



WELCOME

Advancing Care, One Breath at a Time

Seabreeze STAT Trials Investigator Meeting

San Diego, CA | Friday, September 12, 2025

Investigator Meeting Agenda | San Diego, CA

Seabreeze STAT Trials - *Advancing Care, One Breath at a Time*

Time (PT)	Session Title	Speaker(s)
08:30–08:40	Welcome to Seabreeze STAT Trials: Why This Program Matters	Dr. Barry Quart (Connect)
08:40–08:55	Meet the Minds Behind the Mission (Introductions & Team Overview) 🎉 <i>Trivia Showdown - Compete for prizes while mastering the protocols</i>	Dr. Raul Collazo, Master of Ceremonies (Connect)
08:55–09:10	Tech Check: iPad Setup & Interactive Tools Demo	Turner Papke (Array)
09:10–09:45	🎉 Rademikibart Revealed: The Science Driving the Trials + Live Q&A	Dr. Cristian Rodriguez (Connect)
09:45–10:00	🎉 Safety Snapshot & Reporting	Kimberly Manhard (Connect)
10:00–10:20	-- <i>Break & Take a Breather</i>	—
10:20–11:20	🎉 Protocol Power Hour: Asthma & COPD Essentials + Live Q&A	Dr. Marisa “MJ” Jones, Guy Boccia (Connect)
11:20–12:00	Breath by Breath: Spirometry & FeNO in Action	Dr. Erin Lennox (ZEPHYRx)
12:00–01:30	-- Lunch & Learning Stations • Spirometry Demo • Study Start-Up Station	All
01:30-01:40	Diving into Labs: Navigating Blood and the Lab Workflow	Guy Boccia (Connect)
01:40–01:50	🎉 Behind the Scenes: How Safety Committees Keep Trials on Course	Radha Adivikolanu (Connect)
01:50–02:50	Recruitment That Works: • Top Tips from an Expert • Table Talk / Voicing Innovative Recruitment	Dr. Sanjay Ramakrishnan (ABRA Lead Investigator) All
02:50–03:10	Tech at the Core: Randomization Meets Data	Guy Boccia (Connect)
03:10–03:25	-- <i>Break & Moment to Breathe</i>	—
03:25–04:10	🎉 Study Expectations & Monitoring with Meaning: Oversight to Drive Quality	Aubree Malan (ProPharma Group)
04:10–04:30	Closing Notes and Winning Moments (Trivia Champions!)	All

🎉 **Trivia Tip:** Watch for this symbol on the agenda - fastest correct responders have a shot at prizes.

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Welcome

Why This Program Matters

Barry Quart, PharmD
CEO

Asthma and COPD are Associated with Severe Exacerbations that are Difficult to Treat and Often Require Hospitalization

	Asthma	COPD
POPULATION	Affects >24M adults in US with ~40% have at least one exacerbation per year ¹	~15M adults diagnosed in US ² with ~30-50% have at least one exacerbation per year
ADMISSIONS	Due to: Persistent hypoxia, severe respiratory distress, poor response to initial treatment, altered mental status and/or a history of exacerbations drive admission decisions	
	<ul style="list-style-type: none"> • ~1 million ED visits or hospitalizations/yr¹ <ul style="list-style-type: none"> – Population-based studies have estimated that ~12-20% of adults or children with an ED visit will return within the next 7-14 days.^{7,8} – ~50% meet treatment failure criteria within 4 weeks of an exacerbation⁶, with many requiring a re-visit to the ED^{7,8} • Length of stay is typically 2 to 3 days⁹ 	<ul style="list-style-type: none"> • ~1.8 million acute inpatient hospitalizations in 2021³ <ul style="list-style-type: none"> – 11.4% of insured individuals with COPD had at least one COPD-related acute inpatient hospitalization³ – Length of stay is typically 4 to 5 days⁵ – ~18% of patients require re-hospitalization within 30 days of discharge⁴ • ~1.4 million emergency department/observation visits not resulting in inpatient admissions in 2021³ • ~50% fail non-biologic treatment within 4 weeks of an exacerbation⁶

1. Centers for Disease Control and Prevention [CDC]. Most Recent National Asthma Data. https://www.cdc.gov/asthma/most_recent_national_asthma_data.htm. Accessed Aug 7, 2025

2. Centers for Disease Control and Prevention [CDC]. COPD. https://www.cdc.gov/cdi/indicator-definitions/chronic-obstructive-pulmonary-disease.html?utm_source=chatgpt.com. Accessed Aug 7, 2025

3. Bazell C, Alston M, Feigler N, et al. Chronic Obstr Pulm Dis. 2025;12(2):158-174. doi:10.15326/jcopdf.2024.0560

4. Ruan H et al 2023. Ther Adv Respir Dis, Vol. 17: 1–16. DOI: 10.1177/17534666231202742

5. Balavenkataraman A, Saunders H, Helgeson SA. Lung India. 2024 Jan 1;41(1):77-79. doi: 10.4103/lungindia.lungindia_472_23

6. Ramakrishnan S, Russell REK, Mahmood HR, et al. Lancet Respir Med. 2025;13(1):59-68. doi:10.1016/S2213-2600(24)00299-6

7. Aguilar R, et al. J Emerg Med. 2024;67(1):e22-e30. doi:10.1016/j.jemermed.2024.02.002

8. Abbott EE, Vargas-Torres C, Karwoska Kligler S, Spadafore S, Lin MP. 2023;60(5):938-945. doi:10.1080/02770903.2022.2109166

9. Modak M, Rowlands WM, Sleiman J, Attaway AH, Bleecker ER, Zein J. Chronic Obstr Pulm Dis. 2025;12(4):260-273. doi:10.15326/jcopdf.2024.0566

ED = emergency department; COPD = chronic obstructive pulmonary disease



There Remains Significant Unmet Need for Better Treatment Options to Improve Patient Outcomes & Reduce Burden on Healthcare Systems



EXACERBATION RECURRENCE

Reduction in overall frequency of ED visits

Management of asthma and COPD exacerbations and the prevention of ED revisits or hospital readmissions remain challenging



HOSPITALIZATION AND RE-ADMISSION RATES

Decrease the Proportion of Patients Admitted

Asthma and COPD patients are routinely hospitalized upon presentation to the ED with an exacerbation



BIOLOGICS / ADVANCED THERAPIES

Deliver Improved Efficacy Over SoC

There has been a lack of innovation in the acute exacerbation setting with the need for a therapeutic option that works both acutely and for chronic prevention of future exacerbations



Meet the Minds Behind the Mission

Team Overview & Introductions

Raul Collazo, PhD
VP, Global Medical Strategy

Meet the Team



Barry Quart, PharmD
Chief Executive Officer

Kimberly Manhard
EVP, Chief Development Officer

Raul Collazo, PhD
VP, Global Medical Strategy

Cristian Rodriguez, MD
Medical Monitor
Lead for Seabreeze STAT Asthma & Argentina

Peter Polos, MD, PhD
Medical Monitor
Lead for Seabreeze STAT COPD

Guy Boccia, MA
Sr Director, Clinical Development Strategic
Operations

Radha Adivikolanu, MSPH
Sr Manager, Clinical Operations

Marisa "MJ" Jones, PharmD
Clinical Trials Associate Manager

Sabina Mathur
Clinical Trials Senior Manager

Belinda Williams, CCRA
Senior Clinical Trials Specialist

Jamee Cluer
Contracts and Budgets

Debbie Inman
Clinical Research Associate

Tani Williams, RN
Clinical Research Associate

Erin Beard
Executive Assistant

Marissa Kinney, PMP
Assoc. Director,
Program Management



Meet the Team

propharma

Aubree Malan, Senior Clinical Lead

Jenica Hemingway, Clinical Research Associate

Curtis Sims, Clinical Research Associate

activa
cro
Contract Research Organization

Pablo Roel, Clinical Project Manager

Martin Ezequiel Siciliano, Clinical Research Associate

ZEPHYR_x

Erin Lennox, PhD, VP Clinical Research

Scout

James Lyden

Dani Orth

Chloe Bryant

 **Array**[®]

Turner Papke

Jack Francis

connect
BIOPHARMA 

- Restroom location
- Cell phone reminder
- No video recording 😊

- Input any questions you have into your iPad at **any time!**
 - They will be sent to the team!

Reminder: Have fun! Don't be afraid to ask questions!



Trivia Questions with Chances to Win Prizes!

- *Be the fastest with the correct answer* — and you could win a prize!

Winning Moments Await!

- Trivia Champions will be crowned at the end of the meeting — will you be one of them?



Tech Check

iPad Setup & Interactive Tools Demo

Turner Papke
Sr Project Manager, Array

Using Your iPad - Array Platform Overview

The screenshot shows the Array platform interface on an iPad. At the top, the Array logo is on the left, and a user profile icon with the initials 'dd' and a share icon are on the right. Below the logo is a navigation bar with tabs: PRESENTATION, AGENDA, TEAM BIOS, ATTENDEES, RESOURCES, EVALUATION, GAME, and TECHNICAL SUPPORT. The main content area displays a slide titled 'Phase II Findings' from 'MED COMPANY X'. The slide features a line graph on the left showing data for Group A and Group B over four weeks, and a pie chart on the right showing the distribution of four trials (A, B, C, D). Below the charts is a bar chart comparing 'Pre' and 'Post' data for each trial. At the bottom of the slide, there is a 'PREVIOUS SLIDE' button and a 'Rewind slides [< scroll back]' button. Below the slide is a control bar with icons for 'ASK QUESTION', 'TAKE NOTE', 'RATE SLIDE', and 'SAVE SLIDE'. On the left side of the iPad, there are several callout boxes with arrows pointing to specific features: 'View live presentation slides' points to the main content area; 'View Agenda*', 'Presenter Bios*', 'Participant List*', and 'View Protocol or Resources*' point to the navigation bar; 'Ask the presenter a question' points to the 'ASK QUESTION' icon; 'Take a Note on live slides' points to the 'TAKE NOTE' icon; and 'Save Slides throughout presentation' points to the 'SAVE SLIDE' icon. At the top right of the iPad, a callout box labeled 'Profile review & logout' points to the user profile icon.

Profile review & logout

View live presentation slides

View Agenda*

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Array

PRESENTATION AGENDA TEAM BIOS ATTENDEES RESOURCES EVALUATION GAME TECHNICAL SUPPORT

Phase II Findings

MED COMPANY X

PREVIOUS SLIDE

Rewind slides [< scroll back]

ASK QUESTION TAKE NOTE RATE SLIDE SAVE SLIDE

Demo Time – Let's See What Your iPad Can Do!

If you could choose one superpower, which would you choose?

- A. Flying
- B. Superstrength
- C. X-Ray Vision
- D. Laser Eyes
- E. Teleportation
- F. Talk to Animals
- G. Ability to Heal

What are you most excited to do in San Diego?

- A. Attend the IM of course
- B. Eat fish tacos
- C. Go to the beach
- D. Enjoy the sunshine
- E. Go to the World Famous San Diego Zoo / Seaworld
- F. All of the above

connect
BIOPHARMA

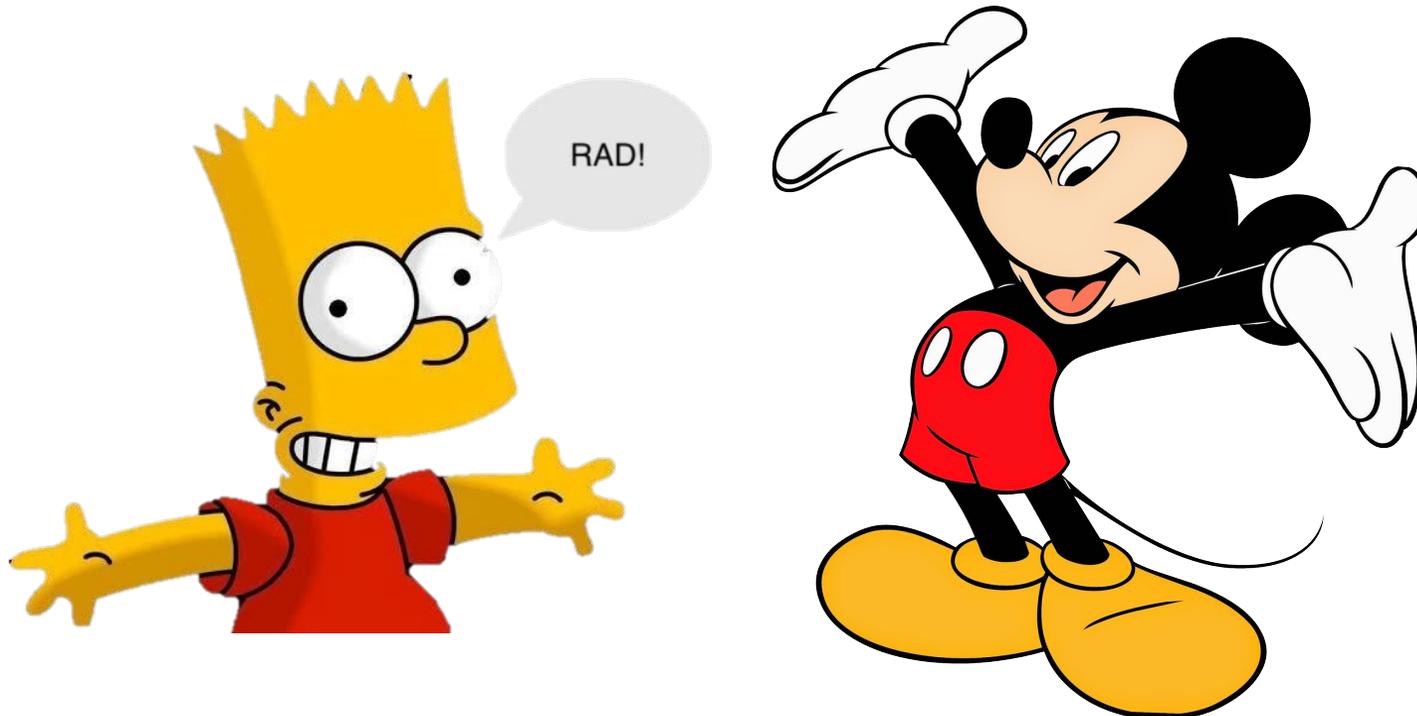


Rademikibart Revealed:

Redefining IL-4R α inhibition and advancing
care in acute exacerbations;
the science driving the trials

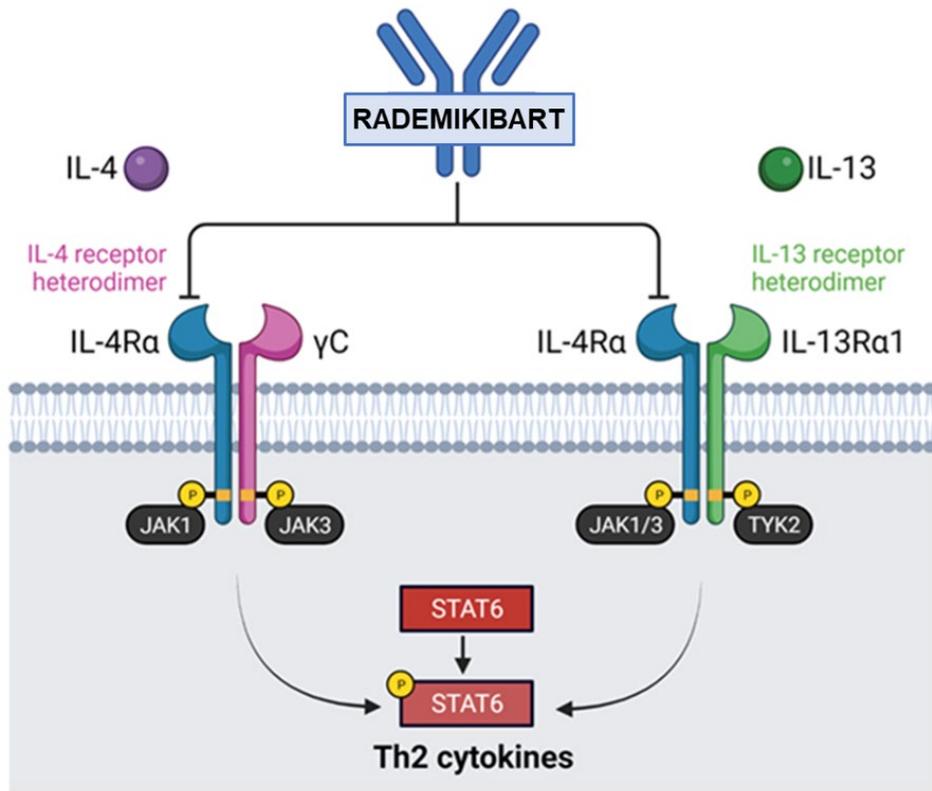
Cristian Rodriguez, MD
*Lead Medical Monitor CBP-201-206 &
Argentina Region*

- Why is our investigational product named rademikibart?
 - A. Because Mickey Mouse and Bart Simpson are rad (bacán)!
 - B. Because it is a mono-specific full-length immunoglobulin
 - C. Because we couldn't use -mab
 - D. All of the above**



Rademikibart Shows Potential For Less Frequent Dosing, Greater Sustained Efficacy Data, and Faster Onset Observed in Asthma Trials

Rademikibart is a next generation human monoclonal IgG4 antibody directed against IL-4R α , a common subunit for IL-4 and IL-13 receptors. Blockade of IL-4 and IL-13 binding to IL-4R α results in inhibition of both IL-4 and IL-13 signaling.



Rademikibart Characteristics

Targets a distinct and larger portion of the IL-4 binding epitope on IL-4R α than dupilumab which may allow it to better block both IL-4 and IL-13 signaling¹

- Compared to dupilumab*, highly potent IC₅₀:
 - Reducing JAK-STAT signaling²
 - Cell proliferation²
 - TARC release²

Potential Clinical Relevance

Reduces type 2 inflammation, IgE levels, eosinophil recruitment, and improves lung function

Compared to dupilumab

- Greater clinical response
- Faster onset of action
- Less frequent dosing potential

AD=atopic dermatitis; COPD=chronic obstructive pulmonary disease; IC50=half-maximal inhibitory concentration; IL=interleukin; JAK=janus kinase; STAT=signal transducers and activators of transcription; TARC=thymus- and activation-regulated chemokine.

* Based on head-to-head in vitro comparison with dupilumab.

1. Bunick CG. J Invest Dermatol. Published online August 5, 2025. doi:10.1016/j.jid.2025.06.1574

2. Zhang L, Ding Y, Wang Q, et al. Sci Rep. 2023;13(1):12411 doi:10.1038/s41598-023-39311-2

Robust Data from Completed Global Phase 2 Study in Moderate-to-Severe Asthma Patients

Efficacy and Safety Study of CBP-201 (rademikibart) in Patients With Moderate to Severe Persistent Asthma (NCT04773678)



Key Inclusion Criteria:

- Moderate to severe uncontrolled asthma
 - Existing treatment with medium to high dose ICS in combination with a second controller (e.g., LABA, LTRA, or theophylline) for at least 3 months with a stable dose ≥1 month prior to the screening visit.
 - Pre-bronchodilator FEV₁ 40 to 85% of predicted normal at Visits 1 and 2, prior to randomization.
 - Screening or historical blood eosinophil count ≥150 cells/μL (amended to ≥300 cells/μL)
 - No eosinophil count requirement for patients on maintenance OCS
 - ACQ score ≥1.5 at Visits 1 and 2, prior to randomization.
 - At least 1 documented asthma exacerbation in the 12 months prior to the date of informed consent that required use of a systemic corticosteroid

Primary Endpoints:

- Change from Baseline in FEV₁ at Week 12 (in clinic with central overread)

Secondary Efficacy Endpoints:

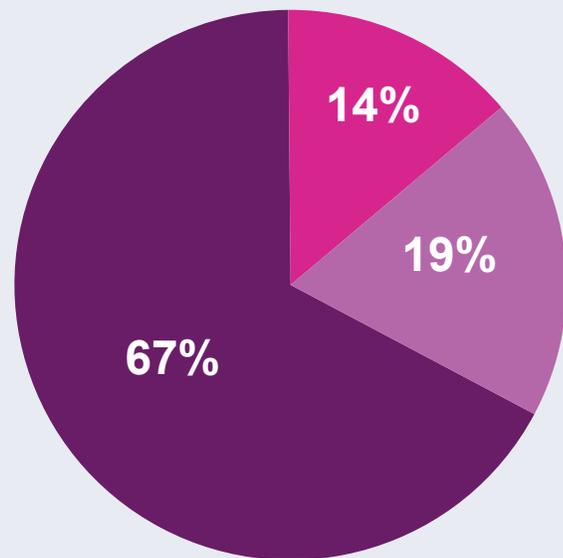
- Change from Baseline in FEV₁ at other timepoints
- Asthma Exacerbations
- PROs (ACQ, symptom diary, at-home lung function)
- PD markers (FENO, eosinophils, ECP, periostin, TARC)
- Rescue medication use

<https://doi.org/10.1164/rccm.202409-1708OC>

Global Phase 2 Asthma Trial Enrollment

Good representation across North America, Asia Pacific and European regions with 67% Patients Enrolled in the US

Patient Distribution by Country/Region
 ■ USA ■ Asia ■ Europe



Demographics	Placebo (N = 108) n (%)	Rademikibart 150 mg (N = 106) n (%)	Rademikibart 300 mg (N = 108) n (%)	Overall Population (N=322) n (%)
Race				
American Indian or Alaska Native	1 (0.9)	0	0	1 (0.3)
Asian	17 (15.7)	18 (17.0)	14 (13.0)	49 (15.2)
Black or African American	10 (9.3)	6 (5.7)	5 (4.6)	21 (6.5)
Native Hawaiian or Other Pacific Islander	0	0	1 (0.9)	1 (0.3)
White	79 (73.1)	82 (77.4)	88 (81.5)	249 (77.3)
Other	1 (0.9)	0	0	1 (0.3)
Ethnicity				
Hispanic or Latino	45 (41.7)	40 (37.7)	36 (33.3)	121 (37.6)

Global Phase 2 Asthma Trial - Baseline Demographics

Baseline Characteristics	Placebo (n=108)	Rademikibart 150 mg Q2W (n=106)	Rademikibart 300 mg Q2W (n=108)	Overall Population (N=322)
Age, mean (SD)	54.8 (12.4)	51.6 (12.0)	52.7 (12.9)	53.0 (12.5)
Female, n (%)	60 (55.6)	70 (66.0)	68 (63.0)	198 (61.5)
Body-mass index (kg/m ²), mean (SD)	30.5 (7.4)	30.4 (6.8)	30.5 (6.6)	30.5 (6.9)
Pre-bronchodilator FEV ₁ (mL), mean (SD)	1836.3 (577.8)	1908.3 (646.8)	1901.9 (589.5)	1882.0 (604.2)
Percent Predicted FEV ₁ , mean (SD)	61.6 (10.8)	63.3 (10.9)	64.7 (12.4)	63.1 (11.4)
FEV ₁ Reversibility (%) at screening, mean (SD)	28.0 (14.9)	24.4 (11.2)	27.5 (15.4)	26.6 (14.0)
FeNO (ppb), mean (SD)	31.6 (31.5)	35.8 (35.1)	33.8 (32.7)	33.7 (33.0)
ACQ Score, mean (SD)	2.72 (0.64)	2.71 (0.72)	2.68 (0.71)	2.70 (0.67)
Eosinophil count (cells/μL) , mean (SD)	299 (229)	268 (179)	320 (220)	296 (211)
Eosinophil Counts, n (%)				
< 150 cells/μL	26 (24.1)	26 (24.5)	23 (21.3)	75 (23.3)
150 - < 300 cells/μL	41 (38.0)	42 (39.6)	35 (32.4)	118 (36.6)
≥ 300 cells/μL	41 (38.0)	38 (35.8)	50 (46.3)	129 (40.1)
Presence of Atopic Medical Condition, n (%)	62 (57.4)	65 (61.3)	63 (58.3)	190 (59.0)
Use of Maintenance Oral/Systemic Corticosteroids at Randomization, n (%)	21 (19.4)	15 (14.1)	10 (9.2)	46 (14.3)
Exacerbations in last 12 months prior to screening mean (SD)	1.13 (0.39)	1.11 (0.35)	1.10 (0.33)	1.12 (0.36)

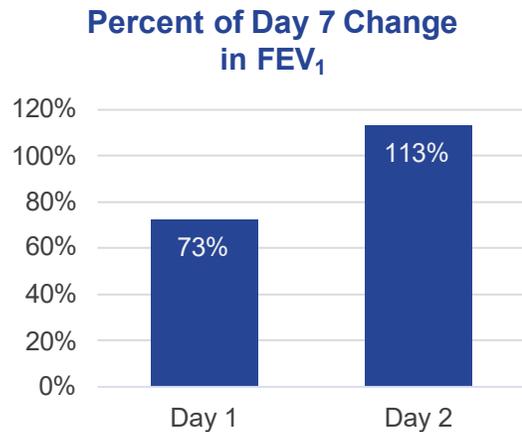
SD, standard deviation. ACQ-Asthma Control Questionnaire (over 1.5 is considered strong indication of inadequate control), higher scores indicate less control. FEV₁ - Forced expiratory volume in one second. A patient is considered to have an atopic medical condition if he/she has or has had any of the following conditions at screening: atopic dermatitis, allergic conjunctivitis, allergic rhinitis, eosinophilic esophagitis, food allergy, or hives.

Global Phase 2 Asthma Trial

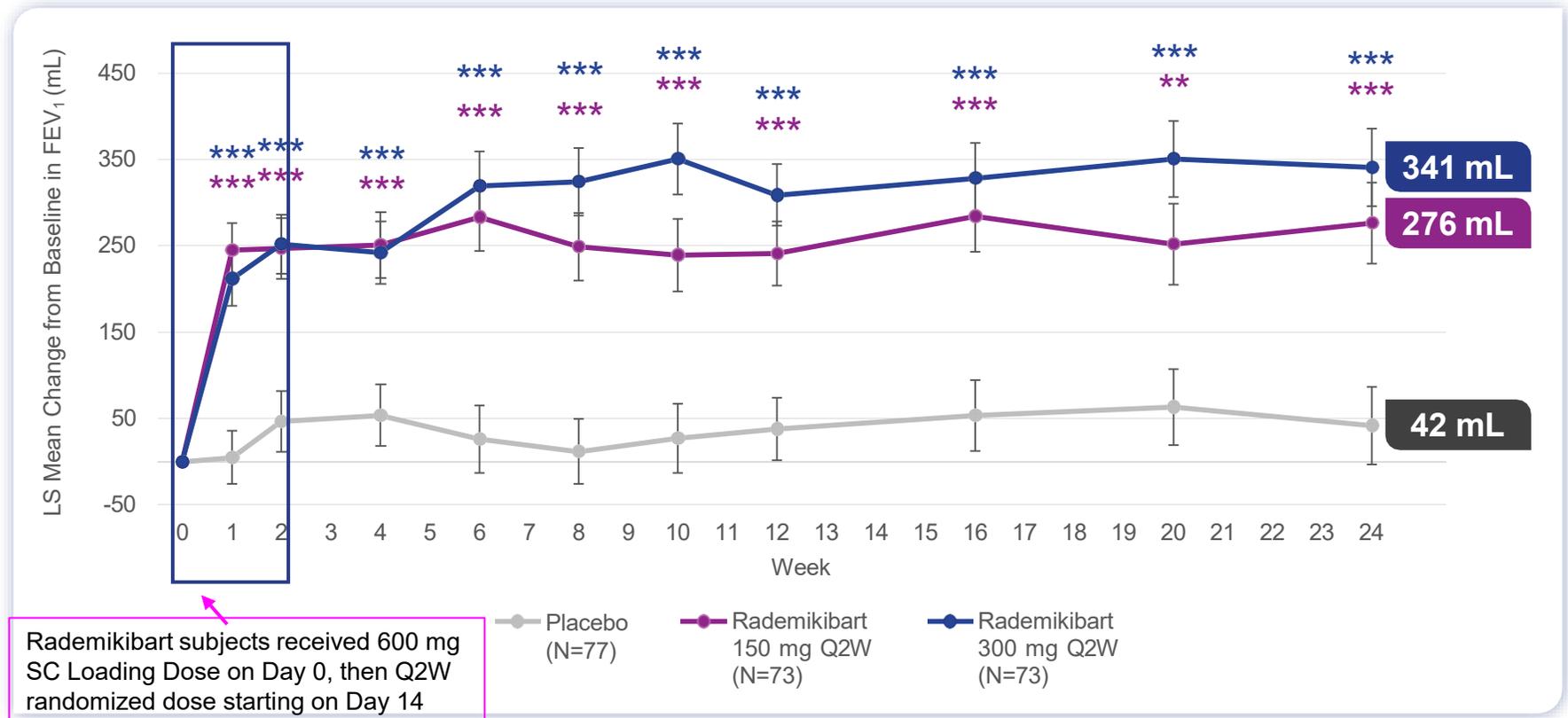
Rapidly Improved and Sustained FEV₁ Values Observed with rademikibart Treatment

Rademikibart treatment associated with rapid, significant changes in FEV₁ as early as Week 1, which were sustained for the duration of the 24-week study

Home daily lung function data demonstrated 73% of improvement seen on Day 7 was observed by Day 1, with 113% by Day 2:



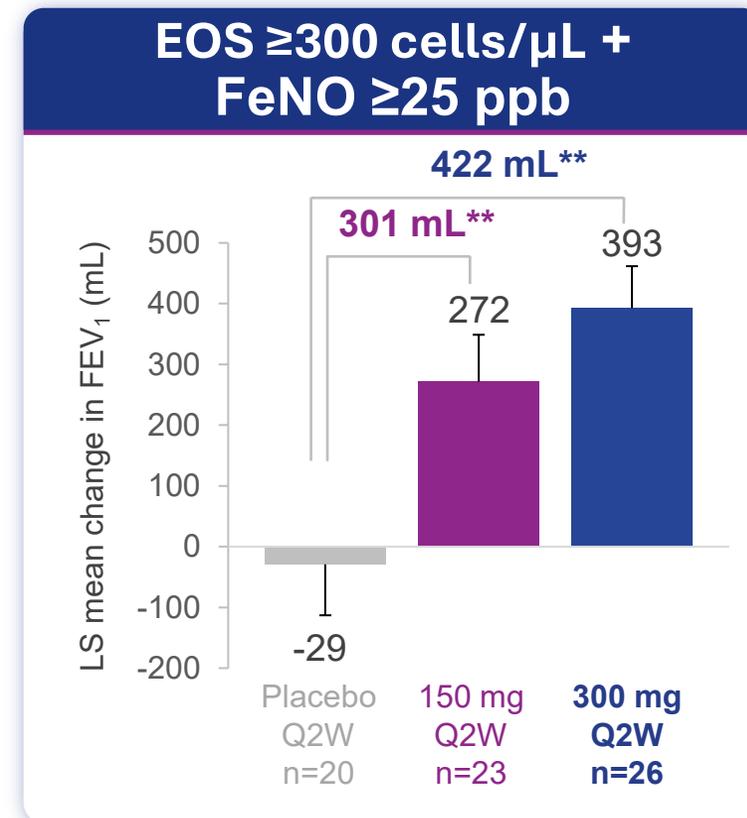
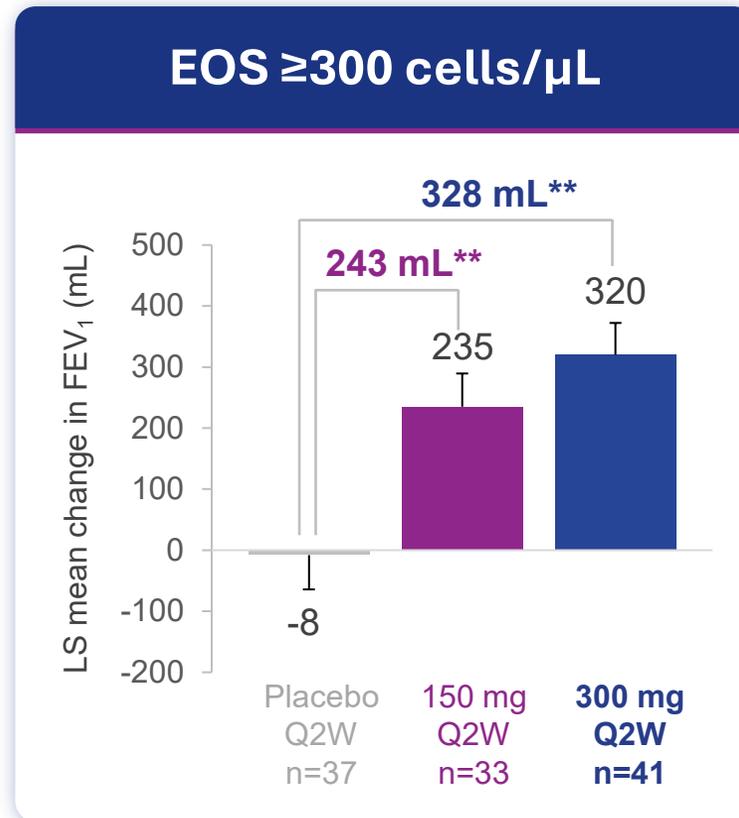
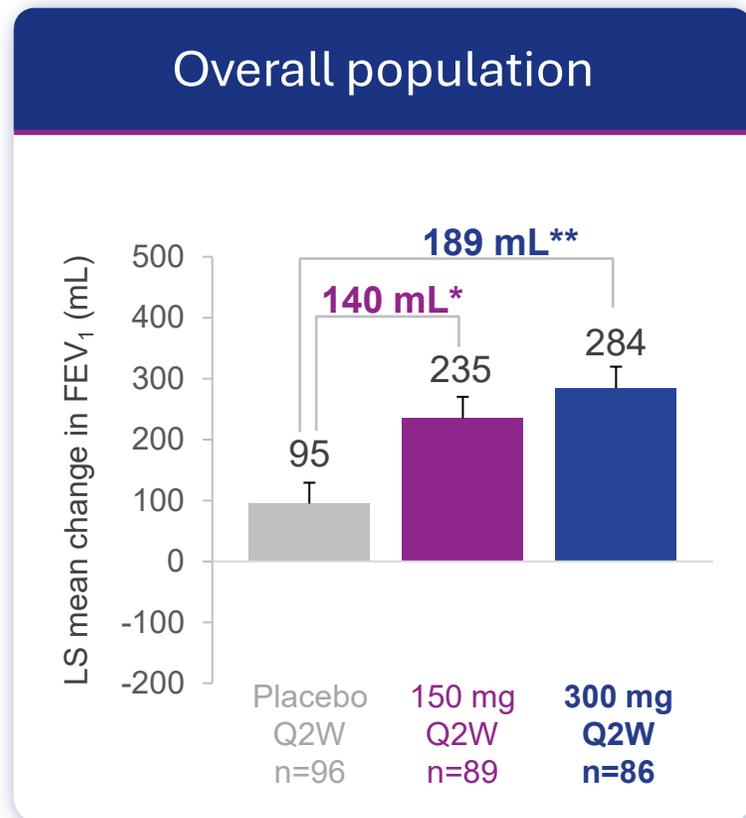
Change in Pre-bronchodilator FEV₁ over time in Patients with an Eosinophil Count ≥150 cells/μL at Baseline



***p<0.001, **p<0.01, *p<0.05. Data were analyzed with ANCOVA FEV₁ = Forced expiratory volume in one second.

Prebronchodilator FEV₁ at Week 12 (primary endpoint)

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



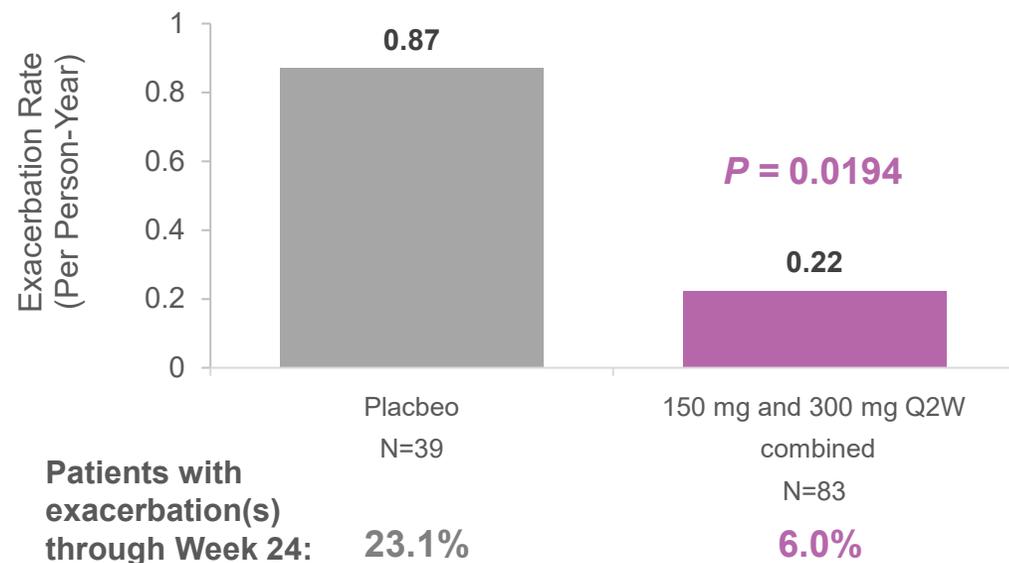
*p=0.01; **p<0.001. Standard error bars. Data analyzed by ANCOVA (analysis of covariance). FEV₁, forced expiratory volume in one second; LSM, least squares mean; Q2W, every other week.

Annualized asthma exacerbation rate (AAER)

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

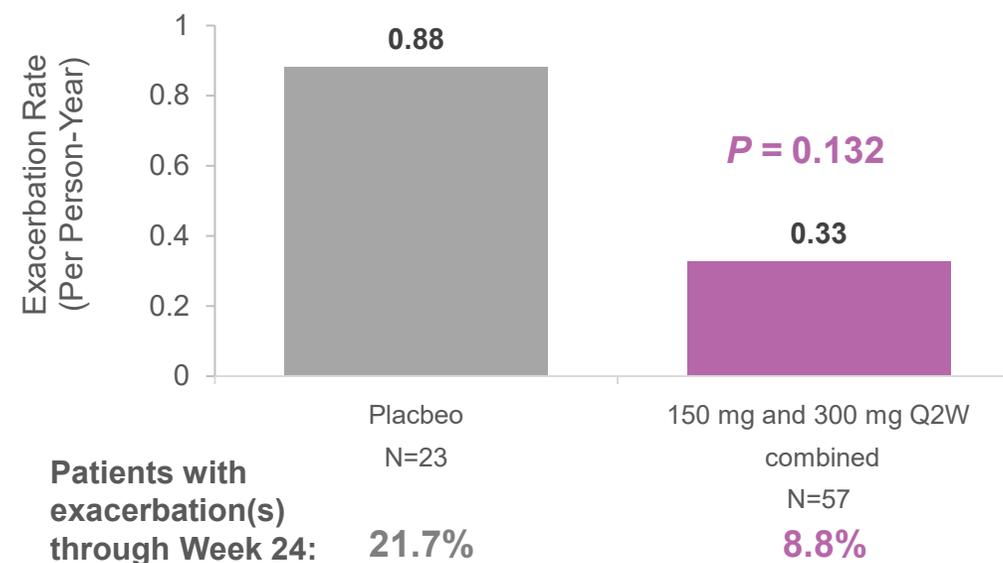
≥ 150 cells/ μL (EOS) + ≥ 25 ppb (FeNO)

AAER decreased by 74%
(Rate ratio = 0.2572)



≥ 300 cells/ μL (EOS) + ≥ 25 ppb (FeNO)

AAER decreased by 63%
(Rate ratio = 0.3707)



Hospital/ER visits due to asthma exacerbation (Overall population)

Placebo (108)
2 (1.9)

Rademikibart 150 mg (106)
1 (0.9)

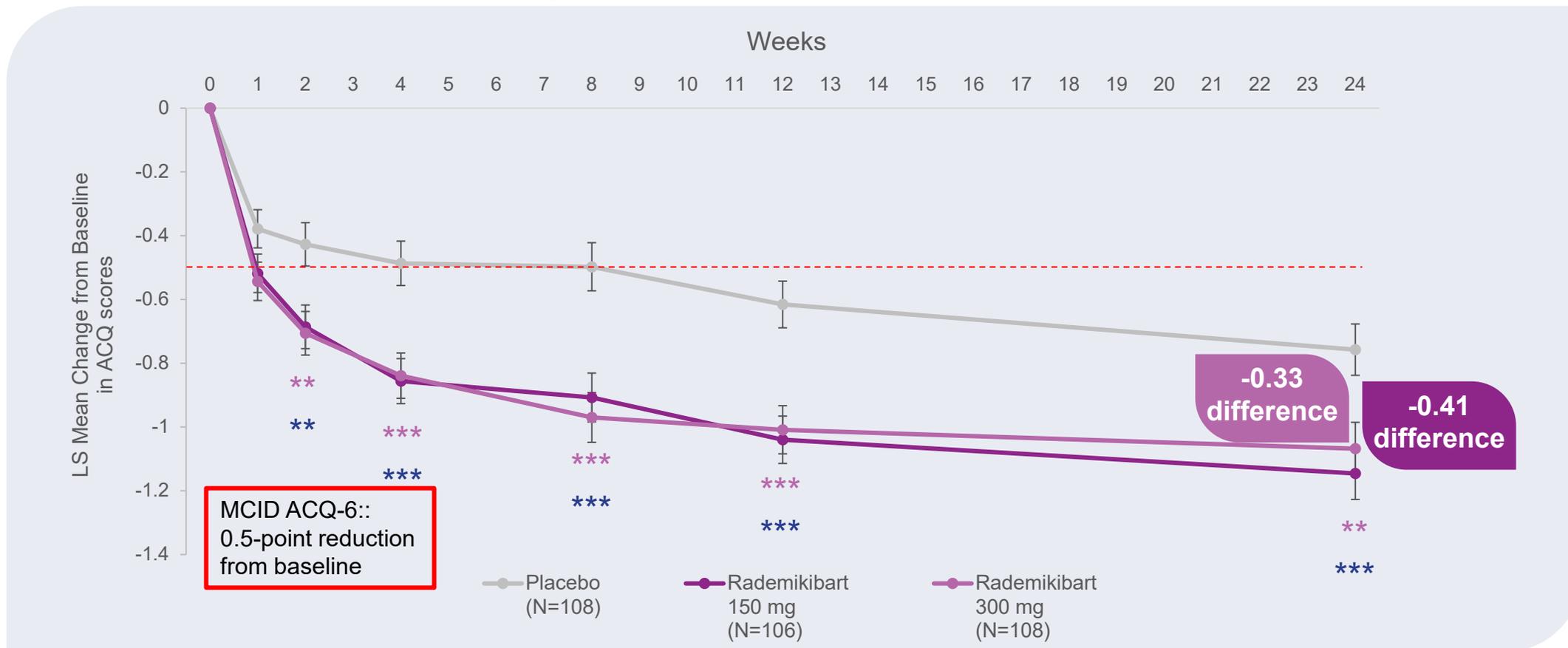
Rademikibart 300g (108)
1 (0.9)

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.

Patient Reported Outcomes Improved with rademikibart

Asthma Control Questionnaire (ACQ) Scores

Measuring the adequacy of asthma control and change in asthma control started early and was sustained to Week 24
Change from Baseline in ACQ Scores



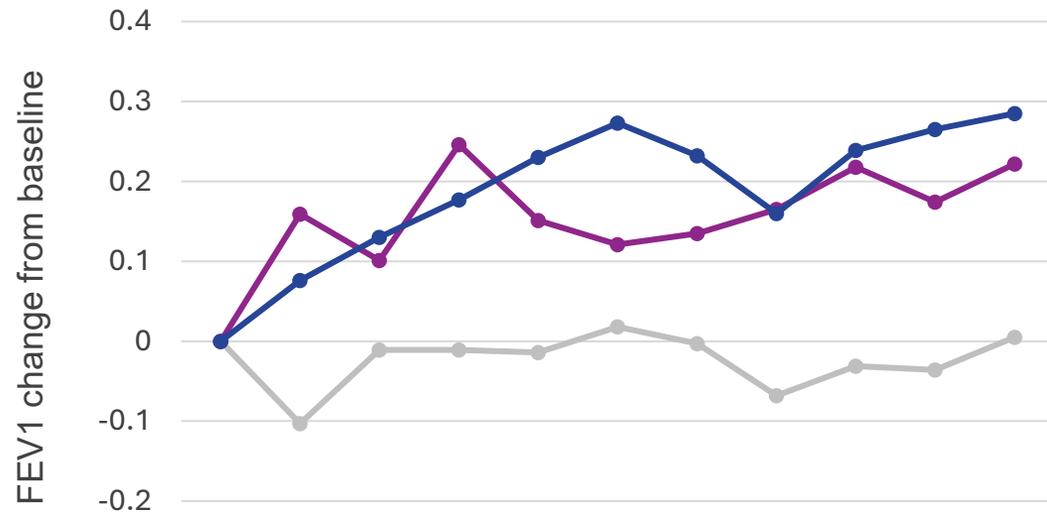
Std Error Bars; ***p<0.001, **p<0.01, *p<0.05. Week 24 values are differences in arithmetic means.

Asthma Control Questionnaire (ACQ) Scores = Questions 1-5 and 7 of the standard ACQ questionnaire. This is a validated variant on the ACQ which incorporates the first 5 PRO questions plus an FEV1 categorical variable ("Q7" from the clinic PFT). There is no albuterol component to the score ("Q6). MCID: Minimal Clinically Important Difference

Analysis of COPD-Like Subjects from Phase 2 Asthma Study

Asthma onset age > 40 year and post-bronchodilator FEV1/forced vital capacity < 0.7 at screening visit

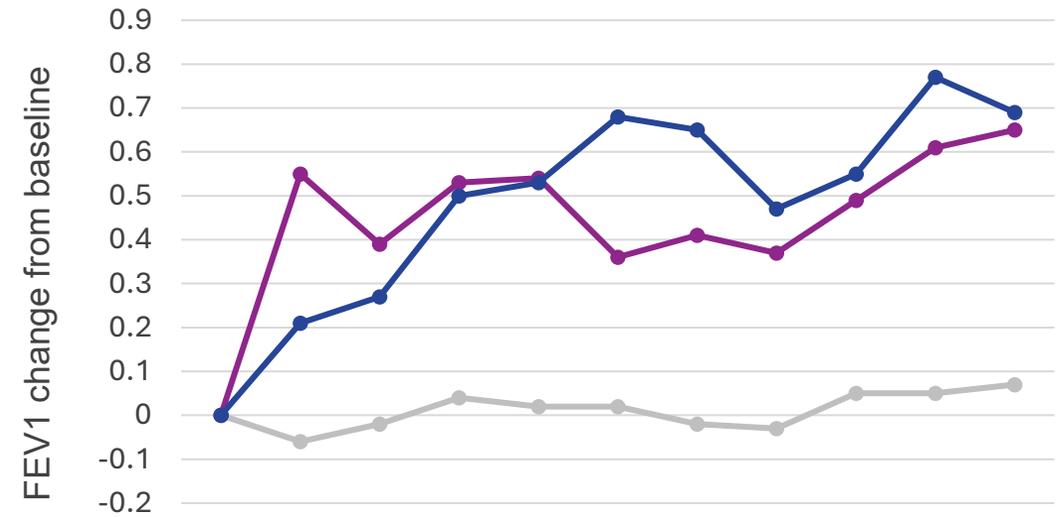
COPD-like Subjects from WW-002
All EOS levels



Week	1	2	4	6	8	10	12	16	20	24
Placebo (N)	27	24	24	26	23	25	26	23	23	22
150 mg (N)	17	16	16	16	15	13	14	17	14	14
300 mg (N)	19	21	19	19	17	20	18	16	19	17

● Placebo
 ● CBP-201 150 mg
 ● CBP-201 300 mg

COPD-like Subjects from WW-002
EOS ≥300 cells/uL



Week	1	2	4	6	8	10	12	16	20	24
Placebo (N)	8	8	7	8	6	8	8	7	7	7
150 mg (N)	5	5	5	4	3	4	4	5	3	3
300 mg (N)	6	7	6	7	6	7	5	6	6	6

● Placebo
 ● Rademikibart 150 mg
 ● Rademikibart 300 mg

EOS = eosinophils. FEV1 = Forced expiratory volume in one second

Competitive Landscape of Placebo Adjusted Improvement from Baseline In Pre-bronchodilator FEV₁

Rademikibart exhibited best-in-class potential in lung function improvement

Source	MoA	Product	FDA Approv. in last 10 yrs	Study	N (Pbo/Tx)	% patients with EOS ≥300 cells/μL	Week	First response week	Placebo adjusted improvement from baseline in FEV ₁	Placebo adjusted improvement from baseline in FEV ₁ (EOS ≥300 cells/μL)
Phase 2	IL-4Rα	Rademikibart	--	Phase 2 Asthma	108/108	46.3%	12	1	270 mL*	328 mL
							24		299 mL*	420 mL
				COPD-Like Patients†	27/19	31.6%	12	1	228 mL	500 mL
							24		290 mL	620 mL
Biologic Phase 3 trial results	IL-4Rα	Dupilumab	2018	Asthma: QUEST ¹	231/633	41.8%	12	2	130 mL	240 mL
			2024	COPD: NOTUS ⁵	465/470	60.8	12	2	82 mL	113 mL
	IL-5Rα	Benralizumab	2017	SIROCCO ³ Q4W	407/399	68.9%	48	4	--	106 mL
				CALIMA Q4W ⁶	440/425	67.5%	56		--	125 mL
	IL-5	Reslizumab	2016	STUDY 1 ²	244/245	--	52	4	126 mL	--
				STUDY 2 ²	232/232	--			90 mL	--
	TSLP	Tezepelumab	2021	NAVIGATOR ⁴	528/531	41.5%	52	2	130 mL	230 mL

For Illustrative Purposes Only: Not a head-to-head trial. Differences exist between trial designs, subject characteristics and geographical regions – caution should be exercised when comparing data across trials

EOS=eosinophils; FDA=Food and Drug Administration; FEV₁ = Forced expiratory volume in one second; IL=Interleukin; MoA=mechanism of action; Pbo=Placebo; TSLP=thymic stromal lymphopietin; Tx=treatment group.

*EOS ≥150 cell/μL

†Patients from Phase 2 asthma study with asthma onset age > 40 year and post-bronchodilator FEV₁/forced vital capacity < 0.7 at screening visit

1. QUEST – Castro M et al. N Engl J Med 2018;378:2486-96. 2. STUDY 1&2- Castro M et al. Lancet Respir Med. 2015 May;3(5):355-66. 3. SIROCCO – Bleecker ER et al. Lancet. 2016 Oct 29;388(10056):2115-2127. 4. NAVIGATOR – Menzies-Gow A et al N Engl J Med 2021;384:1800-9. 5. NOTUS – Bhatt et al N Engl J Med 2024;390:2274-2283; 6. CALIMA – FitzGerald JM et al. Lancet 2016 Sept 5; S0140-6736(16)31322-8

Safety Summary

No new safety signals were noted compared to previous rademikibart trials

- ❖ AEs were evenly distributed among treatment groups and similar to placebo
- ❖ Injection site reactions were mostly mild and transitory
- ❖ No SAEs were considered related to investigational product.
- ❖ No AEs related to hyper-eosinophilia.

Any Adverse Event	Placebo (N = 108) n (%)	Rademikibart 150 mg (N = 106) n (%)	Rademikibart 300 mg (N = 108) n (%)
Subjects with at least one AE	64 (59.3)	78 (73.6)	77 (71.3)
Any Serious AE	3 (2.8)	2 (1.9)	3 (2.8)
Any Grade 3 or 4 AEs	4 (3.7)	3 (2.8)	3 (2.8)
Any AE leading to death	0	0	0
Any AE leading to discontinuation	2 (1.9)	4 (3.8)	3 (2.8)
TEAEs occurring in ≥5% of subjects in the treatment groups			
COVID-19*	11 (10.2)	10 (9.4)	16 (14.8)
Nasopharyngitis	5 (4.6)	6 (5.7)	6 (5.6)
Cough	18 (16.7)	7 (6.6)	14 (13.0)
Dyspnoea	13 (12.0)	9 (8.5)	11 (10.2)
Asthma	10 (9.3)	8 (7.5)	8 (7.4)
Wheezing	11 (10.2)	8 (7.5)	7 (6.5)
AEs of special interest			
Conjunctivitis	0	1 (0.9)	1 (0.9)
Injection site reactions	0	14 (13.2)	8 (7.4)

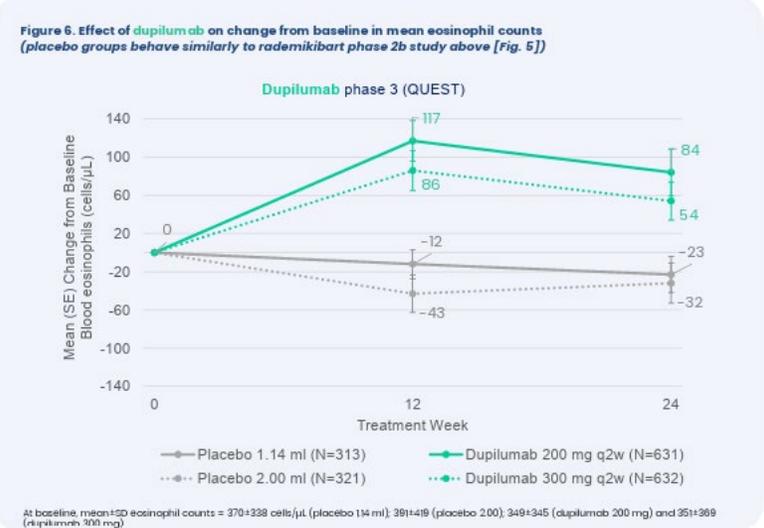
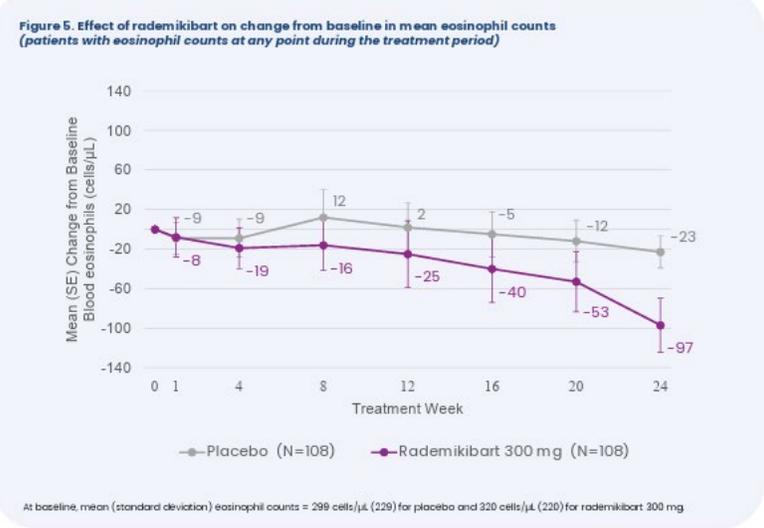
* Trial dates (April 2021 – Sept 2023) overlapped with COVID-19 pandemic

AE, Adverse Event; TEAE, Treatment Emergent AE. No AESIs of keratitis, anaphylaxis, parasitic/opportunistic infections, pregnancy, or symptomatic overdose were reported in any treatment group.

- Conjunctivitis includes any Preferred Term that included the terms: *conjunctivitis, allergic conjunctivitis, Conjunctival injection, bacterial conjunctivitis, viral conjunctivitis, giant papillary conjunctivitis, eye irritation, and eye inflammation.*

- Herpes infection includes any Preferred Term that included the terms: *herpes virus infection, herpes zoster, herpes simplex, herpes simplex reactivation, oral herpes.*

Substantially Fewer Hyper-Eosinophilia Episodes with rademikibart than with Dupilumab



	Ph2 Rademikibart Trial ¹		Dupilumab QUEST Trial ²	
	Placebo (N=108)	Rademikibart 300 mg (N=108)	Placebo (N=634)	Dupilumab 200/300 mg (N=1263)
Baseline EOS <500, n	91	85	484	497
<i>Post-baseline peak >1500 EOS</i>	1.1%	0%	2.7%	6.6%
<i>Post-baseline peak >3000 EOS</i>	0%	0%	0%	1.20%
Baseline EOS ≥500, n	16	20	149	114
<i>Post-baseline peak >1500 EOS</i>	18.8%	10.0%	17.4%	42.5%
<i>Post-baseline peak >3000 EOS</i>	0%	0%	2.7%	12.9%
Safety				
Eosinophil related TEAEs	0%	0%	0.6%	4.0%

Rate with rademikibart is lower than placebo

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

1. Collazo et al ATS 2025 Poster #13132. 2. Wechsler et al. J Allergy Clin Immunol Pract. 2022;10(10):2695-2709. doi:10.1016/j.jaip.2022.05.019; Eosinophil data figures – Collazo et al ATS 2025, Poster #13132 EOS=eosinophils;



Rapid and Sustained Clinical Response was Observed with Over 24 Weeks of rademikibart Treatment

Global Phase 2 results suggest best-in-class potential for rademikibart

Best-in-Class Potential

Significant improvements in lung function (FEV₁)

- Placebo adjusted FEV₁ improvement ranged from **140 mL** (150 mg, P = 0.05) to **189 mL** (300 mg, P < 0.001) at Week 12
- Improvements were seen **as early as Week 1** and were **sustained through the 24 weeks** of treatment (P < 0.001)
- **73% of improvement** seen on Day 7 was observed by the morning after the first dose with home spirometry
- **~ 9% increase** in mean % predicted FEV₁ in each treatment group versus 2.7% in the placebo group (P < 0.001)
- Patients with EOS ≥ 300 cells/μl saw up to 420 mL (300 mg) placebo adjusted FEV₁ improvement at Week 24

Strong trends in reductions in exacerbations

- Greatly reduced the annual exacerbation rate and hospital/ER visits due to asthma exacerbation vs placebo

Improved asthma control

- ACQ numerical separations as early as Week 1 with statistical differences occurring from Week 2 to Week 24

Safety

- Rademikibart was generally well tolerated over 24 weeks of treatment
- Reduction of eosinophils vs increase with dupilumab (reduces risk of SAEs associated with elevated eosinophils)

Next Steps

Clinically differentiated effects of greater response, faster onset, and less frequent dosing fuels our excitement to launch the SEASBREEZE STAT trials with a single-dose of rademikibart for acute exacerbations that maintains lung function for a full month

- What are the characteristics of participants who benefitted most from rademikibart treatment?
 - A. Eosinophil count of < 150 cells/ μ l
 - B. Females
 - C. FeNO of 15 ppb
 - D. Eosinophil count ≥ 300 cells/ μ l and FeNO ≥ 25 ppb**



Safety Snapshot & Reporting

Kimberly Manhard
*Executive Vice President,
Chief Development Officer*

- 1498 participants received at least 1 dose rademikibart in 9 completed trials (IB Edition 8)
 - 384 - healthy
 - 214 - moderate-to-severe persistent asthma with T2 inflammation
 - 26 - chronic rhinosinusitis with nasal polyps (CRSwNP) (terminated early due to COVID pandemic)
 - 874 - moderate-to-severe AD
 - 12 adolescents
- ~522 additional participants received at least 1 dose rademikibart in 4 new trials as of 8Jun2025 (Annual Report)
 - 182 - healthy (two Phase 1 studies: 1 completed & 1 ongoing)
 - ~86 - moderate-to-severe persistent asthma with T2 inflammation (Phase 3 52-week study in China enrolling)
 - 1 adolescent
 - 254 - moderate-to-severe AD (Phase 3 52-week study in China fully enrolled and ongoing)
 - 53 adolescents
- **~2,020 total study participants have received at least 1 dose of rademikibart, including 66 adolescents (as of 8Jun2025)**

Safety Snapshot

Rademikibart Doses Evaluated in Clinical Trials

- Single doses in healthy participants
 - 75 mg to 600 mg SC
 - 300 mg IV 30-minute infusion
- Multiple doses in participants with asthma, CRSwNP & AD
 - 75 mg, 150 mg and 300 mg QW x 10 wks
 - 600 mg loading dose + 150 mg SC Q2W x 24 wks
 - 600 mg loading dose + 300 mg SC Q2W x up to 52 wks
 - 600 mg loading dose + 300 mg SC Q4W x up to 36 wks
- **1,218 participants received a single 600 mg SC dose of rademikibart**
 - 1005 in completed studies
 - 218 additional in ongoing studies

Abbreviations: AD = atopic dermatitis; CRSwNP = chronic rhinosinusitis with nasal polyps; IV = intravenous; QW = every week; Q2W = every 2 weeks; Q4W = every 4 weeks; SC = subcutaneous

- **Adverse Event (AE)**

- Defined as any untoward medical occurrence associated with the use of a drug in humans, whether or not considered drug related.
- Can be any unfavorable and unintended sign, symptom, or disease temporarily associated with the use of an Investigational Product, whether or not considered causally associated with the use of the Investigational Product.
- Any abnormal laboratory value, vital sign result, or ECG or X-ray findings deemed clinically significant by the Investigator, regardless of causal relationship, must be reported as an Adverse Event.
- A clinical diagnosis, rather than the changes in laboratory analyte or other assessment, should be recorded.

- Most Common Adverse Events (>5% and higher than placebo)
 - Asthma trial (pooled doses):
 - COVID-19 (12.1%)
 - injection site erythema (6.5%)
 - nasopharyngitis (5.6%)
 - AD trials (pooled analysis):
 - COVID-19 (14.3%)
 - upper respiratory tract infection (9.0%)
 - hyperlipidaemia (5.4%)

- **Serious Adverse Event (SAE)**

- Any untoward medical occurrence that, at any dose:

- Results in death
- Is life-threatening
- Requires inpatient hospitalization or prolongation of existing hospitalization

- Following events do not meet definition:

- hospitalization for elective treatment of a pre-existing condition that does not worsen from baseline,
- hospitalizations for a standard procedure for IP administration,
- routine monitoring of the studied indication not associated with any deterioration in condition,
- hospitalization for social or convenience reasons, or
- hospitalization or an emergency room visit lasting less than 24 hours (unless it meet the criteria of an important medical or a life-threatening event).

- Results in persistent disability/incapacity
- Results in a congenital anomaly/birth defect
- Important medical events

- Events that may not result in death, be life-threatening, or require hospitalization may be considered serious when, based upon appropriate medical judgement, they may jeopardize the participant and may require medical or surgical intervention to prevent one of these (serious) outcomes listed in this definition

- Serious Adverse Events (SAEs)
 - 48 SAEs in 34 of 1498 (2.3%) participants who received rademikibart in 9 completed trials (IB, Edition 8)
 - 43 unique SAEs; remaining 5 SAEs occurred twice:
 - COVID-19, asthma, acute MI, arteriosclerosis coronary artery, bile duct stone
 - None considered possibly related to rademikibart by Investigator or Sponsor
 - 18 unique SAEs in 16 of 608 additional participants in 4 new trials (as of 8Jun2025)
 - 9 participants on rademikibart, and 9 participants on blinded treatment
 - **No trend of significant untoward risk based on reported SAEs**

- **Adverse Events of Special Interest (AESI)**

- Defined as AEs of potential scientific or medical concern; may be serious or non-serious
- 7 AESIs Initially assigned by US FDA based on DUPIXENT safety data across multiple indications

AESI	Completed Clinical Studies in Patients						Totals (N=1114) n (%)
	Asthma	Atopic Dermatitis				CRSwNP	
	WW002 (n=214)	AU002 (n=23)	WW001 (n=170)	CN002 (n=321)	CN003 (n=360)	WW003 (n=26)	
Conjunctivitis	2	0	5	18	12	0	37 (3.3%)
Keratitis	0	0	0	3	1	0	4 (0.36%)
Anaphylactic reaction	0	0	0	1	0	0	1 (0.09%)
ISRs lasting > 24 hours	22	0	0	17	19	3	61 (5.5%)
AST/ALT increased to >5 × ULN	0	0	1	1	1	0	3 (0.27%)
Parasitic and opportunistic infections	0	0	0	1	0	0	1 (0.09%)
Symptomatic drug overdose	0	0	0	0	0	0	0

- Modified AEsIs based on data from completed studies:
 - Limited 'ISRs lasting >24 hours' to CTCAE Grade 3 or greater
 - Removed 'AST/ALT increase >5 × ULN'; new protocols require cases of DILI to be closely monitored
 - Removed 'symptomatic drug overdose' as no cases have reported
- For Seabreeze STAT trials
 - Conjunctivitis
 - Keratitis
 - Severe (CTCAE Grade 3 or greater) injection site reaction persisting for >24 hours
 - Injection Site Reaction Assessment Tool included in Protocol Appendix D
 - Parasitic and opportunistic infections
 - According to publication by Winthrop et al 2015; Protocol Appendix H, Table 7 – discuss with Medical Monitor
 - Anaphylaxis
 - According to publication by Sampson et al 2006; Protocol Appendix H, Table 8

- **Drug-Induced Liver Injury (DILI)**
 - Specifically refers to cases that meet ALL of the following 3 criteria:
 - ALT or AST >3x ULN during Treatment Assessment Period, and
 - Total bilirubin > 2xULN during Treatment Assessment Period; without cholestasis at baseline (serum alkaline phosphatase [ALP] increased), and
 - No other identifiable causes explaining simultaneous elevation of aminotransferases and total bilirubin, such as viral hepatitis A,B, C, or E or other acute liver diseases, or concomitant use of other drugs that may induce liver injury.
- **Unanticipated Adverse Device Effect (UADE)**
 - Required by US FDA regulations when a study includes a device (eg, prefilled syringe)
 - Defined as:
 - a **serious** effect on health or safety or any **life-threatening** problem or death caused by, or associated with, a device, if that effect, problem, or death was not previously identified in nature, severity, or degree of incidence in the investigational plan, or
 - any other unanticipated **serious** problem associated with a device that relates to the rights, safety, or welfare of participants.

SAEs, Serious AESIs, DILI, UADE associated with an SAE

- Within **24 hours** of the Investigator becoming aware of event

Non-serious AESIs

- Within **72 hours** of the Investigator becoming aware of event

Pregnancy of female participants

- Within **24 hours** of the Investigator becomes aware of the pregnancy

Break – Return at 10:20 am PT

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Take a Breather

- Join us in the foyer for light snacks and a moment to recharge.