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Reduction in Annualized Exacerbations with Rademikibart in Eosinophilic-driven Type 2 Asthma

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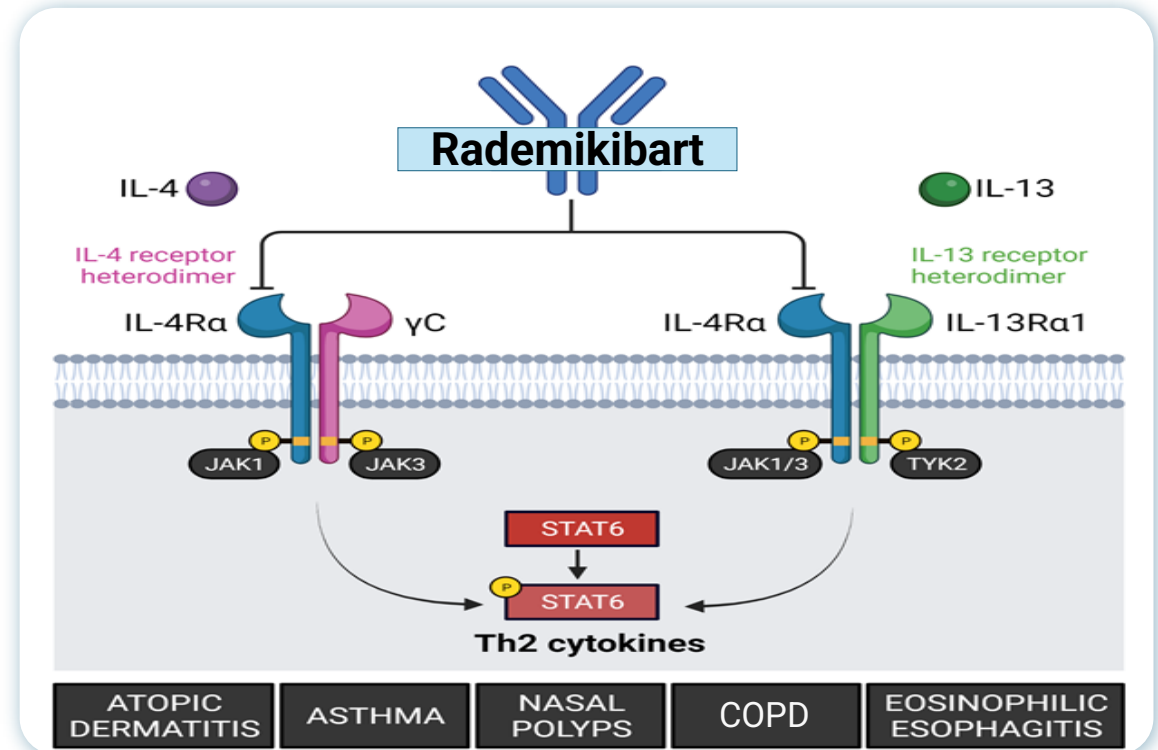
- **Rekha Chaudhuri:**
 - Lecture fees - GSK, AstraZeneca, Teva, Chiesi and Sanofi
 - Advisory Board Meetings - GSK, AstraZeneca and Celltrion
 - Consultant to Connect Biopharma
 - Sponsorship to attend international scientific meetings - Chiesi and Sanofi
 - Research grant - AstraZeneca for a UK multi-centre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

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

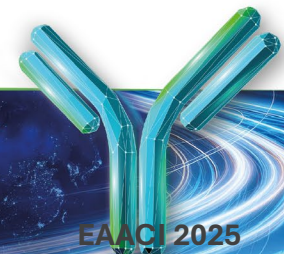
Rademikibart – a novel IL-4Ra blocker

Rademikibart (formerly CBP-201)

- Binds to different IL-4Ra epitopes with higher affinity than dupilumab, potently inhibiting IL-4 and IL-13 signaling^{1,2}
- Rademikibart shows ~30% greater potency than dupilumab in blocking IL-4 and IL-13–induced STAT6 signaling in vitro¹, which could enhance its functional efficacy in improving lung function and reducing long term exacerbations in patients with moderate to severe asthma³.



References: 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.
IL, interleukin; IL-4Ra, IL-4-receptor alpha.



Objective

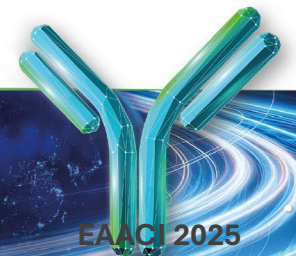
Background

- In a phase 2b trial, lung function and asthma control improved rapidly and was sustained across 24 weeks^{1,2}
- With regard to exacerbations of asthma, the primary study:
 - Was not powered to definitively assess asthma exacerbation rates
 - Included many patients with baseline eosinophils <150 cells/ μ L and/or a FeNO level <25 ppb

Objective

- To investigate asthma annualized exacerbation rates in patients with clear Type 2 inflammation–driven asthma, as indicated by elevated baseline eosinophil counts and FeNO levels, in the Phase 2b trial

References: 1. Kerwin, E et al. Am J Respir Crit Care Med. 2025; 5:749-758. 2. Collazo R, et al. ATS 2025. Poster #13121.
IL, interleukin; IL-4R α , IL-4-receptor alpha, ppb, parts per billion



The phase 2b asthma trial of rademikibart

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

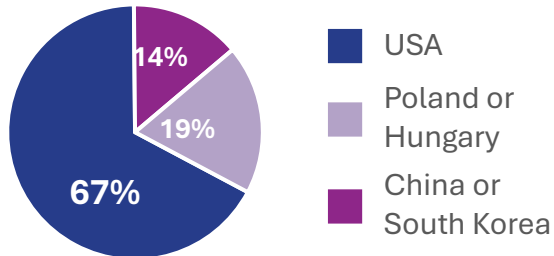
Primary endpoint: absolute change from baseline in prebronchodilator (trough) FEV₁ at Week 12

Adults with moderate-to-severe uncontrolled asthma

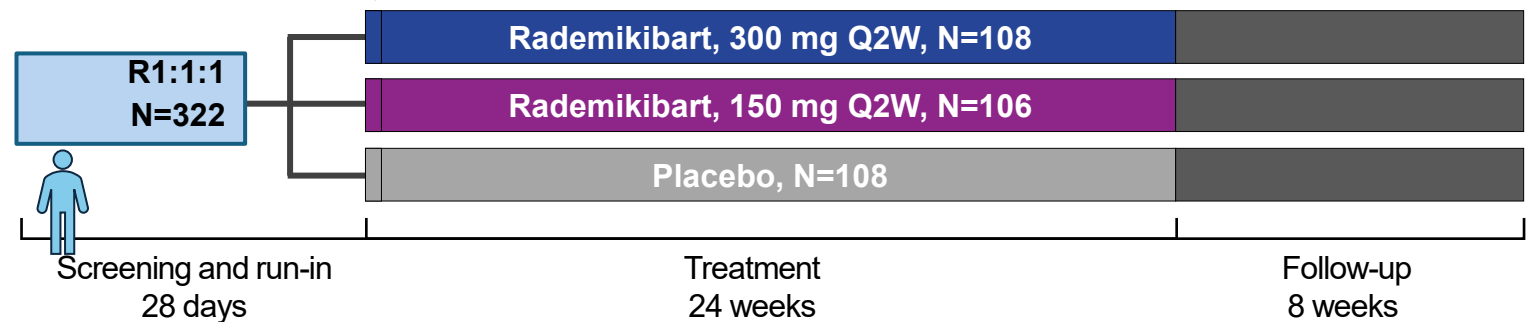


- ACQ-6 ≥ 1.5 and prebronchodilator FEV₁ 40–85% of predicted normal, at screening and baseline
- Medium-to-high dose ICS and reliever/controller for ≥ 90 days (stable dose ≥ 28 days) at screening, maintained in the study without dose adjustment
- ≥ 1 asthma exacerbation in the past year (requiring systemic 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

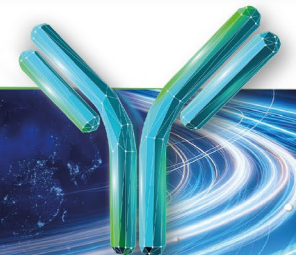
Enrollment began April 2021, with study completion September 2023



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.



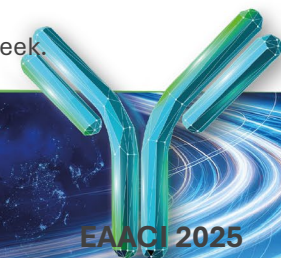
Baseline characteristics

Patients with baseline eosinophils ≥ 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)
Race, White ^b	57 (69.5)	61 (76.2)	67 (78.8)	26 (63.4)	26 (68.4)	37 (74.0)
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)
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)
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)
Atopic medical condition, n (%)	52 (63.4)	57 (71.2)	52 (61.2)	28 (68.3)	26 (68.4)	31 (62.0)
Maintenance oral/systemic CS, n (%)	12 (14.6)	8 (10.0)	3 (3.5)	6 (14.6)	2 (5.3)	0

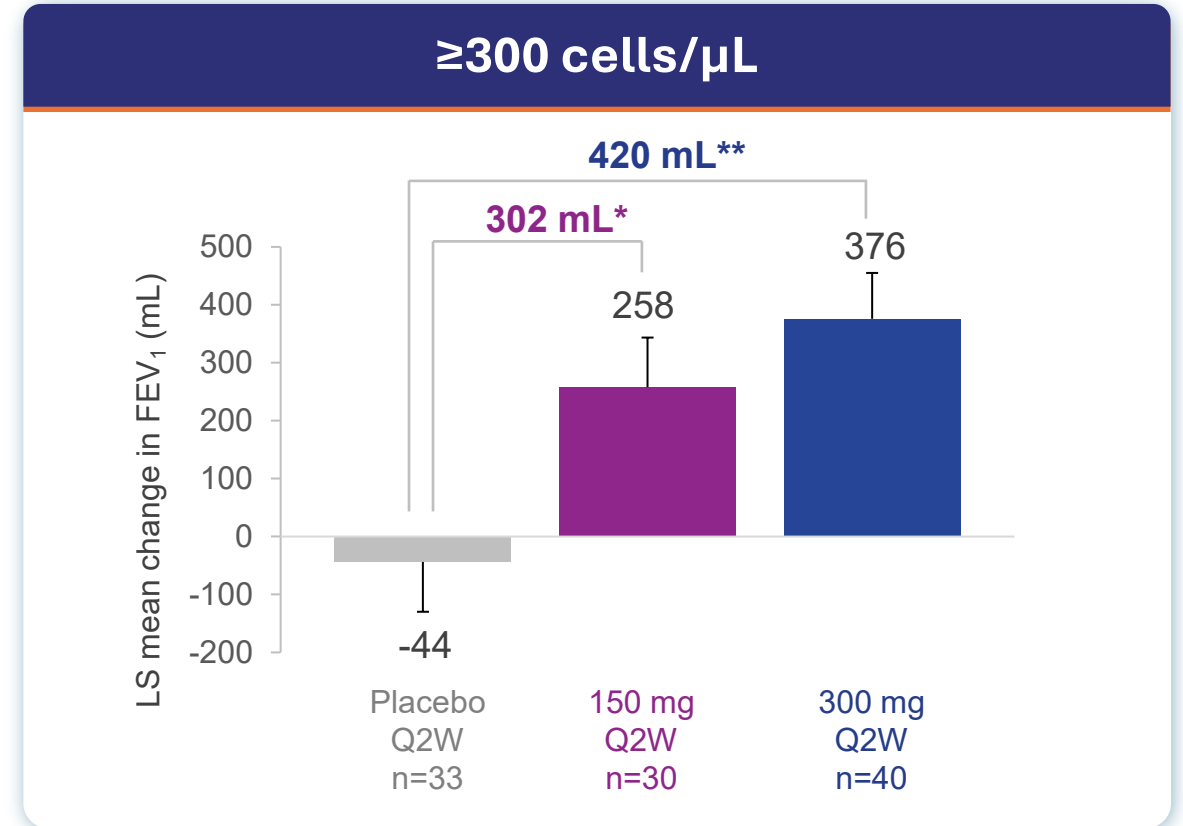
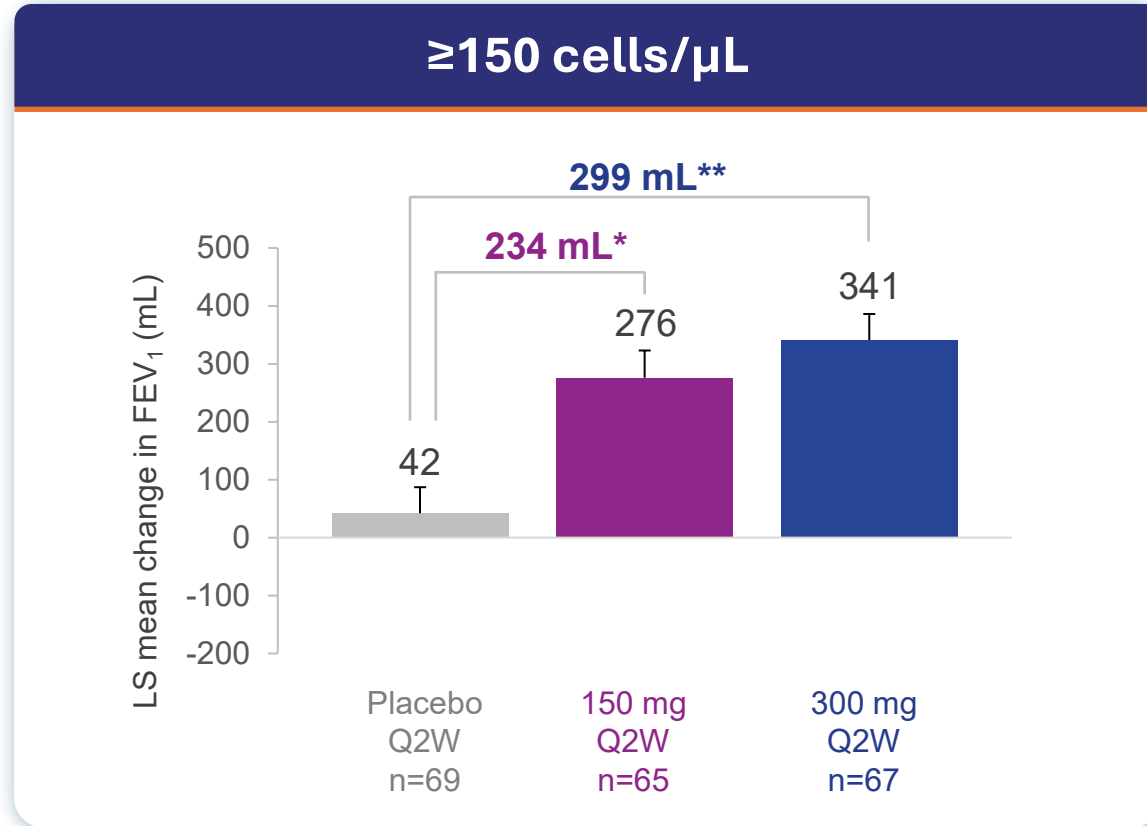
^aRademikibart groups. ^bMost of the other patients were Asian.

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



Prebronchodilator (trough) FEV₁ at Week 24 of therapy

Change from baseline in the elevated baseline eosinophil subgroups



* $p \leq 0.002$; ** $p < 0.0001$. 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.

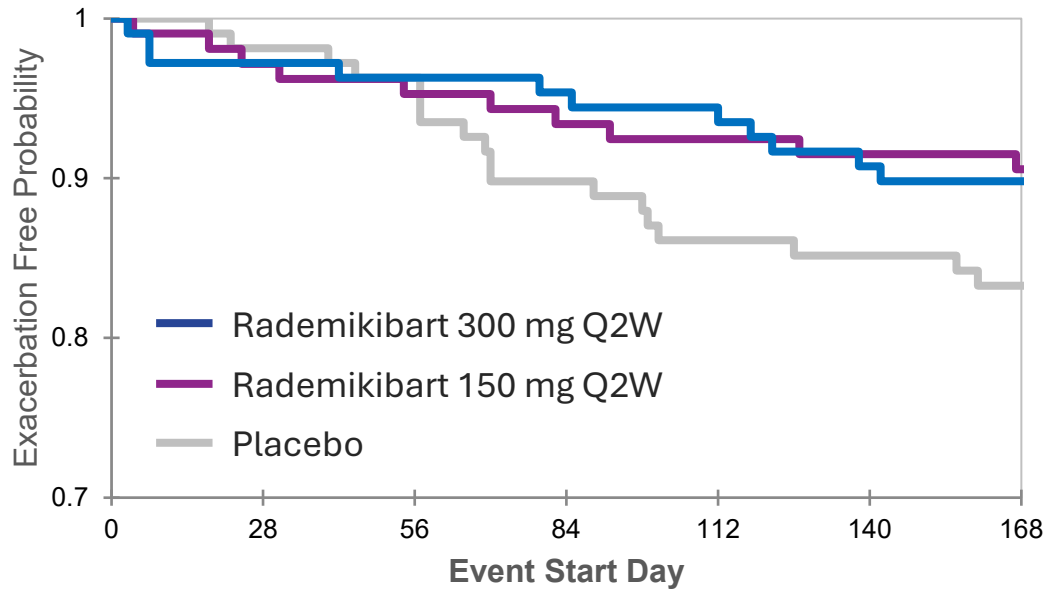


Annualized asthma exacerbation rate (AAER)

Overall population

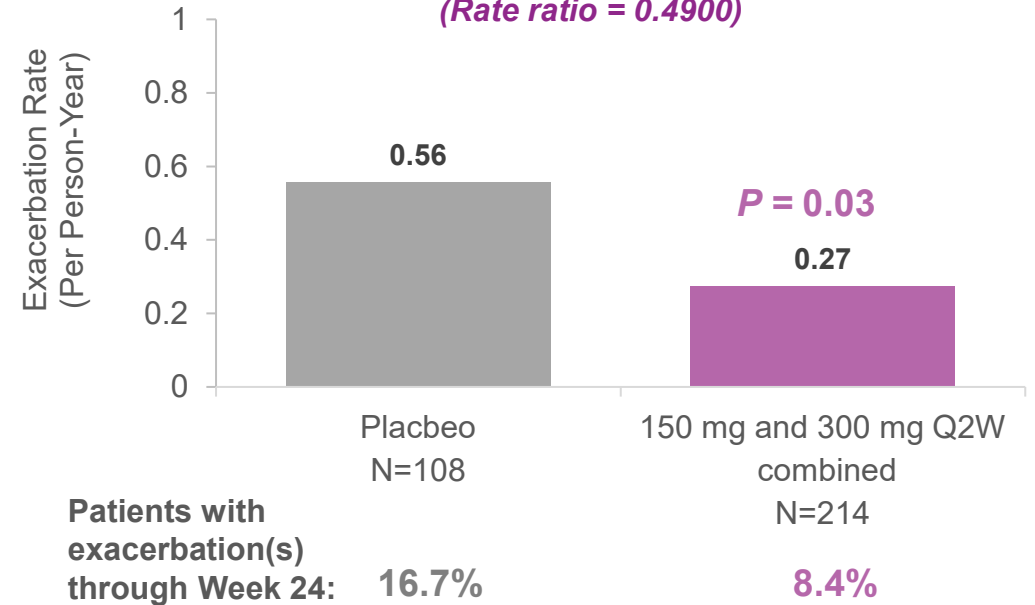
Overall population

Exacerbation-Free Status Curve



Overall population

AAER decreased by 51%
(Rate ratio = 0.4900)



Exacerbation defined as hospitalization or urgent medical care due to asthma, treatment with approximately 4 times the patient's normal dose of inhaled corticosteroids, or treatment with systemic steroids. AAER was calculated as total number of asthma exacerbations while patients were on treatment divided by total duration of treatment in years. AAER was estimated using Poisson model. AAER, annualized asthma exacerbation rate; Q2W, every other week.

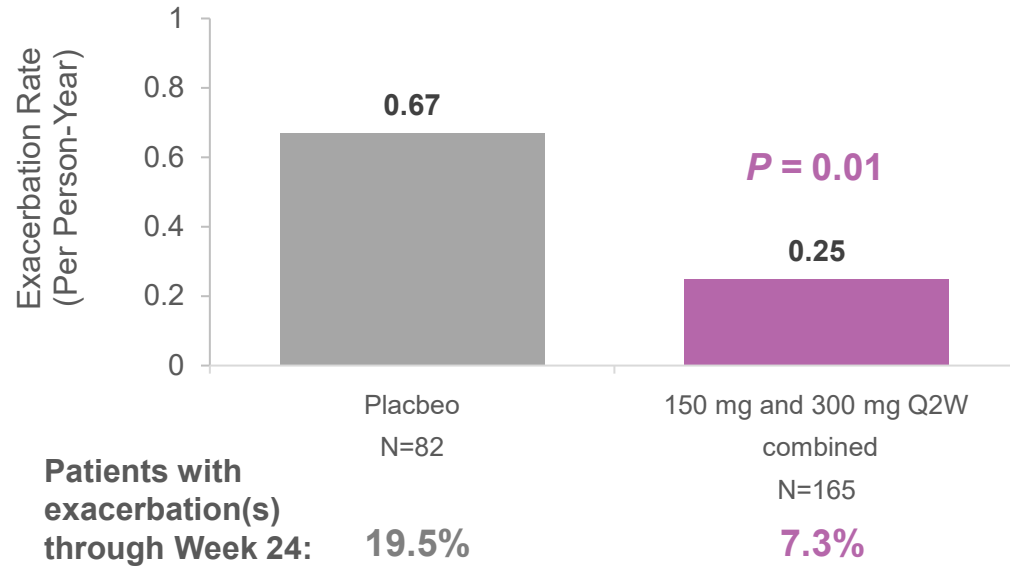


Annualized asthma exacerbation rate (AAER)

Patients with baseline eosinophils ≥ 150 or ≥ 300 cells/ μL

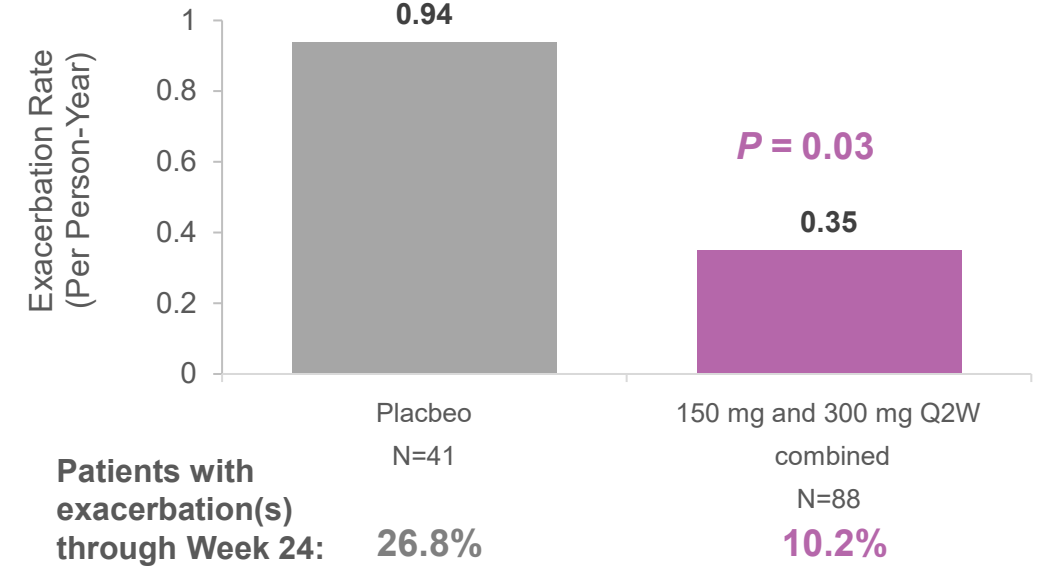
Eosinophils ≥ 150 cells/ μL

AAER decreased by 63%
(Rate ratio = 0.3709)

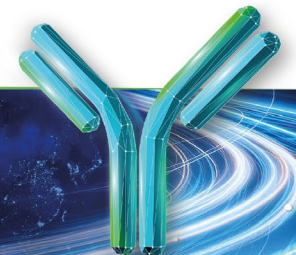


Eosinophils ≥ 300 cells/ μL

AAER decreased by 63%
(Rate ratio = 0.3727)



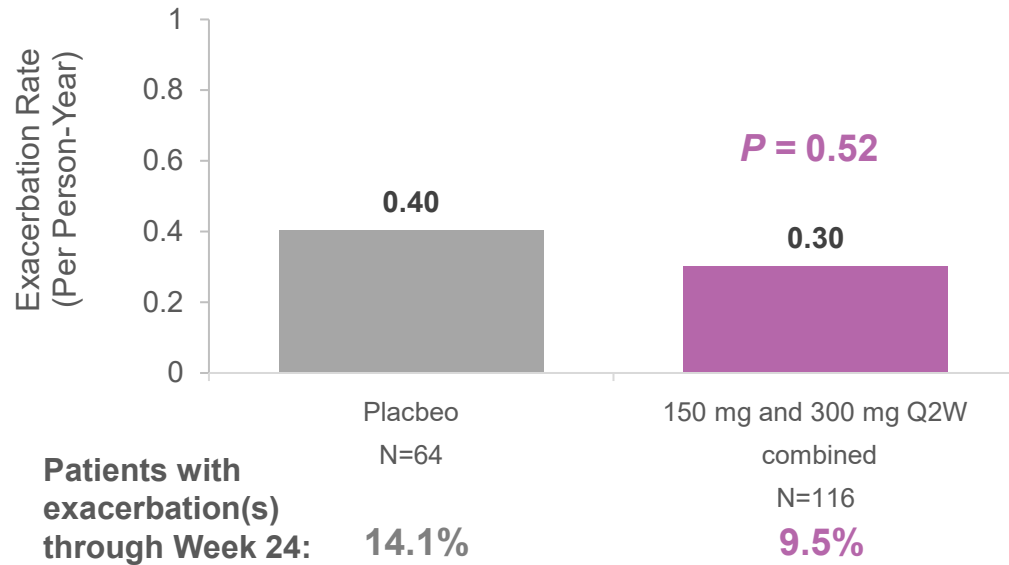
Exacerbation defined as hospitalization or urgent medical care due to asthma, treatment with approximately 4 times the patient's normal dose of inhaled corticosteroids, or treatment with systemic steroids. AAER was calculated as total number of asthma exacerbations while patients were on treatment divided by total duration of treatment in years. AAER was estimated using Poisson model. AAER, annualized asthma exacerbation rate; Q2W, every other week.



Annualized asthma exacerbation rate (AAER)

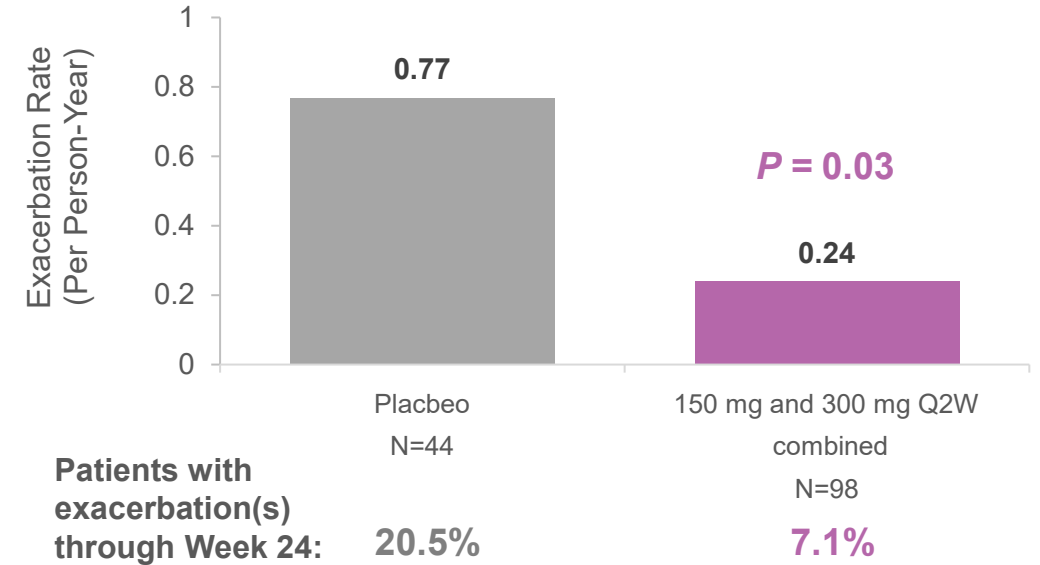
Patients with baseline FeNO <25 vs ≥25 ppb

FeNO <25 ppb

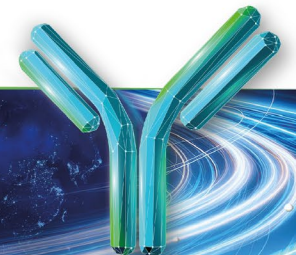


FeNO ≥25 ppb

AAER decreased by 69%
(Rate ratio = 0.3113)



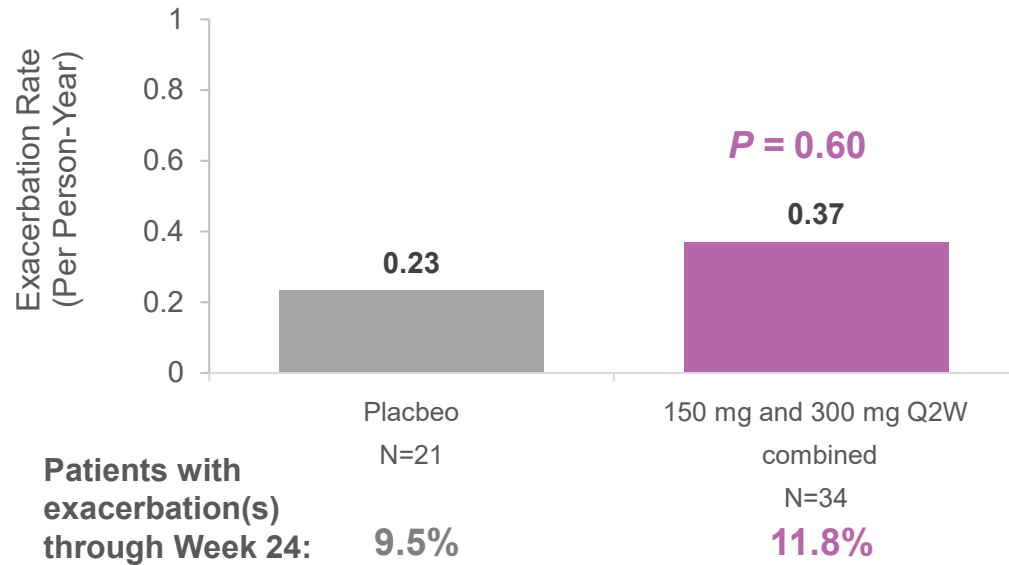
Exacerbation defined as hospitalization or urgent medical care due to asthma, treatment with approximately 4 times the patient's normal dose of inhaled corticosteroids, or treatment with systemic steroids. AAER was calculated as total number of asthma exacerbations while patients were on treatment divided by total duration of treatment in years. AAER was estimated using Poisson model. AAER, annualized asthma exacerbation rate; Q2W, every other week.



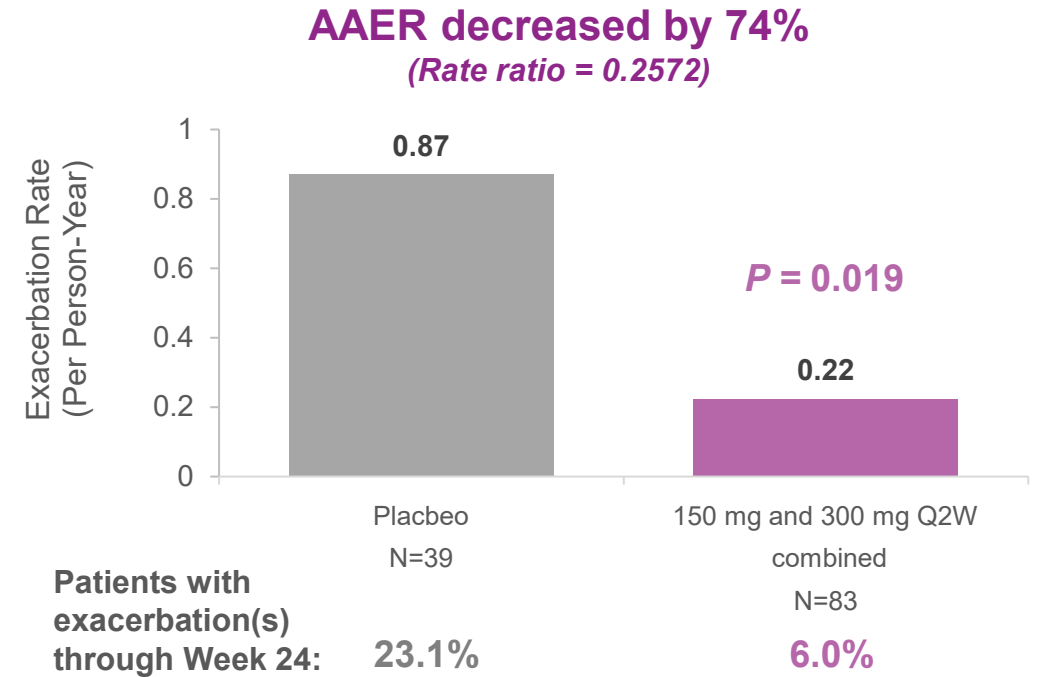
Annualized asthma exacerbation rate (AAER)

Patients with baseline eosinophils ≥ 150 or ≥ 300 cells/ μL and ≥ 25 ppb FeNO

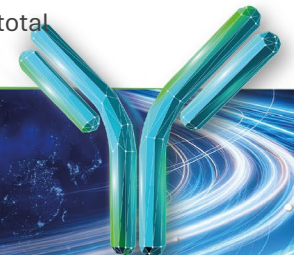
<150 cells/ μL (EOS) + <25 ppb (FeNO)



≥ 150 cells/ μL (EOS) + ≥ 25 ppb (FeNO)



Exacerbation defined as hospitalization or urgent medical care due to asthma, treatment with approximately 4 times the patient's normal dose of inhaled corticosteroids, or treatment with systemic steroids. AAER was calculated as total number of asthma exacerbations while patients were on treatment divided by total duration of treatment in years. AAER was estimated using Poisson model. AAER, annualized asthma exacerbation rate; EOS, Eosinophils Q2W, every other week.



Adverse events - Patients with baseline eosinophils ≥ 150 or ≥ 300 cells/ μL

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	1 (1.2)	3 (3.8)	2 (2.4)	6 (2.4)	0	0	1 (2.0)	1 (0.8)
Preferred Terms in >5% of patients in total in either subgroup								
Cough	16 (19.5)	5 (6.3)	13 (15.3)	34 (13.8)	8 (19.5)	2 (5.3)	9 (18.0)	19 (14.7)
COVID-19	9 (11.0)	7 (8.8)	15 (17.6)	31 (12.6)	4 (9.8)	3 (7.9)	7 (14.0)	14 (10.9)
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)
Injection site erythema	0	6 (7.5)	7 (8.2)	13 (5.3)	0	6 (8.8)	2 (3.4)	8 (4.1)
Nasopharyngitis	5 (6.1)	2 (2.5)	5 (5.9)	12 (4.9)	5 (12.2)	1 (2.6)	3 (6.0)	9 (7.0)
Urinary tract infection	2 (2.4)	7 (8.8)	3 (3.5)	12 (4.9)	1 (2.4)	5 (13.2)	1 (2.0)	7 (5.4)
Any eosinophilic AEs ^d	0	0	2 (2.4)	2 (0.8)	0	0	0	0

^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. AE, adverse event; Q2W, every other week; SOC, System Organ Class.



Conclusions

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

- This phase 2b trial highlights rademikibart's potential to reduce asthma exacerbations, particularly in those with increased eosinophils and FeNO
- Although exacerbation rate was an exploratory endpoint, the reduction is compatible with significant improvements in lung function (FEV₁) and asthma control (ACQ-6) in the study^{1,2}
- Rademikibart was generally well tolerated
- Future studies are needed to confirm the long-term reductions in asthma exacerbations, the safety profile of rademikibart, and its position in the asthma treatment landscape

References: 1. Kerwin, E et al. Am J Respir Crit Care Med. 2025; 5:749-758. 2. Collazo R, et al. EAACI 2025 Abstract 001678
AE, adverse event; ACQ, Asthma Control Questionnaire; CS, corticosteroid; FEV₁, Forced expiratory volume in one second; Q2W, every other week.

