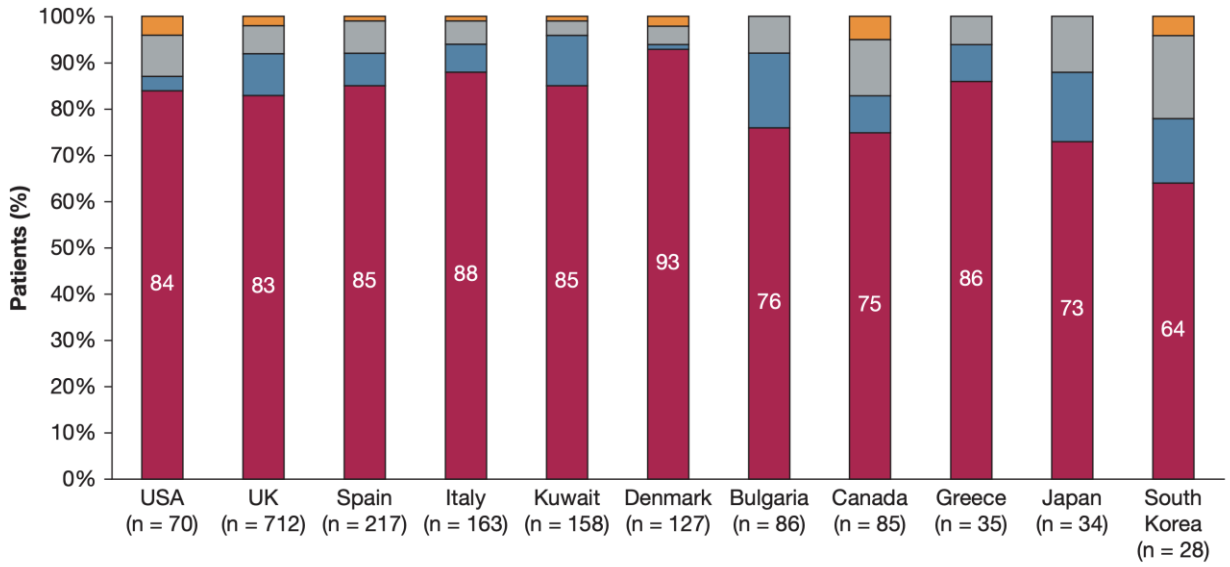
[Asthma Original Research]

CHEST

Eosinophilic and Noneosinophilic Asthma

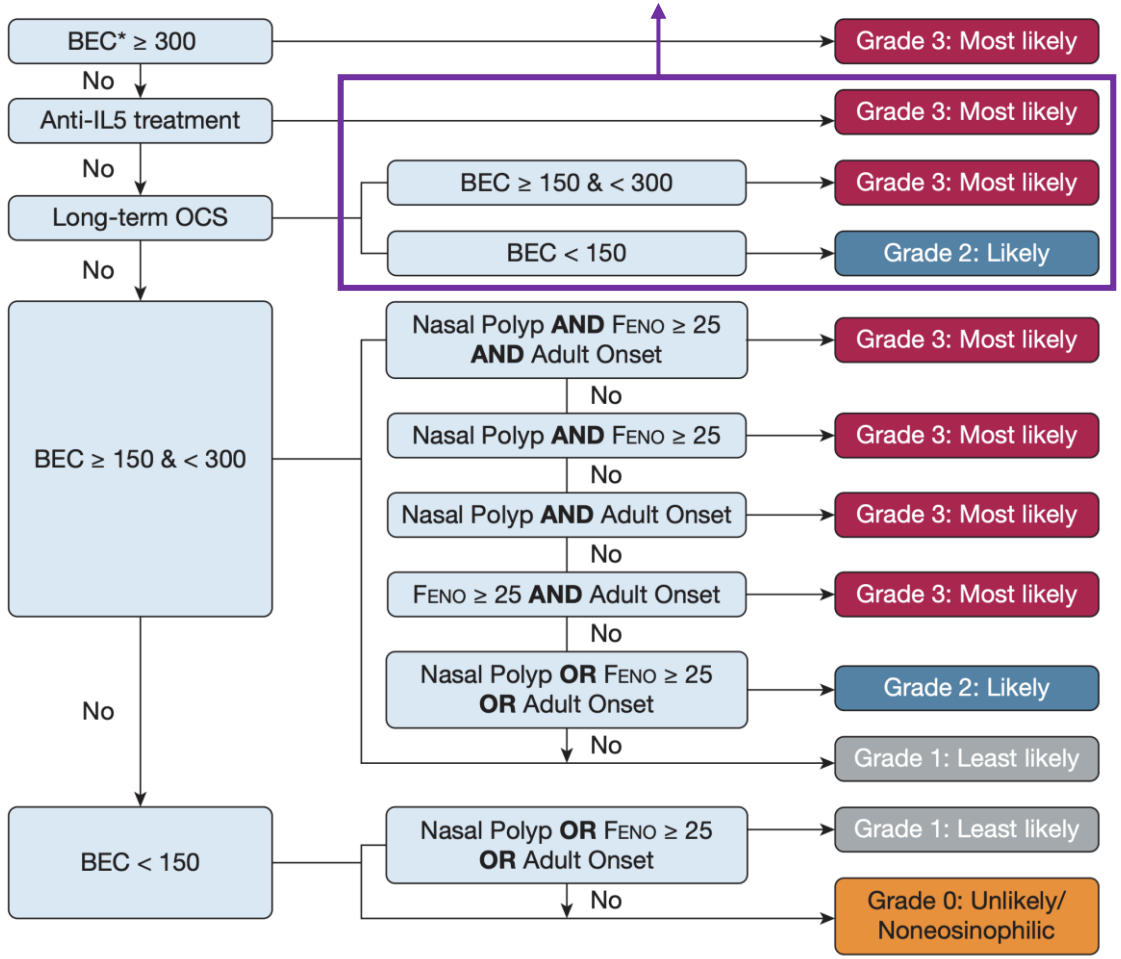
Check for updates

An Expert Consensus Framework to Characterize Phenotypes in a Global Real-Life Severe Asthma Cohort



64~93%

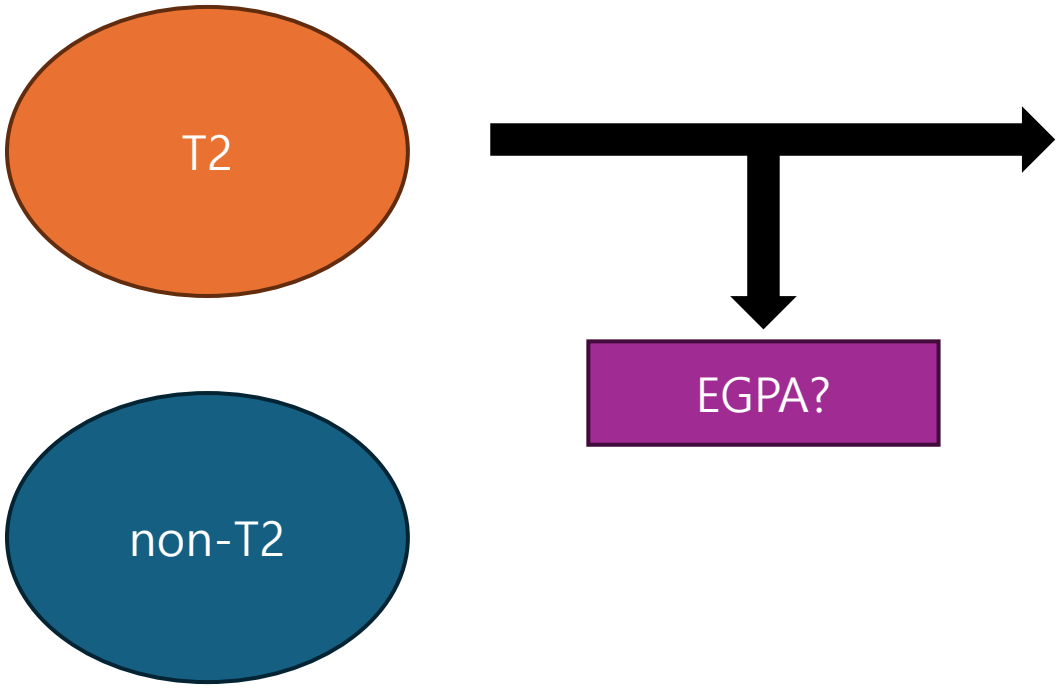
17%

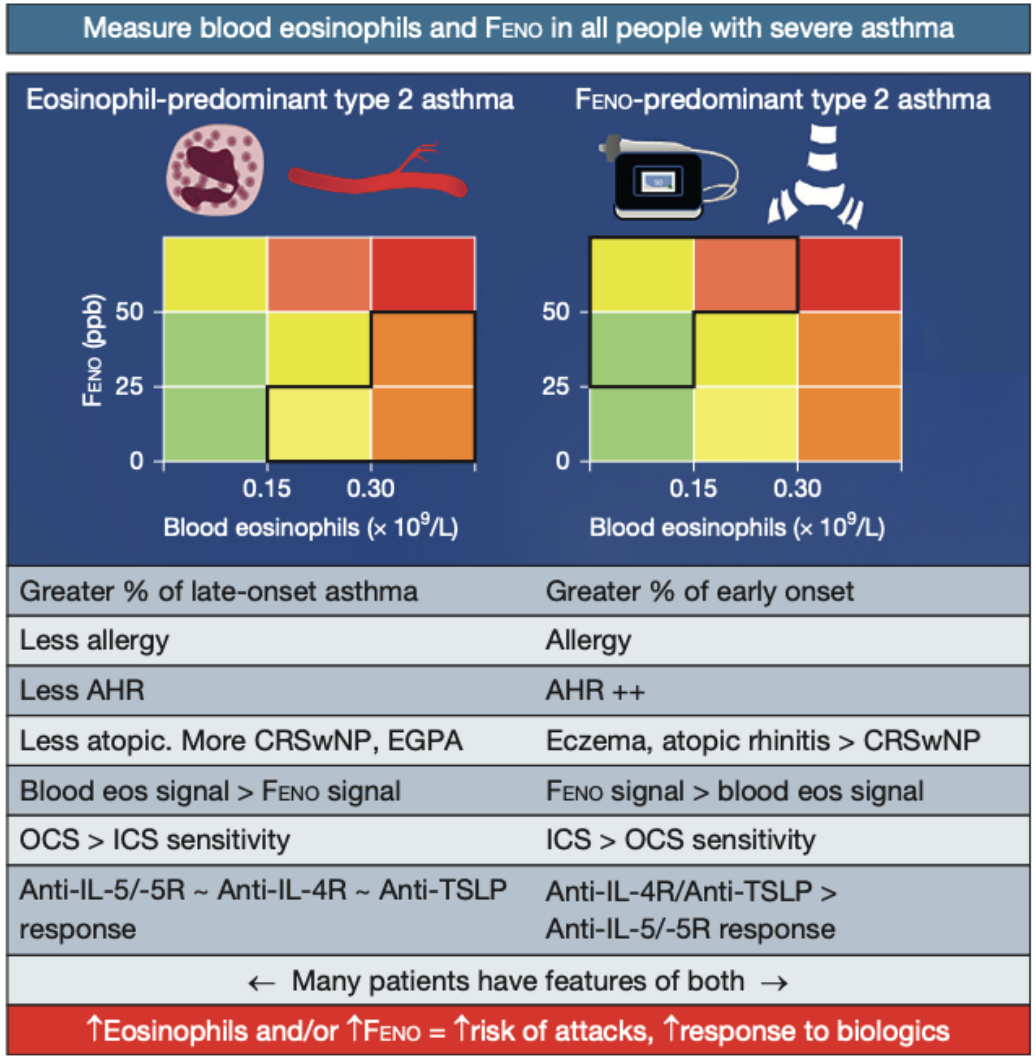


Therapeutic strategy of biologics approved in asthma

Therapeutic Strategy (Biologic)	Selection Criteria	Asthma Attacks	OCS Sparing	ACQ	FEV_1	AHR	Comorbidities	Comments
Anti-IgE (omalizumab)	Serum IgE 30-700 with perennial aeroallergen sensitization	+	Unclear	+	0	0	CSU ++ CRSwNP + Food allergy ++	Mostly studied in moderate asthma, less in very severe
Anti-IL-5 and anti-IL-5R (mepolizumab, reslizumab, benralizumab)	Blood eosinophils ≥ 0.15 $\times 10^9$ cells/L at screening or ≥ 0.3 $\times$ 10^9/L in past year	++	++	+	+	0/+	EGPA[a] ++ HES[a] ++ CRSwNP +	Major clinical effects proportional to eosinophilia
Anti-IL-4 and anti-IL-13 (dupilumab)	Blood eosinophils ≥ 0.15 $\times$ 10^9/L, FENO ≥ 25 ppb, or both	++	++	+	++	Unclear[b]	AD ++ CRsNP ++ EoE ++ PN ++	Induces transient eosinophilia independent of efficacy
Anti-TSLP (tezepelumab)	None[c]	++	0	+	++	+	?	Major efficacy when blood eosinophils, FENO, or both are raised; lesser yet significant efficacy when biomarkers low

Potential features of blood eosinophil and FeNO-predominant type 2 high-inflammatory asthma





Chest. 2025 Feb;167(2):330-342.

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Currently available biologics and consideration

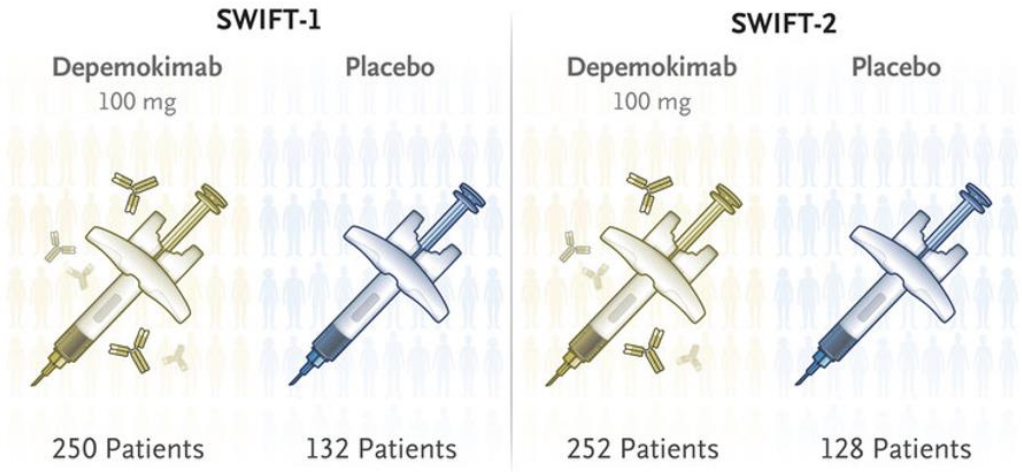
Future of Biologic Therapy for Asthma

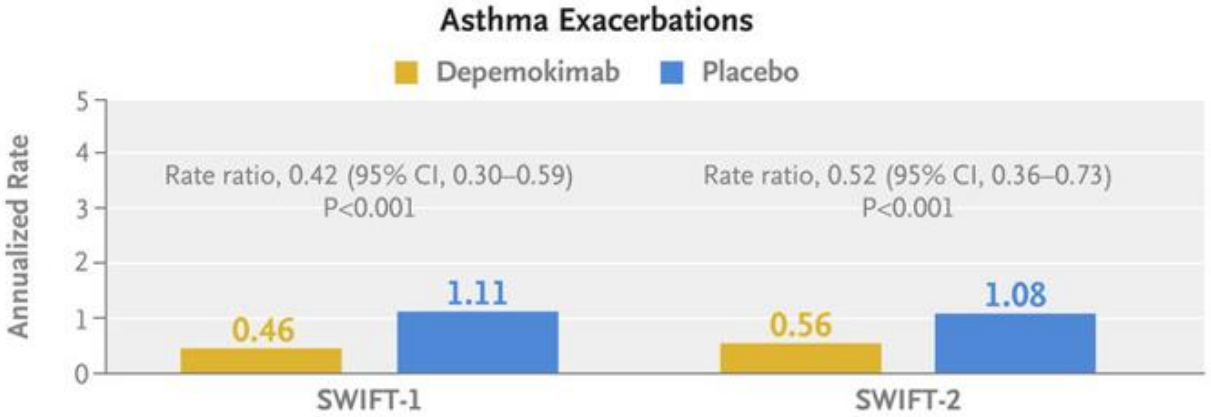
Ultra-long-acting biologic therapy

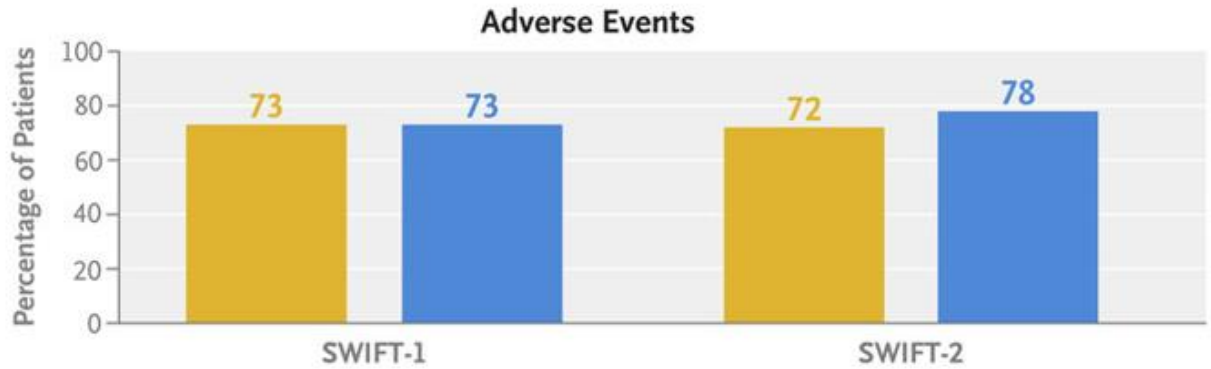
ORIGINAL ARTICLE

Twice-Yearly Depemokimab in Severe Asthma with an Eosinophilic Phenotype

Authors: David J. Jackson, Ph.D., Michael E. Wechsler, M.D., Daniel J. Jackson, M.D., David Bernstein, M.D., Stephanie Korn, M.D., Ph.D., Paul E. Pfeffer, Ph.D., Ruchong Chen, M.D., Ph.D., +9, for the SWIFT-1 and SWIFT-2 Investigators* Author Info & Affiliations







End Point	SWIFT-1			SWIFT-2			Pooled Trials	
	Depemokimab (N=250)	Placebo (N=132)	P Value†	Depemokimab (N=252)	Placebo (N=128)	P Value†	Depemokimab (N=502)	Placebo (N=260)
Primary end point								
Annualized rate of exacerbations at 52 wk (95% CI)	0.46 (0.36 to 0.58)	1.11 (0.86 to 1.43)	<0.001	0.56 (0.44 to 0.70)	1.08 (0.83 to 1.41)	<0.001	0.51 (0.43 to 0.60)	1.11 (0.92 to 1.33)
Rate ratio (95% CI)	0.42 (0.30 to 0.59)			0.52 (0.36 to 0.73)			0.46 (0.36 to 0.59)	
Percent between-group difference in annual rate (95% CI)	58 (41 to 70)			48 (27 to 64)			54 (41 to 64)	
No. of exacerbations‡	120	150		153	167		273	317
Secondary end points								
Change from baseline in SGRQ score at 52 wk§	−13.03±1.11	−9.67±1.54	0.08	−14.80±1.04	−12.49±1.46	0.20	−13.92±0.76	−11.04±1.06
Treatment difference (95% CI)	−3.36 (−7.11 to 0.39)			−2.31 (−5.84 to 1.23)			−2.88 (−5.43 to −0.32)	
Change from baseline in ACQ-5 score at 52 wk¶	−0.82±0.07	−0.77±0.09		−0.81±0.07	−0.70±0.09		−0.81±0.05	−0.73±0.06
Treatment difference (95% CI)	−0.04 (−0.27 to 0.18)			−0.11 (−0.33 to 0.11)			−0.08 (−0.24 to 0.07)	
Change from baseline in prebronchodilator FEV_1 at 52 wk — liter	0.16±0.03	0.16±0.04		0.24±0.03	0.18±0.04		0.20±0.02	0.17±0.03
Treatment difference (95% CI)	−0.01 (−0.089 to 0.088)			0.06 (−0.04 to 0.15)			0.03 (−0.04 to 0.09)	
Change from baseline in asthma nightly symptom diary at 52 wk‖	−1.39±0.12	−1.30±0.17		−1.18±0.09	−0.97±0.13		NA	
Treatment difference (95% CI)	−0.09 (−0.50 to 0.31)			−0.21 (−0.52 to 0.09)				
Change from baseline in asthma daily symptom diary at 52 wk‖	−1.33±0.10	−1.25±0.14		−1.13±0.08	−0.93±0.11		NA	
Treatment difference (95% CI)	−0.08 (−0.42 to 0.26)			−0.21 (−0.48 to 0.07)				
Annualized rate of exacerbations leading to hospitalization or ED visit at 52 wk (95% CI)**	NA			0.05 (0.02 to 0.09)	0.11 (0.05 to 0.22)		0.02 (0.01 to 0.04)	0.09 (0.05 to 0.15)
Rate ratio (95% CI)	NA			0.42 (0.16 to 1.13)			0.28 (0.13 to 0.61)	
Percent reduction in annual rate (95% CI)	NA			58 (−13 to 84)			72 (39 to 87)	
Number of exacerbations	5	13		16	18		21	31

OCS maintainers 3~10%; No evaluation for FeNO

D21 TERMINATOR: CONTROL OF AIRWAY INFLAMMATION AND IMMUNE RESPONSE IN ASTHMA / Poster Discussion Session / Wednesday, May 22/08:15 AM-10:15 AM / San Diego Convention Center, Room 31A-C (Upper Level)

A Multiple Ascending-dose Study With Verekitug, A Novel Antibody to the Human Thymic Stromal Lymphopoietin Receptor, in Adults With Asthma

D. Singh[1], A. Deykin[2], P. Lloyd[3], I. Nestorov[4], A. Kalra[2], S. Biswas[2], A. Sinha[2], C. Brickman[5], O. Becker[6]; [1]University of Manchester, Manchester, United Kingdom, [2]Upstream Bio Inc, Waltham, MA, United States, [3]KinDyn Consulting Ltd, Warnham, United Kingdom, [4]IN PKPD LLC, Acton, MA, United States, [5]Chaim Brickman Consulting Ltd, Zur Hadassah, Israel, [6]Oren Becker Consulting Ltd, Mevasseret Zion, Israel.

Study Design

RCT, double-blind, placebo-controlled
32 adults with mild-moderate asthma (↑ BEC)
4 dose cohorts (25–300 mg), SC, up to 3 doses
Observation: 32 weeks

Results

Well-tolerated: No serious AEs
Linear PK, full receptor occupancy
FeNO (↓ 43.4%) & BEC (↓ 42.6%)
Rapid effect in 2 weeks, sustained up to 24 weeks
Persistent anti-drug antibody in 21%

Conclusion

Safe, potent, long-acting biologic
Supports further development for severe asthma

VALIANT trial: Severe Asthma

Design
Multicenter RCT
Total enrollment: ~436 adults with **severe asthma**

Dosing Groups (1:1:1:1 randomization)
100 mg SC Q12W
400 mg SC **Q24W**
100 mg SC **Q24W**
Placebo

Primary Outcomes
Frequency of asthma exacerbations
Lung function and asthma control
Safety and tolerability

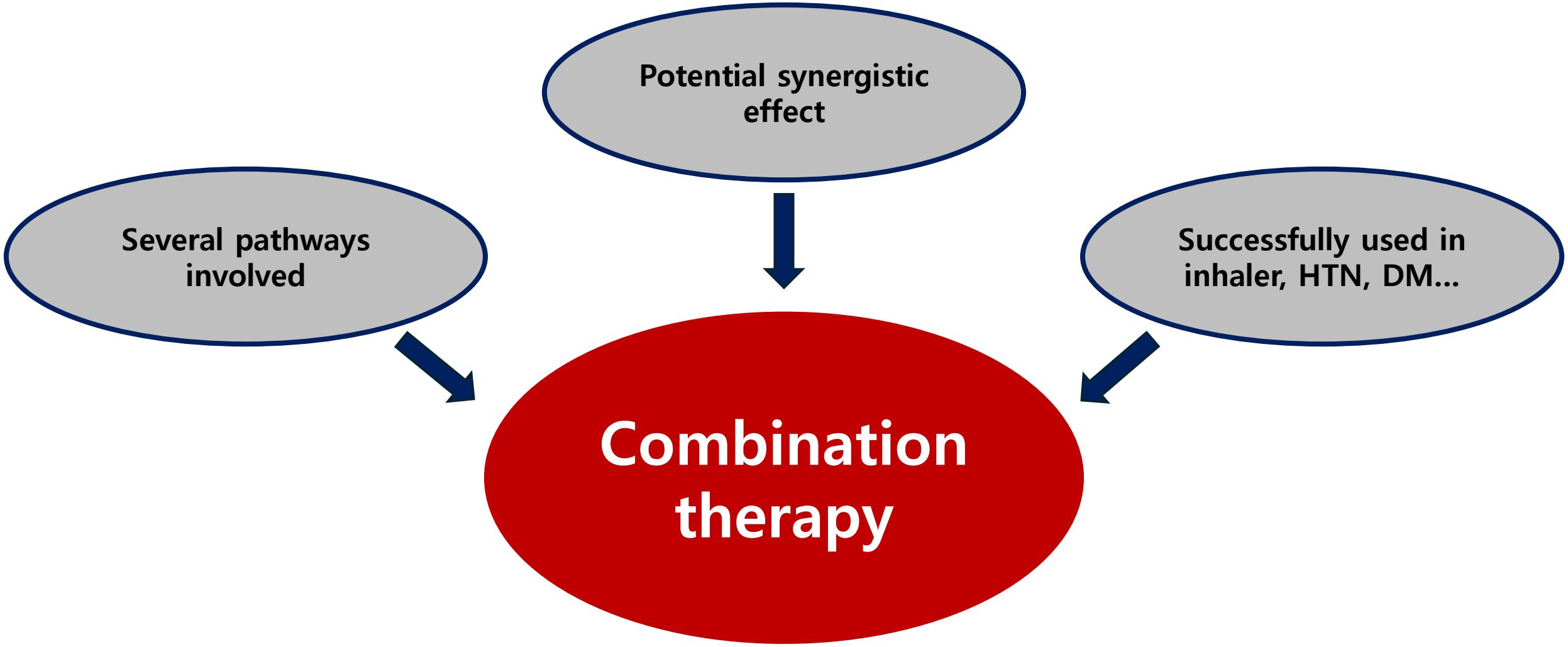
VIBRANT trial: CRSwNP

Design
Multicenter RCT
Total enrollment: ~70 adults with CRSwNP

Dosing Groups
Verekitug SC **Q24W**
Placebo

Primary Outcomes
Reduction in endoscopic nasal polyp size and extent
Safety and tolerability

Biologics combination therapy

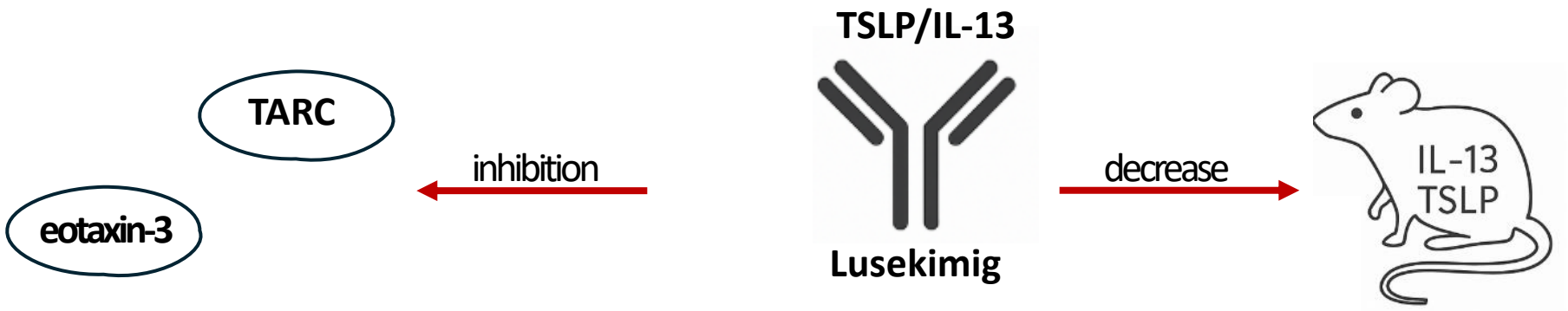


Conference Abstract Free

TSLP AND IL-13 Dual Blockade By Lunsekimig Provides Broader Benefits On Type-2 Inflammation

Yui-Hsi Wang | Hamid Mattoo | Joo-Hye Song Show More

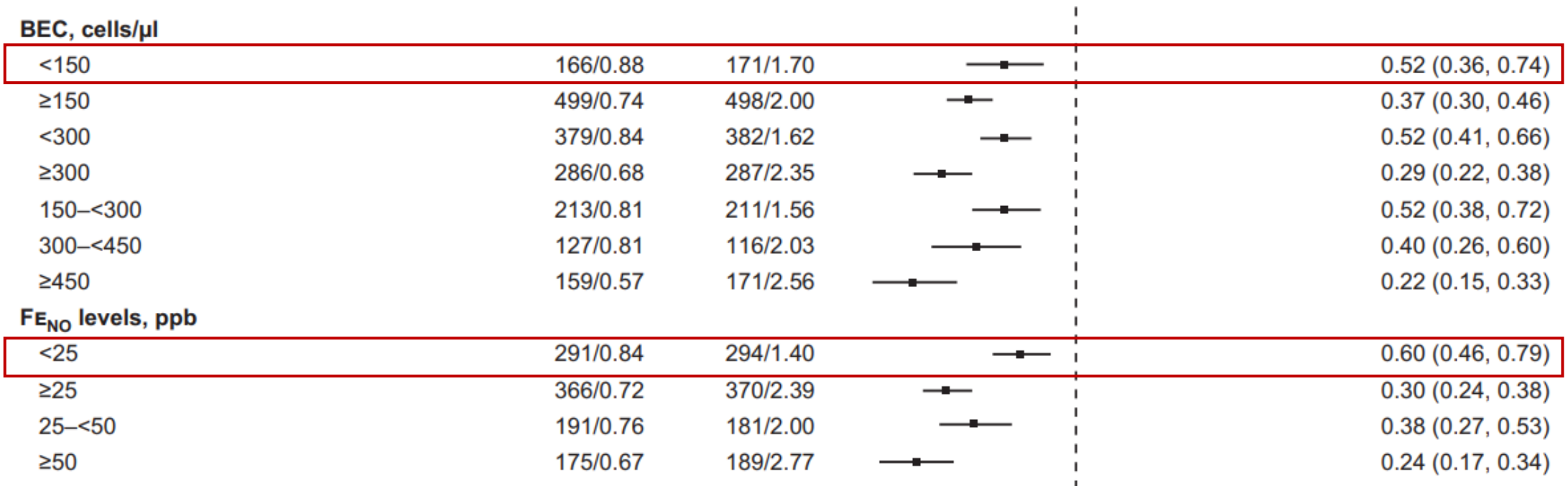
European Respiratory Journal 2024 64(suppl 68): PA4861; DOI: https://doi.org/10.1183/13993003.congress-2024.PA4861



“dual-targeting approach to TSLP and IL-13 inhibition may result in synergistic function”

Efficacy of Tezepelumab in Severe, Uncontrolled Asthma: Pooled Analysis of the PATHWAY and NAVIGATOR Clinical Trials

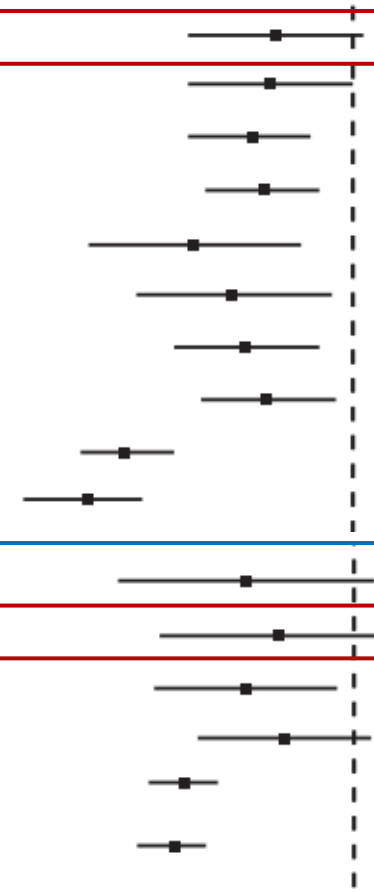
Jonathan Corren[1], Andrew Menzies-Gow[2,15], Geoffrey Chupp[3], Elliot Israel[4], Stephanie Korn[5,6], Bill Cook[7], Christopher S. Ambrose[7], Åsa Hellqvist[11], Stephanie L. Roseti[9], Nestor A. Molfino[12], Jean-Pierre Llanos[13], Neil Martin[15,16], Karin Bowen[8], Janet M. Griffiths[10], Jane R. Parnes[14], and Gene Colice[9]



Efficacy of Tezepelumab in Severe, Uncontrolled Asthma: Pooled Analysis of the PATHWAY and NAVIGATOR Clinical Trials

Jonathan Corren[1], Andrew Menzies-Gow[2,15], Geoffrey Chupp[3], Elliot Israel[4], Stephanie Korn[5,6], Bill Cook[7], Christopher S. Ambrose[7], Åsa Hellqvist[11], Stephanie L. Roseti[9], Nestor A. Molfino[12], Jean-Pierre Llanos[13], Neil Martin[15,16], Karin Bowen[8], Janet M. Griffiths[10], Jane R. Parnes[14], and Gene Colice[9]

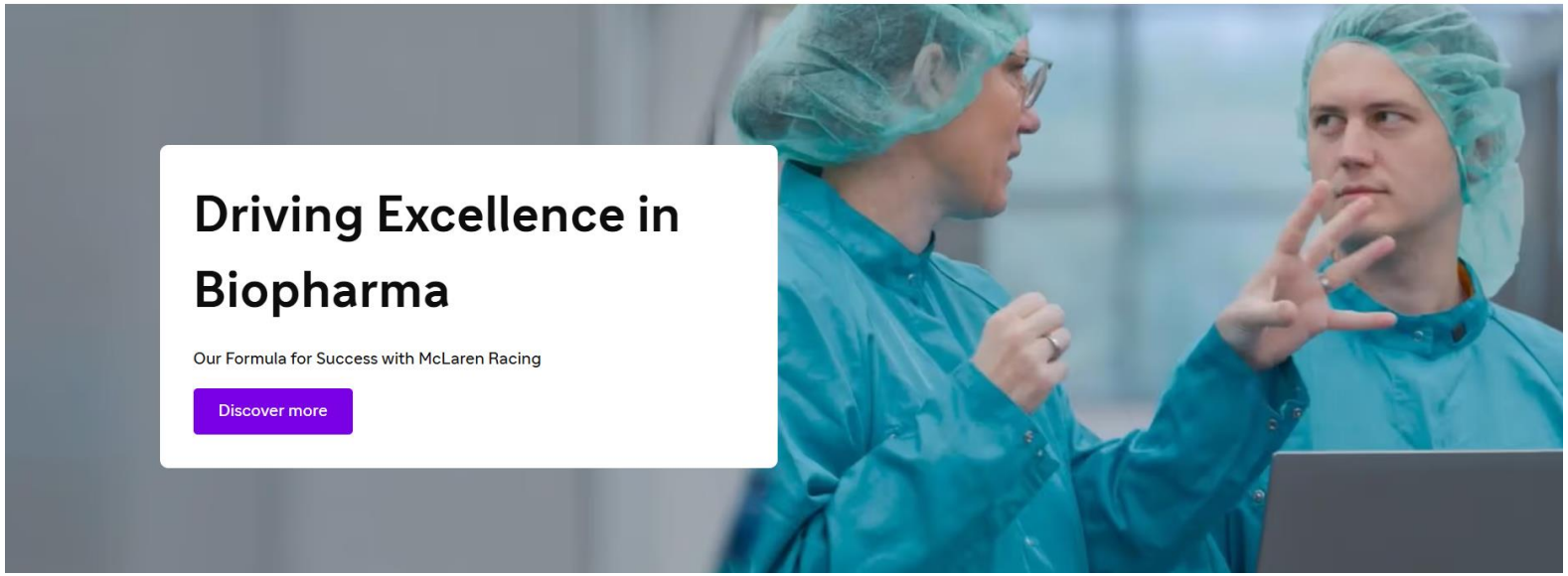
BEC <150 and FE_{NO} <25 (excl mOCS)	100/0.71	88/1.09	0.65 (0.40, 1.06)
BEC <150 and FE_{NO} <25	106/0.91	99/1.43	0.63 (0.40, 1.00)
BEC <300 and FE_{NO} <25 (excl mOCS)	197/0.72	187/1.28	0.57 (0.40, 0.79)
BEC <300 and FE_{NO} <25	208/0.87	202/1.44	0.61 (0.44, 0.83)
BEC <150 and FEIA negative (excl mOCS)	68/0.68	57/1.64	0.41 (0.23, 0.75)
BEC <150 and FEIA negative	71/0.85	69/1.65	0.51 (0.30, 0.89)
BEC <300 and FEIA negative (excl mOCS)	130/0.84	125/1.53	0.55 (0.37, 0.83)
BEC <300 and FEIA negative	145/1.03	143/1.65	0.62 (0.43, 0.91)
BEC ≥150 and FE_{NO} ≥25	309/0.69	301/2.43	0.28 (0.22, 0.37)
BEC ≥300 and FE_{NO} ≥25	200/0.65	195/2.88	0.23 (0.16, 0.31)
BEC <150, FE_{NO} <25 and FEIA negative (excl mOCS)	51/0.68	45/1.23	0.55 (0.27, 1.12)
BEC <150, FE_{NO} <25 and FEIA negative	52/0.81	49/1.22	0.66 (0.34, 1.30)
BEC <300, FE_{NO} <25 and FEIA negative (excl mOCS)	89/0.78	85/1.43	0.55 (0.33, 0.91)
BEC <300, FE_{NO} <25 and FEIA negative	94/0.97	90/1.43	0.68 (0.42, 1.10)
BEC ≥150 or FE_{NO} ≥25 or FEIA positive	612/0.77	618/1.99	0.39 (0.32, 0.47)
BEC ≥300 or FE_{NO} ≥25 or FEIA positive	568/0.74	575/2.02	0.37 (0.30, 0.44)



Efficacy of tezepelumab in patients with severe asthma and persistent airflow obstruction

Elliot Israel[1], Mario Castro[2], Christopher S. Ambrose[3], Jean-Pierre Llanos[4], Nestor A. Molfino[5], Nicole L. Martin[6,7], Sandhia S. Ponnarambil[8] and Neil Martin[9,10]

Biomarker level at baseline	Patients with PAO					Patients without PAO				
	LS mean±SE change from baseline L				LS mean difference (95% CI) L	LS mean±SE change from baseline L				LS mean difference (95% CI) L
	Tezepelumab 210 mg Q4W	n	Placebo	n		Tezepelumab 210 mg Q4W	n	Placebo	n	
BEC cells·μL^{-1}										
<150	0.03±0.05	79	−0.01±0.04	91	0.04 (−0.08–0.17)	0.10±0.05	87	0.17±0.05	80	−0.07 (−0.19–0.06)
≥150	0.30±0.02	306	0.10±0.02	302	0.20 (0.14–0.27)	0.24±0.03	187	0.10±0.03	194	0.15 (0.07–0.23)
<300	0.10±0.03	198	0.02±0.03	209	0.08 (0.00–0.16)	0.13±0.03	177	0.11±0.03	172	0.03 (−0.06–0.11)
≥300	0.40±0.03	187	0.13±0.03	184	0.27 (0.18–0.35)	0.32±0.04	97	0.13±0.04	102	0.19 (0.08–0.30)



Lunsekimig: potential for broader use in chronic obstructive pulmonary disease (COPD)

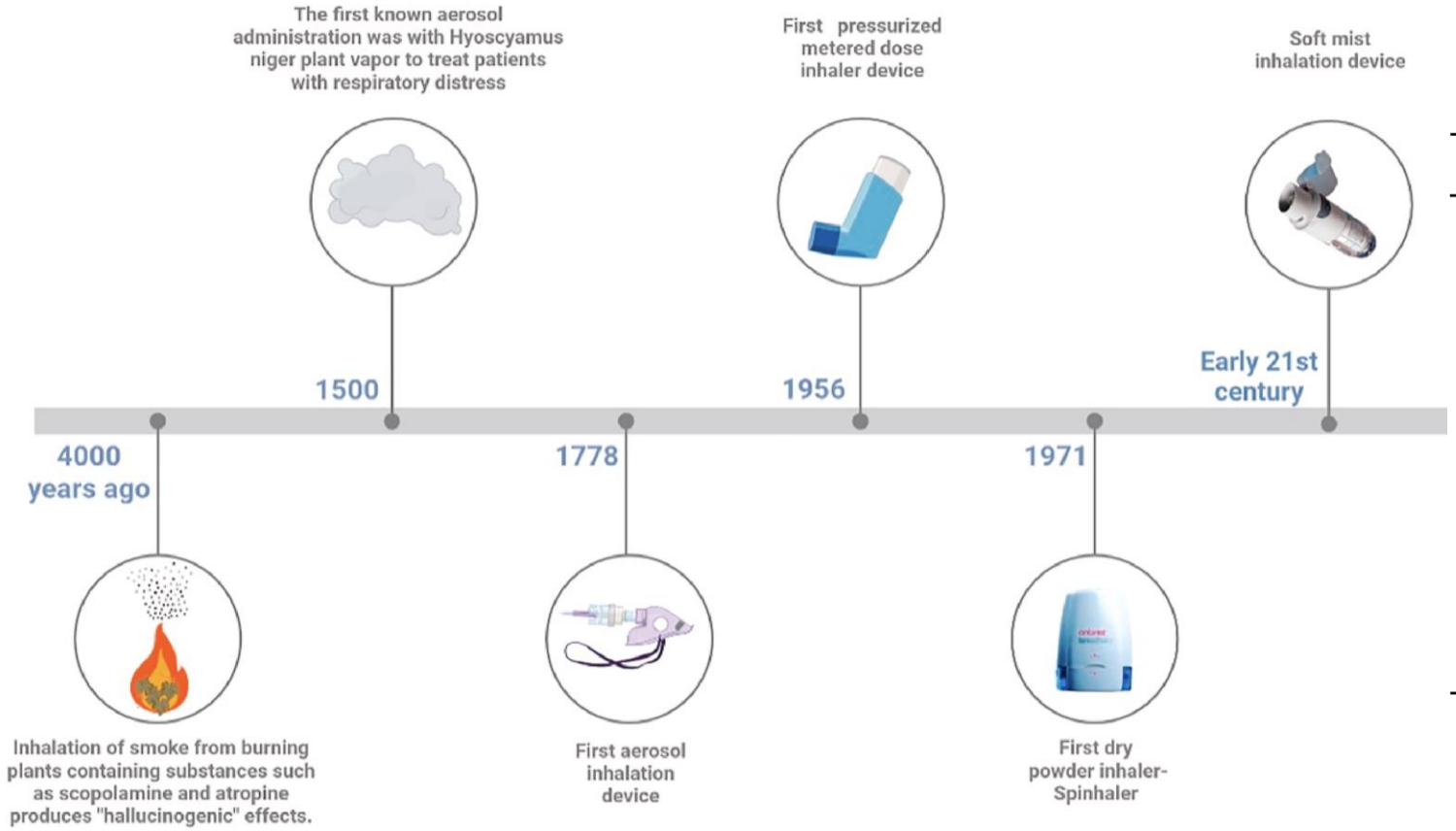
Lunsekimig is being explored in a broad population of asthma patients, regardless of their inflammation and severity status.

The readout of the AIRCULES phase 2 study (clinical study identifier: NCT06102005) in moderate to severe asthma is anticipated in 2026 while the AIRLYMPUS phase 2 study (clinical study identifier: NCT06676319) in high-risk asthma was initiated in Q4 2024.

The readout of the phase 2 study in patients with chronic rhinosinusitis with nasal polyps (clinical study identifier: NCT06454240) is anticipated in 2026.

A phase 2/3 study in COPD is anticipated to begin in 2025.

Inhaled biologics therapy



	Elements
Advantages	1. No first-pass effect of the liver.
	2. High bioavailability, reduced drug utilization dose and reduced side effects.
	3. Large alveolar surface area, fast absorption, rapid onset of action.
	4. Non-invasive and low risk of infection.
	5. Continuous drug release.
Disadvantages	1. pH stability and enzyme degradation.
	2. Physiologically tolerated components.
	3. Particle size and aerodynamic behavior.
	4. Regulatory and formulation requirements.
	5. May cause lung disease.

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Inhaled anti-TSLP antibody fragment, ecleralimab, blocks responses to allergen in mild asthma

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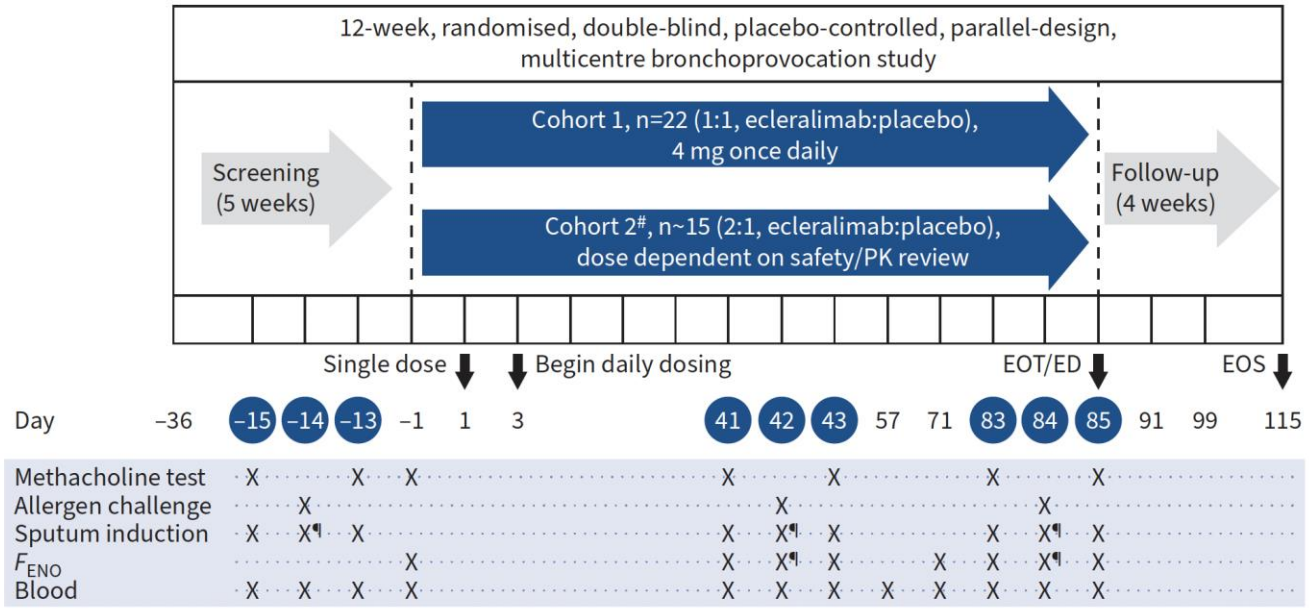
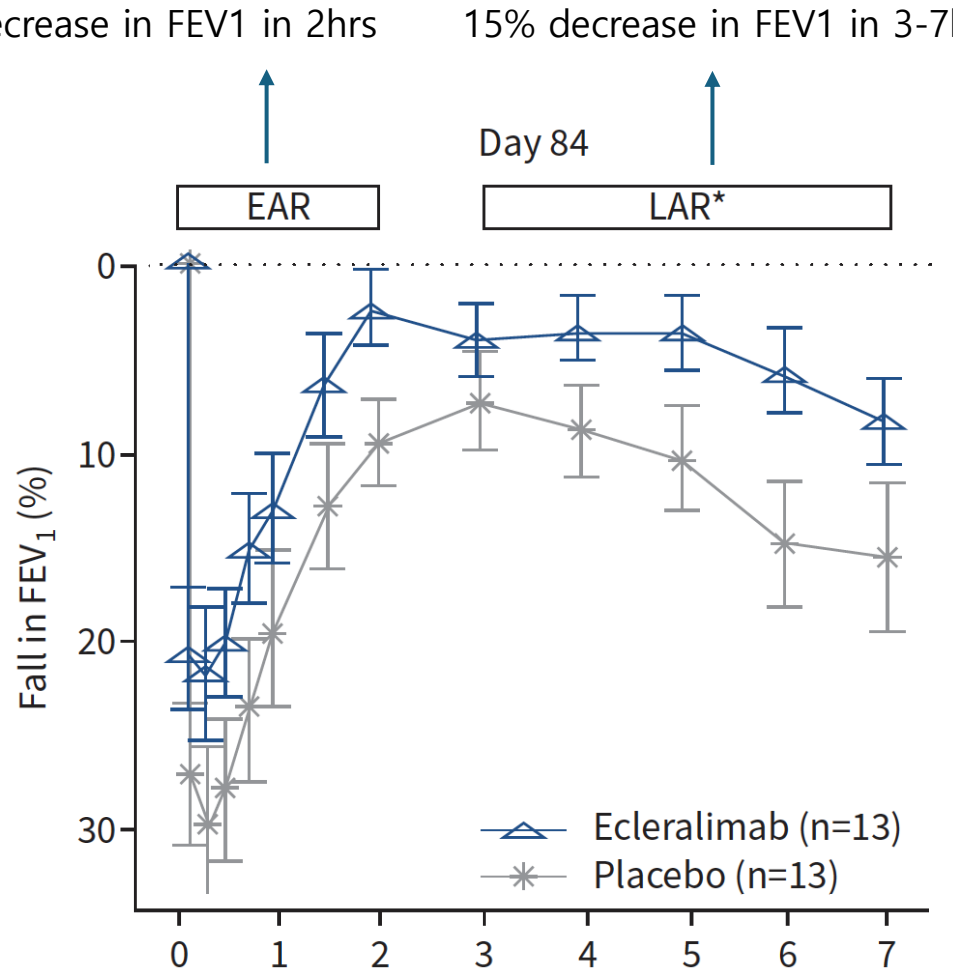


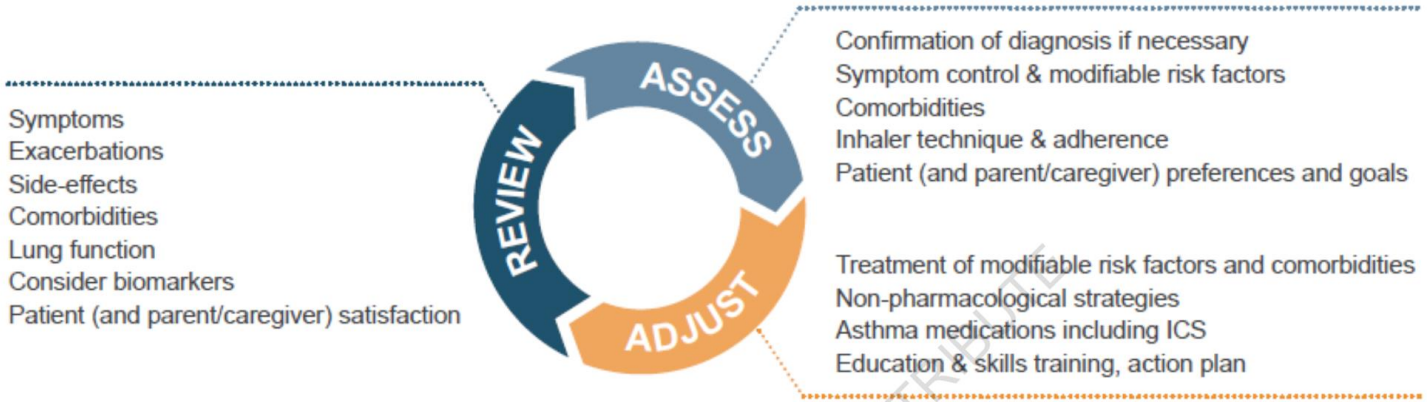


"하루 한 알로 살 뺀다"…일라이 릴리, 경구형 비만 치료제 임상 '성공적'

기사입력 : 2025년04월17일 22:56 | 최종수정 : 2025년04월17일 22:57

GINA 2025
Adults & adolescents 12+ years

Personalized asthma management
Assess, Adjust, Review
for individual patient needs



TRACK 1: PREFERRED CONTROLLER and RELIEVER
Using ICS-formoterol as the reliever* reduces the risk of exacerbations compared with using a SABA reliever, and is a simpler regimen

STEPS 1 – 2
AIR-only*: low-dose ICS-formoterol as needed

STEP 3
MART* with low-dose maintenance ICS-formoterol

STEP 4
MART* with medium-dose maintenance ICS-formoterol

STEP 5
Add-on LAMA
Refer for assessment of phenotype. Consider trial of high-dose maintenance ICS-formoterol. Consider anti-IgE, anti-IL5/5R, anti-IL4Rα, anti-TSLP

RELIEVER: As-needed low-dose ICS-formoterol*

TRACK 2: Alternative **CONTROLLER and RELIEVER**
Before considering a regimen with SABA reliever, check if the patient is likely to adhere to daily controller treatment

STEP 1
Reliever only; if SABA, take ICS with each dose

STEP 2
Low dose maintenance ICS

STEP 3
Low dose maintenance ICS-LABA

STEP 4
Medium dose maintenance ICS-LABA

STEP 5
Add-on LAMA
Refer for assessment of phenotype. Consider trial of high-dose maintenance ICS-LABA. Consider anti-IgE, anti-IL5/5R, anti-IL4Rα, anti-TSLP

RELIEVER: as-needed ICS-SABA*, or as-needed SABA

See GINA severe asthma guide

Summary

Currently available biologics and consideration

T2-high: biomarker -- BEC, FeNO

Pregnancy

T2 low: Tezepelumab

Future of Biologic Therapy for Asthma

Ultra long-acting biologics: verekitug

Combination biologics: lusekimig

Inhaled biologics: ecleralimab