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Improvement in Lung Function with Rademikibart in Eosinophilic-driven Type 2 Asthma

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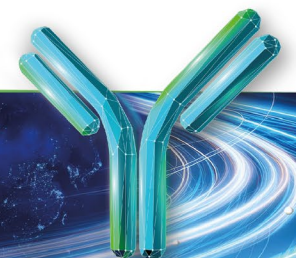
EAACI 2025, June 13 - 16, 2025

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- **Rekha Chaudhuri:**
 - Lecture fees - GSK, AstraZeneca, Teva, Chiesi and Sanofi
 - Advisory Board Meetings - GSK, AstraZeneca and Celltrion
 - Consultant to Connect Biopharma
 - Sponsorship to attend international scientific meetings - Chiesi and Sanofi
 - Research grant - AstraZeneca for a UK multi-centre study

- **Raúl Collazo and Barry Quart** are employees and shareholders of Connect Biopharma

Background

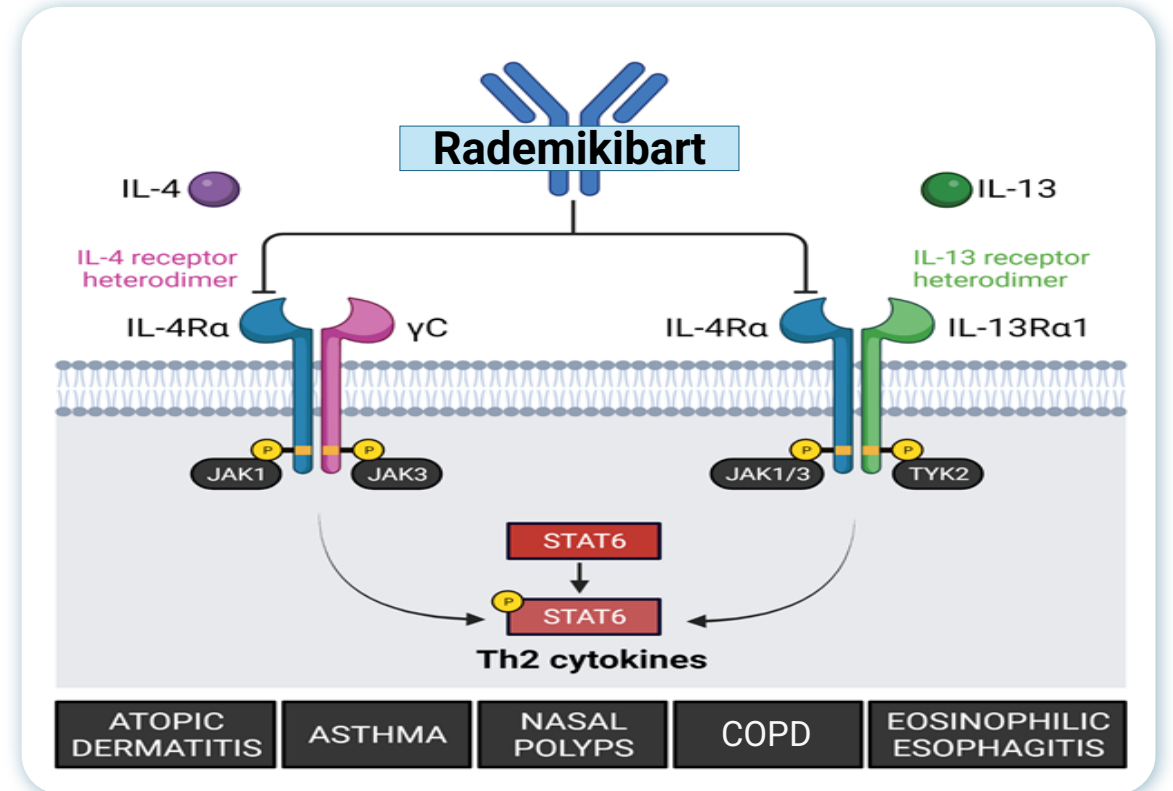
Rademikibart, an IL-4R α blocker, improves asthma outcomes

Rademikibart (formerly CBP-201)

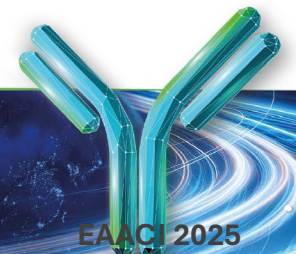
- Targets IL-4R α , binding tightly to different epitopes than dupilumab, potently inhibiting IL-4 and IL-13 signaling^{1,2}
- Lung function improved rapidly, sustained across 24 weeks, in the overall population of a phase 2b trial^{3,4}

Objective

- To further evaluate lung function in patients with Type 2 inflammation–driven asthma, as indicated by baseline eosinophil counts, in the Phase 2b trial



1. Zhang L, et al. Sci Rep. 2023;13:12411. 2. Bunick A, et al. ATS 2025. Poster #12320. 3. Kerwin, E et al. Am J Respir Crit Care Med. 2025; 5:749-758. 4. Collazo R, et al. ATS 2025. Poster #13121. GINA, Global Initiative for Asthma; ICS, inhaled corticosteroid; IL, interleukin; IL-4R α , IL-4-receptor alpha; LABA, long-acting β 2-agonist.



The phase 2b asthma trial of rademikibart

Trial name: CBP-201-WW002¹
ClinicalTrials.gov: NCT04773678

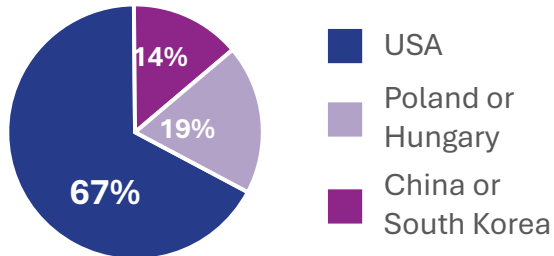
Primary endpoint: absolute change from baseline in prebronchodilator (trough) FEV₁ at Week 12

Adults with moderate-to-severe uncontrolled asthma

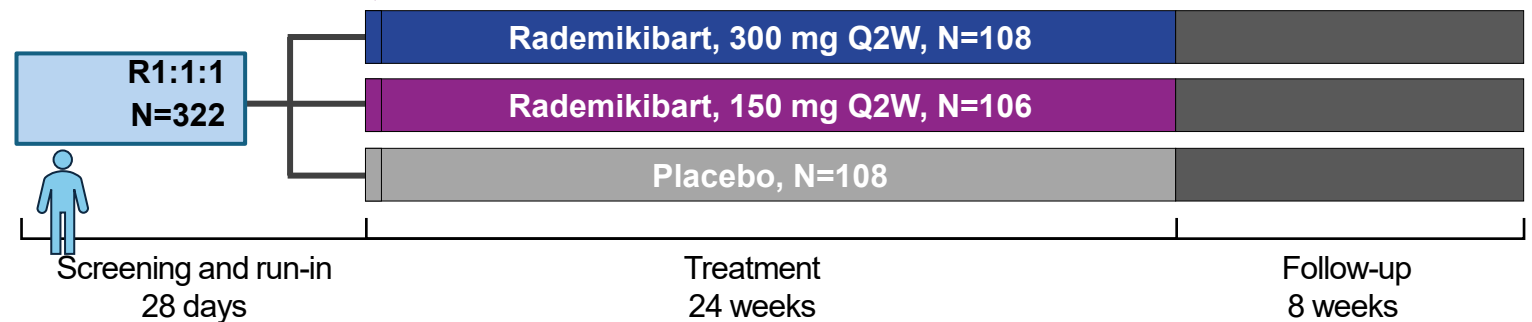


- ACQ-6 ≥ 1.5 and prebronchodilator FEV₁ 40–85% of predicted normal, at screening and baseline
- Medium-to-high dose ICS and reliever/controller for ≥ 90 days (stable dose ≥ 28 days) at screening, maintained in the study without dose adjustment
- ≥ 1 asthma exacerbation in the past year (requiring systemic CS, $\sim 4x$ baseline ICS dose, or hospitalization/emergency care)
- Screening blood eosinophils ≥ 150 cells/ μL , amended in the protocol to ≥ 300 cells/ μL , and no eosinophil requirement if using maintenance oral CS

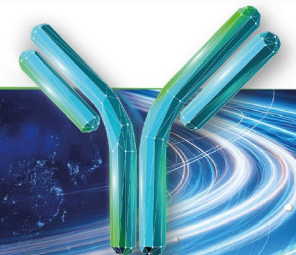
Enrollment began April 2021, with study completion September 2023



600 mg loading dose or placebo equivalent



1. Kerwin, E et al. Am J Respir Crit Care Med. 2025; 5:749-758. ACQ, Asthma Control Questionnaire; CS, corticosteroid; FEV₁, forced expiratory volume in one second; ICS, inhaled corticosteroid; R, randomized; Q2W, every other week.



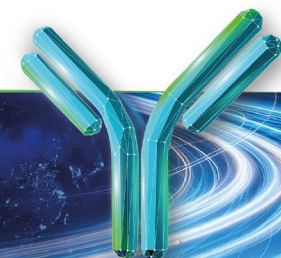
Baseline characteristics

Overall population

Characteristic*	Placebo (N=108)	Rademikibart 150 mg Q2W (N=106)	Rademikibart 300 mg Q2W (N=108)
Age (years)	54.8 (12.4)	51.6 (12.0)	52.7 (12.9)
Female, n (%)	60 (55.6)	70 (66.0)	68 (63.0)
Body mass index (kg/m ²)	30.5 (7.4)	30.4 (6.8)	30.5 (6.6)
Prebronchodilator FEV₁ (mL)	1,836 (578)	1,908 (647)	1,902 (590)
Percent predicted FEV₁	61.6 (10.8)	63.3 (10.9)	64.7 (12.4)
FEV ₁ reversibility (%) [†]	28.0 (14.9)	24.4 (11.2)	27.5 (15.4)
FeNO (ppb)	31.6 (31.5)	35.8 (35.1)	33.8 (32.7)
ACQ-6 score	2.72 (0.64)	2.71 (0.72)	2.68 (0.71)
Eosinophil counts (cells/μL)	299 (229)	268 (179)	320 (220)
Eosinophil counts, n (%)			
< 150 cells/μL	26 (24.1)	26 (24.5)	23 (21.3)
150 < 300 cells/μL	41 (38.0)	42 (39.6)	35 (32.4)
≥ 300 cells/μL	41 (38.0)	38 (35.8)	50 (46.3)
Maintenance oral/systemic CS, n (%) [‡]	21 (19.4)	15 (14.1)	10 (9.2)
Exacerbations across the past 12 months [†]	1.13 (0.39)	1.11 (0.35)	1.10 (0.33)

*Mean (standard deviation) at baseline, unless otherwise noted. [†]At screening. [‡]At randomization.

ACQ, Asthma Control Questionnaire. CS, corticosteroid. FEV₁, Forced expiratory volume in one second. Q2W, every other week.



Baseline characteristics

Elevated baseline eosinophil subgroups (≥ 150 or ≥ 300 cells/ μL)

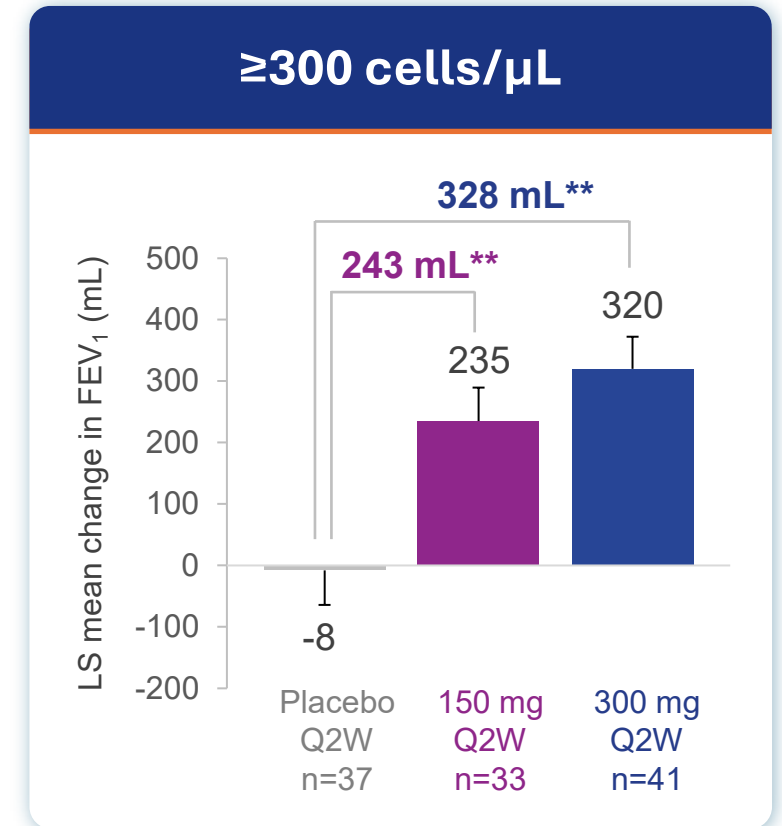
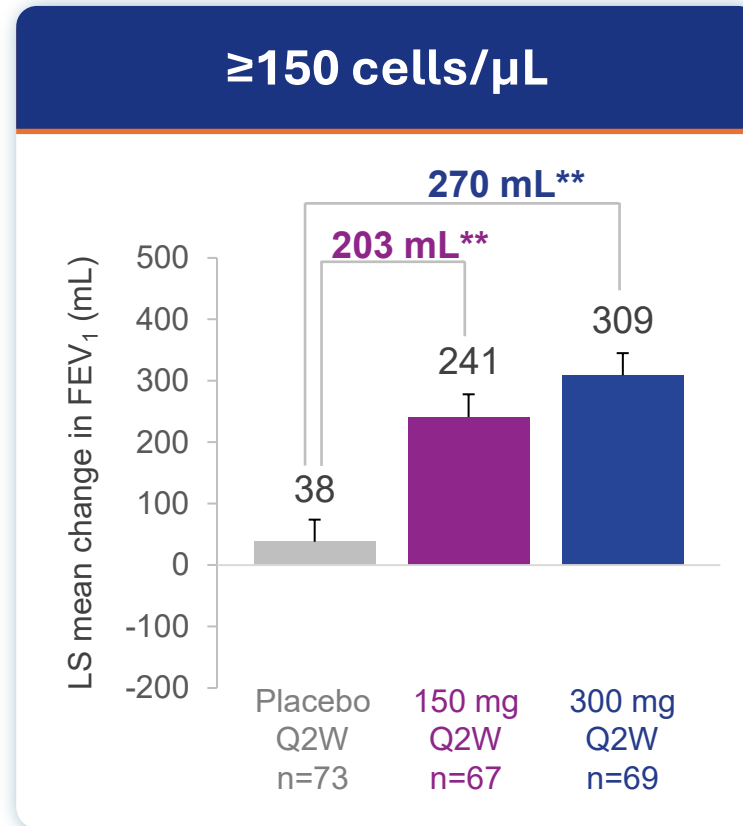
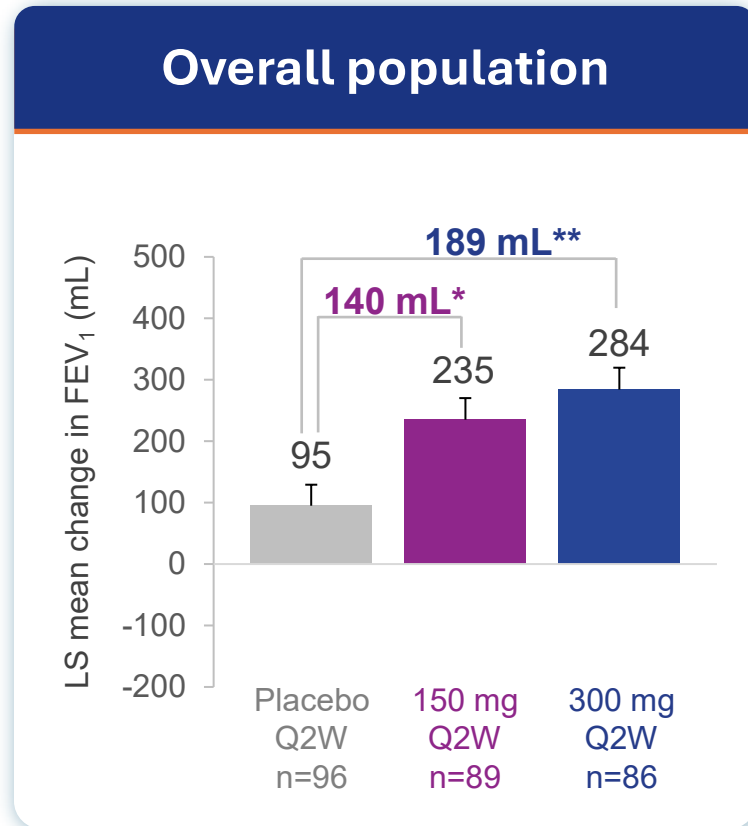
Mean (standard deviation) at baseline, unless otherwise noted	≥ 150 cells/ μL			≥ 300 cells/ μL		
	Placebo N=82	150 mg Q2W ^a N=80	300 mg Q2W ^a N=85	Placebo N=41	150 mg Q2W ^a N=38	300 mg Q2W ^a N=50
Age (years)	55.5 (12.5)	53.1 (11.4)	51.6 (13.0)	55.9 (11.4)	49.8 (11.5)	49.6 (13.1)
Female, n (%)	46 (56.1)	57 (71.2)	54 (63.5)	26 (63.4)	25 (65.8)	28 (56.0)
Body mass index (kg/m ²)	30.2 (7.2)	30.6 (6.8)	30.4 (6.4)	29.3 (7.1)	29.5 (5.8)	30.7 (6.7)
Prebronchodilator FEV ₁ (mL)	1,796 (555)	1,860 (625)	1,932 (589)	1,764 (502)	1,946 (699)	2,050 (557)
Percent predicted FEV ₁	60.8 (11.0)	63.5 (11.3)	65.1 (11.8)	61.9 (10.4)	63.6 (12.2)	66.5 (10.6)
FEV ₁ reversibility (%) at screening	28.4 (15.1)	23.7 (11.0)	27.2 (15.0)	28.7 (16.8)	23.4 (11.8)	25.8 (12.5)
Weekly morning PEF (L/min)	296.0 (117.7)	285.0 (115.1)	327.9 (111.0)	283.6 (110.5)	303.5 (126.8)	337.1 (101.8)
ACQ-6 score	2.74 (0.65)	2.77 (0.72)	2.68 (0.72)	2.87 (0.68)	2.86 (0.75)	2.73 (0.71)
Exacerbations in year before screening	1.12 (0.43)	1.06 (0.33)	1.05 (0.21)	1.15 (0.48)	1.11 (0.45)	1.08 (0.27)
Eosinophil counts (cells/ μL)	366.7 (222.5)	326.8 (168.0)	381.9 (207.9)	527.6 (213.7)	458.9 (155.5)	498.2 (197.9)
FeNO (ppb)	34.1 (31.0)	40.0 (39.0)	38.0 (35.2)	41.2 (37.1)	53.2 (48.2)	46.6 (41.2)
Maintenance oral/systemic CS, n (%)	12 (14.6)	8 (10.0)	3 (3.5)	6 (14.6)	2 (5.3)	0

^aRademikibart groups. ACQ, Asthma Control Questionnaire; CS, corticosteroid; FeNO, fractional exhaled nitric oxide; FEV₁, forced expiratory volume in one second; PEF, peak expiratory flow; Q2W, every other week.

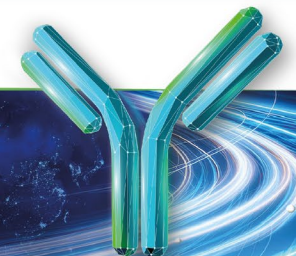


Prebronchodilator FEV₁ at Week 12 (primary endpoint)

Change from baseline in the overall population and elevated baseline eosinophil subgroups

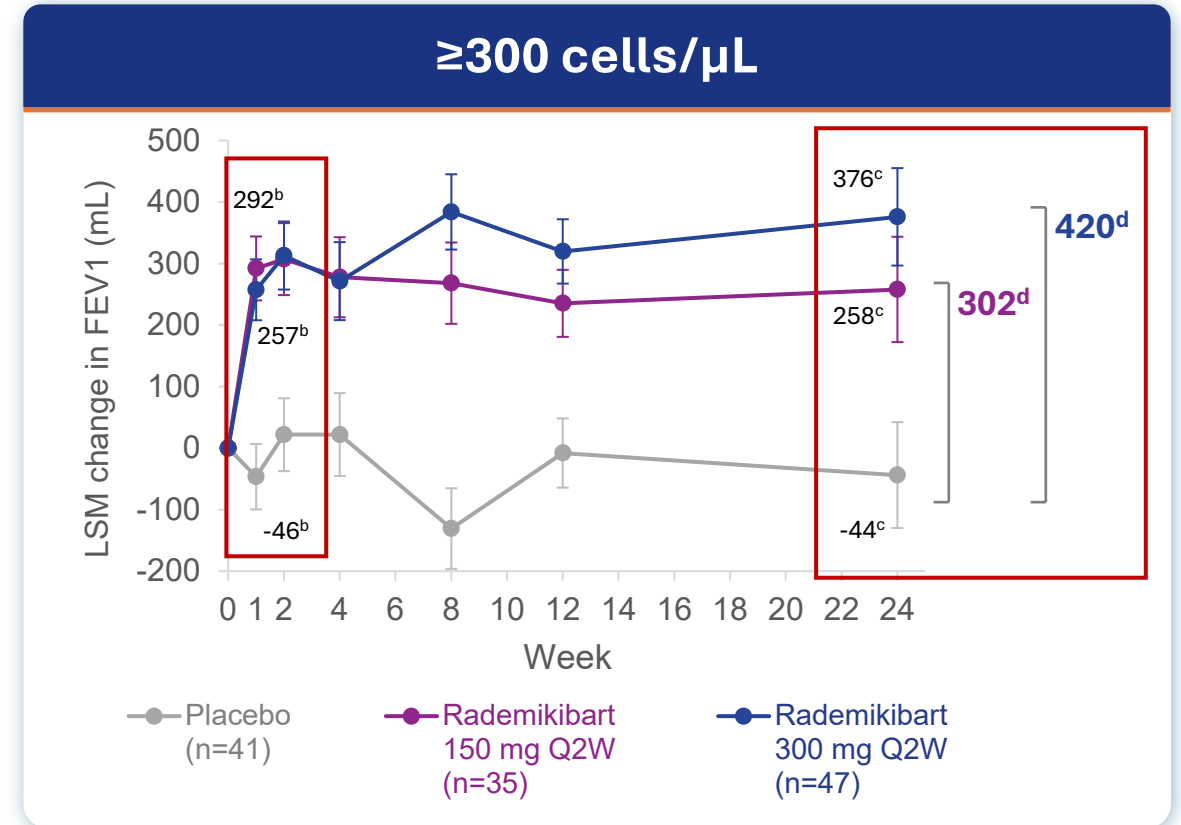
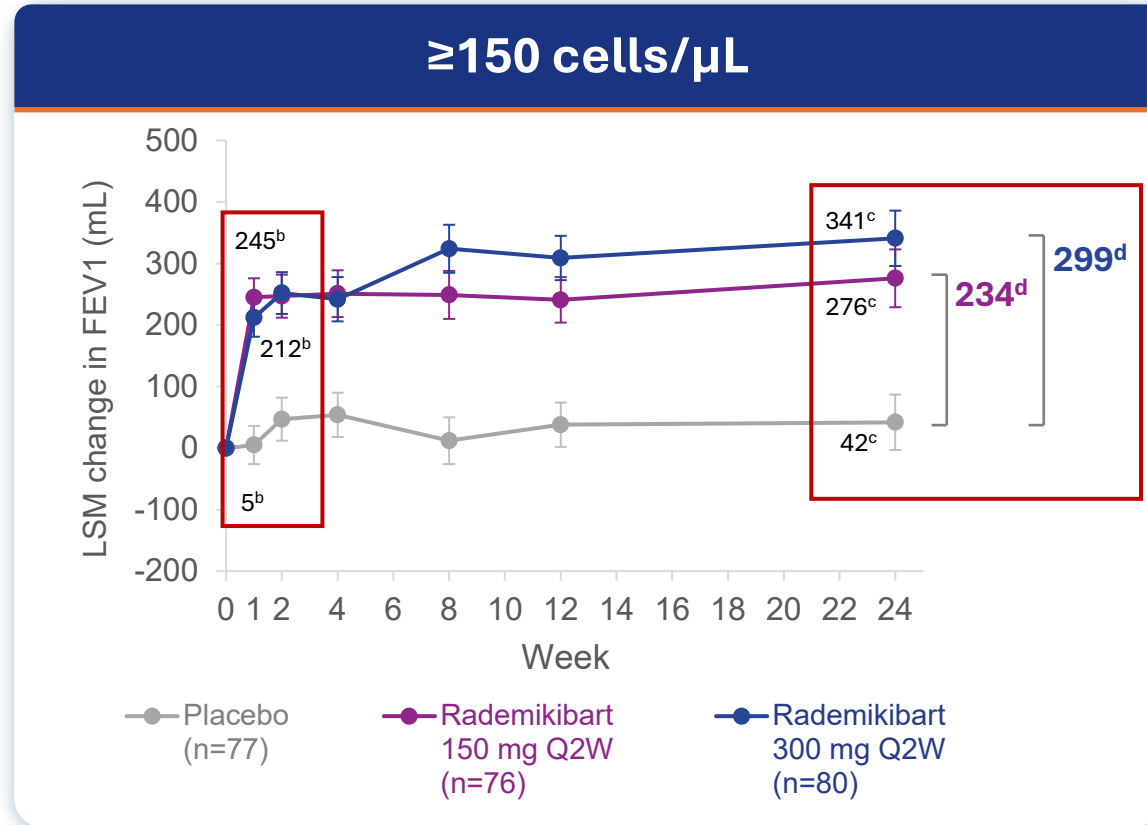


* $p=0.005$; ** $p<0.001$. Standard error bars. Data analyzed by ANCOVA (analysis of covariance). FEV₁, forced expiratory volume in one second; LSM, least squares mean; Q2W, every other week.



Prebronchodilator FEV₁ across 24 weeks of therapy^a

Change from baseline in the elevated baseline eosinophil subgroups



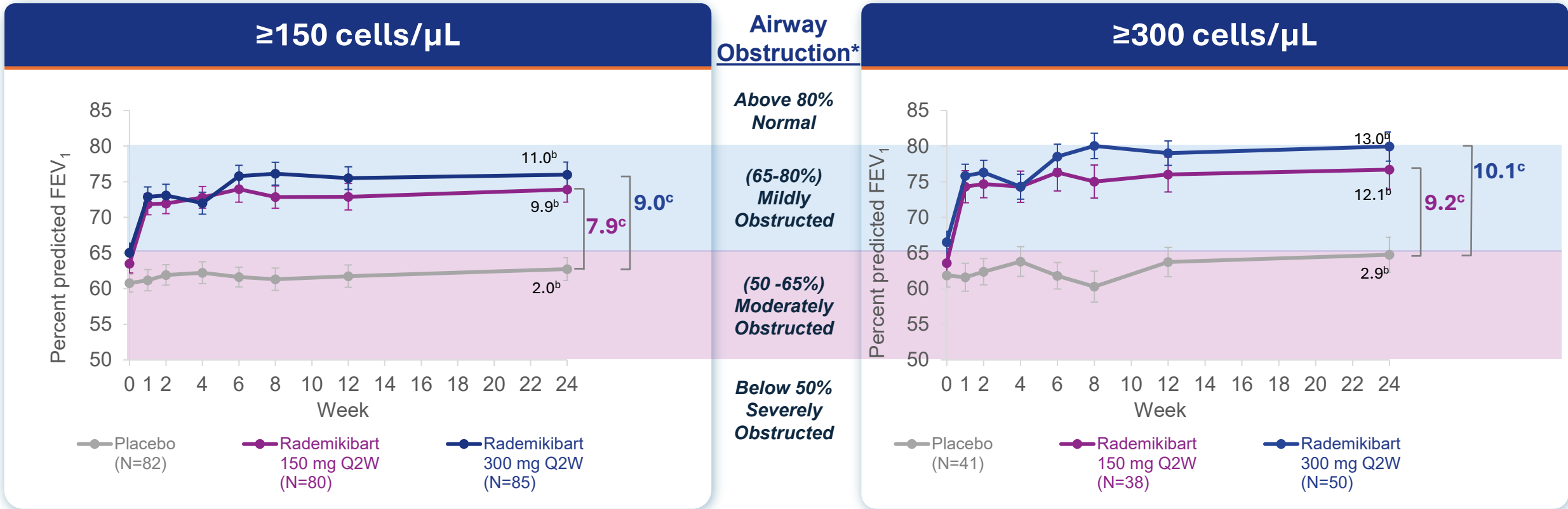
- Rademikibart rapidly improved FEV₁ on home monitoring within 24 hours¹

1. Collazo R, et al. ATS 2025. Poster #13121. ^aAll LSM changes in FEV₁ were statistically significant ($p < 0.001$ at most time points). ^bLSM change at Week 1. ^cLSM change at Week 24. ^dLSM change, adjusted for placebo, at Week 24. Standard error bars. Data analyzed by ANCOVA (analysis of covariance). FEV₁, forced expiratory volume in one second; LSM, least squares mean; Q2W, every other week.



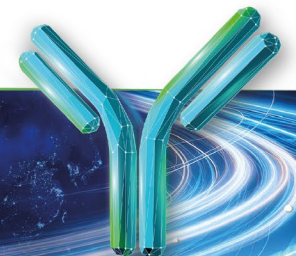
Percent predicted FEV₁ across 24 weeks of therapy^a

Change from baseline in the elevated baseline eosinophil subgroups



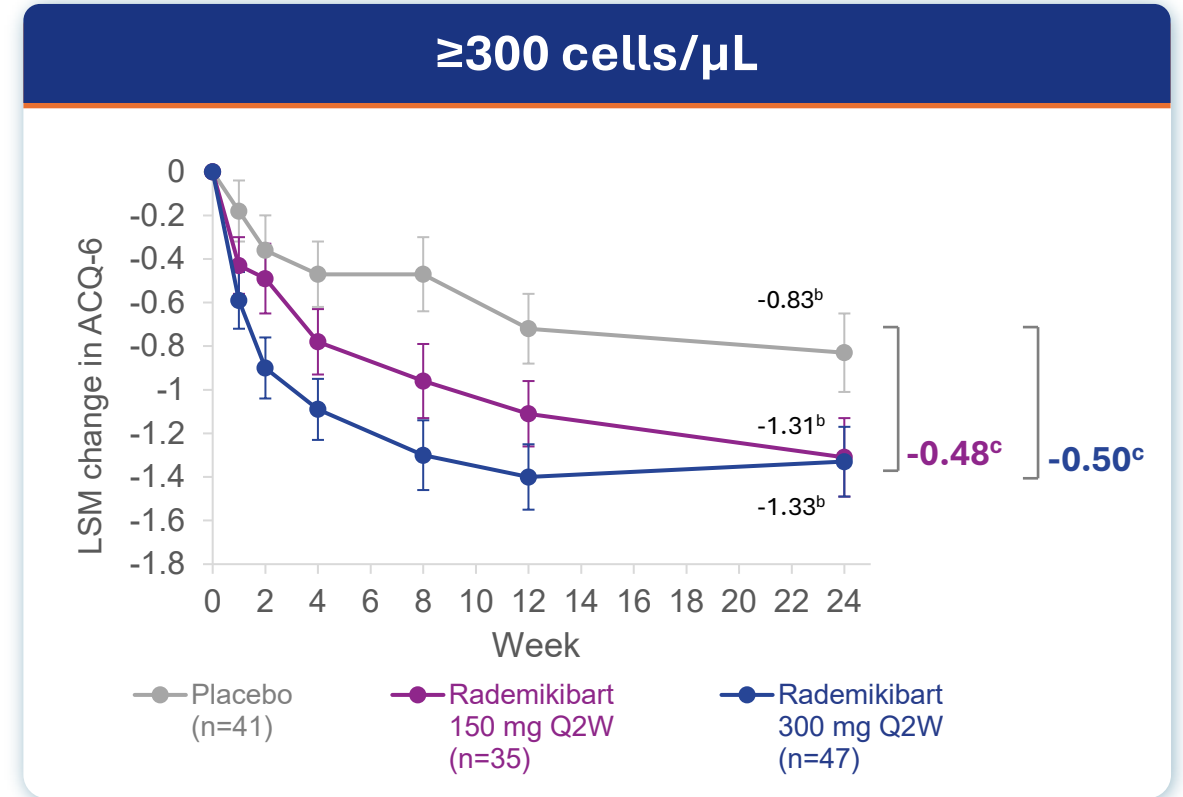
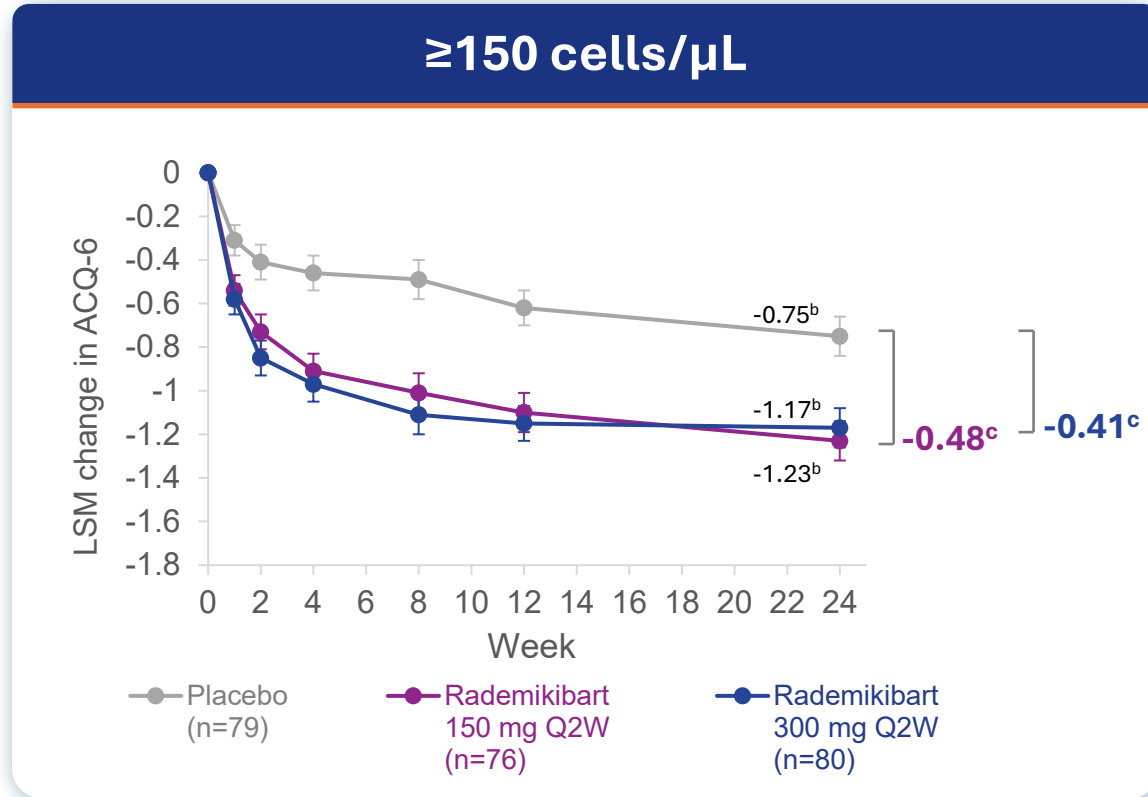
^aThis endpoint was not statistically analyzed. ^bMean change at Week 24. ^cMean change, adjusted for placebo, at Week 24. Standard error bars. FEV₁, forced expiratory volume in one second; Q2W, every other week.

* Generally accepted categories are estimates based on middle aged adults and are likely to differ in older or shorter adults, and in children.



ACQ-6 scores across 24 weeks of therapy^a

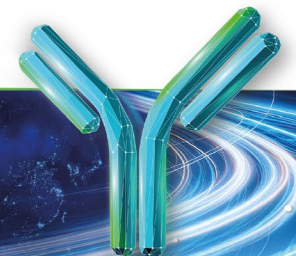
Change from baseline in the elevated baseline eosinophil subgroups



^aMost LSM changes in ACQ-6 scores were statistically significant. ^bLSM change at Week 24. ^cLSM change, adjusted for placebo, at Week 24.

Standard error bars. Data analyzed by ANCOVA (analysis of covariance).

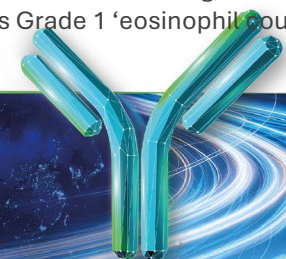
ACQ, Asthma Control Questionnaire, higher scores indicate less control; LSM, least squares mean; Q2W, every other week.



Adverse events

Number of patients with AE (%)	≥150 cells/μL				≥300 cells/μL			
	Placebo N=82	150 mg Q2W ^a N=80	300 mg Q2W ^a N=85	Total ^b N=247	Placebo N=41	150 mg Q2W ^a N=38	300 mg Q2W ^a N=50	Total ^b N=129
Total number of patients with AEs	52 (63.4)	60 (75.0)	67 (78.8)	179 (72.5)	27 (65.9)	30 (78.9)	42 (84.0)	99 (76.7)
Grade 1	12 (14.6)	29 (36.3)	21 (24.7)	62 (25.1)	8 (19.5)	14 (36.8)	13 (26.0)	35 (27.1)
Grade 2	37 (45.1)	28 (35.0)	43 (50.6)	108 (43.7)	17 (41.5)	15 (39.5)	26 (52.0)	58 (45.0)
Grade 3	3 (3.7)	2 (2.5)	2 (2.4)	7 (2.8)	2 (4.9)	0	2 (4.0)	4 (3.1)
Grade 4	0	1 (1.3)	1 (1.2)	2 (0.8)	0	1 (2.6)	1 (2.0)	2 (1.6)
Grade 5	0	0	0	0	0	0	0	0
Serious (none rademikibart related)	2 (2.5)	2 (2.5)	3 (3.5)	7 (2.8)	1 (2.4)	1 (2.6)	3 (6.0)	5 (3.9)
Led to treatment discontinuation ^c	1 (1.2)	3 (3.8)	2 (2.4)	6 (2.4)	0	0	1 (2.0)	1 (0.8)
AEs of particular interest								
Dyspnea	12 (14.6)	8 (10.0)	10 (11.8)	30 (12.1)	10 (24.4)	5 (13.2)	7 (14.0)	22 (17.1)
Asthma	10 (12.2)	6 (7.5)	6 (7.1)	22 (8.9)	5 (12.2)	4 (10.5)	6 (12.0)	15 (11.6)
Wheezing	10 (12.2)	7 (8.8)	5 (5.9)	22 (8.9)	5 (12.2)	3 (7.9)	3 (6.0)	11 (8.5)
Any eosinophilic AEs ^d	0	0	2 (2.4)	2 (0.8)	0	0	0	0
Injection site Preferred Terms in ≥2% of patients in either subgroup: ^e								
Injection site erythema	0	6 (7.5)	7 (8.2)	13 (5.3)	0	1 (2.6)	5 (10.0)	6 (4.7)
Injection site reaction	0	4 (5.0)	4 (4.7)	8 (3.2)	0	1 (2.6)	2 (4.0)	3 (2.3)
Injection site pruritus	0	4 (5.0)	2 (2.4)	6 (2.4)	0	2 (5.3)	2 (4.0)	4 (3.1)
Injection site pain	0	3 (3.8)	3 (3.5)	5 (2.0)	0	1 (2.6)	2 (4.0)	3 (2.3)

^aRademikibart groups. ^bRademikibart and placebo groups. ^cIn the overall population, 9 patients discontinued rademikibart or placebo due to AEs, which all resolved or were resolving, including three patients who discontinued rademikibart due to injection site reactions. ^dNo eosinophilia (Preferred Term) AEs were observed. Two patients experienced non-serious Grade 1 'eosinophil count increased' (n=2) and 'eosinophil percentage increased' (n=1) and did not discontinue study treatment. ^eAll injection site reactions were Grade 1 or 2 in intensity.



Substantially fewer hyper-eosinophilia reports with rademikibart compared to dupilumab

	Ph2b Rademikibart Trial		Dupilumab QUEST Trial ¹	
	Placebo (N=108)	Rademikibart (N=108)	Placebo (N=634)	Dupilumab (N=1263)
Baseline EOS <500, n	91	85	484	497
Post-baseline peak >1500 EOS	1.1%	0%	2.7%	6.6%
Post-baseline peak >3000 EOS	0%	0%	0%	1.2%
Baseline EOS ≥500, n	16	20	149	114
Post-baseline peak >1500 EOS	18.8%	10.0%	17.4%	42.5%
Post-baseline peak >3000 EOS	0%	0%	2.7%	12.9%
Safety				
Eosinophil related TEAEs	0%	0%	0.6%	4.0%

Rate with rademikibart is lower than placebo

>2x the placebo rate and >4x the rate seen with rademikibart

1. Wechsler et al. J Allergy Clin Immunol Pract. 2022;10(10):2695-2709. doi:10.1016/j.jaip.2022.05.019
EOS=eosinophils



Conclusion

Rademikibart shows promise as a targeted therapy for type 2 inflammation-driven asthma

- In this phase 2b trial, rapid improvements in lung function, at Week 1, were particularly pronounced in patients with elevated baseline eosinophils
- In addition to objective lung function, rapid and sustained improvements were also noted in patient reported asthma control
- Rademikibart was well tolerated in patients with eosinophil counts ≥ 150 or ≥ 300 cells/ μL , with no eosinophilia or new safety signals versus the parent phase 2b trial¹
- Further studies are warranted to confirm these findings, and to explore both acute and long-term asthma management with rademikibart, in patients with eosinophilic asthma

1. Kerwin, E et al. Am J Respir Crit Care Med. 2025; 5:749-758. 2. Wechsler ME, et al. J Allergy Clin Immunol Pract. 2022;10:2695-2709. 3. Castro M, et al. N Engl J Med. 2018;378:2486-2496.
AE, adverse event; ACQ, Asthma Control Questionnaire; CS, corticosteroid; FEV₁, Forced expiratory volume in one second; Q2W, every other week.

