Barzolvolimab EMBARQ-CSU1/CSU2 Phase 3 Topline Results

SEPTEMBER 22, 2026

DATA CUTOFF: SEPTEMBER 9, 2026

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For decades, "well-controlled disease" has been accepted as an adequate outcome in CSU.

With barzolvolimab, the data clearly show we have an opportunity to do better for patients…

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EMBARQ-CSU1/CSU2 Pivotal Phase 3 Trials Met Primary and All Key Secondary Endpoints

Novel, First-In-Class Barzolvolimab: Potential Transformational Therapy for People With CSU

Best in disease* rapid, profound, durable efficacy observed.

Efficacy results consistent in omalizumab refractory CSU. 1st CSU treatment to demonstrate this in Ph. 3 trial.

Profound impact on severe angioedema observed. 1st CSU treatment to demonstrate this in Ph. 3 trial.

Efficacy sustained or deepened from weeks 12 to 24 across primary and all key secondary endpoints.

Favorable safety profile consistent with Phase 2 experience.

Results support planned BLA submission in 2027

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*Across reported studies, not based on head-to-head comparisons. Cross study comparisons are limited given differences in the design of the included trials, such as variations in statistical methods, patient populations, and dosing schedules, among other factors.

CSU: Patient Population with a High Unmet Need for More Effective Treatments

Underdiagnosed disease of misery affecting **1.8MM people** in the US alone, characterized by:

- Relentless spontaneous hives
- Unbearable itch
- Sleep disruption
- 55% with disfiguring swelling (angioedema)[1]
- Significant mental health burden
- Impacts all aspects of life[2,3]
- **1.7X increase in all-cause mortality** at 5 years[3]

Complete absence of symptoms/complete control is the treatment goal*…but the* ***vast majority of patients****, even those receiving advanced therapies,* ***continue to suffer*** *from debilitating symptoms and unrelenting anxiety about when the next flare will occur.*

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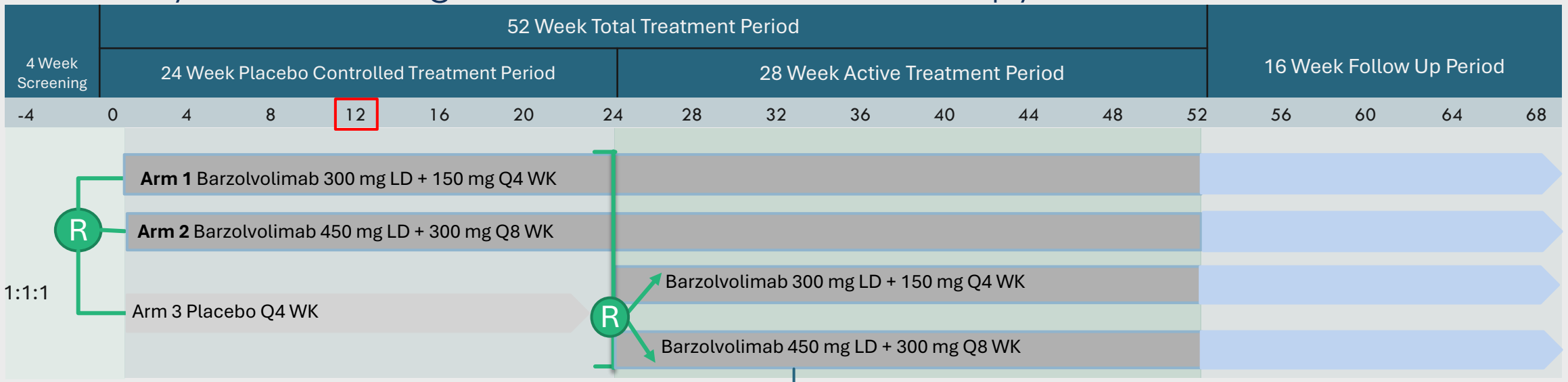
[1]Weller, et al. Dermatol Ther, 2025; [2]Maurer, et al. Allergy, 2017; [3]Kolkhir P, et al. JACI, 2025

EMBARQ CSU

Phase 3 CSU Registration Program: the Largest Program Conducted in Antihistamine Refractory CSU, Including Patients With Advanced Therapy



Study Overview

- Two randomized, double-blind, placebo-controlled, parallel group studies in moderate to severe CSU
- Antihistamine refractory CSU, (1-4x approved dose) including patients with advanced therapy experienced/refractory CSU
- 1,939 patients enrolled across 43 countries and 500+ sites

Primary Endpoint

- Primary Endpoint: mean change from baseline in UAS7 at Week 12
- 90% powered to detect at least a 10-point difference between each of active arm vs placebo in overall population as well as in the subpopulation of omalizumab refractory participants

*Primary endpoint

Key Secondary Endpoints

At Week 12:

- Mean change from baseline in ISS7 and HSS7
- Proportion of participants with UAS7=0
- Proportion of participants with UAS7≤6
- Proportion of participants with AAS7=0 who have AAS7> 0 at baseline
- Mean change from baseline in UAS7 in participants refractory to omalizumab
- Proportion of participants with UAS7=0 in participants refractory to omalizumab

Well-Balanced Patient Population Across Studies Patients had Severe Disease at Baseline

	EMBARQ-CSU1			EMBARQ-CSU2		
	Placebo Q4W (N=325)	Barzolvolimab 150 mg Q4W (N=320)	Barzolvolimab 300 mg Q8W (N=318)	Placebo Q4W (N=321)	Barzolvolimab 150 mg Q4W (N=324)	Barzolvolimab 300 mg Q8W (N=321)
Age (years)	46.4 (14.58)	46.1 (14.49)	47.0 (14.7)	45.7 (14.59)	46.2 (14.53)	46.2 (14.01)
Female, n (%)	235 (72.3)	243 (75.9)	228 (71.7)	215 (67.0)	229 (70.7)	208 (64.8)
Race, White, n (%)	228 (70.2)	233 (72.8)	216 (67.9)	229 (71.3)	225 (69.4)	242 (75.4)
Race, Black, n (%)	35 (10.8)	39 (12.2)	31 (9.7)	6 (1.9)	11 (3.4)	8 (2.5)
Race, Asian, n (%)	40 (12.3)	30 (9.4)	47 (14.8)	49 (15.3)	54 (16.7)	50 (15.6)
Weight (kg)	79.9 (20.47)	79.39 (16.98)	78.34 (18.06)	80.70 (18.96)	78.72 (19.10)	79.94 (19.15)
UAS7 Score	30.9 (7.32)	30.6 (7.44)	30.3 (7.01)	29.3 (7.19)	29.7 (6.87)	29.6 (7.28)
Severe disease UAS7≥28, n (%)	216 (66.5)	213 (66.6)	216 (67.9)	199 (62.0)	203 (62.7)	198 (61.7)
Omalizumab refractory* n (%)	55 (16.9)	52 (16.3)	52 (16.4)	43 (13.4)	44 (13.6)	42 (13.1)
AAS7>0, n (%)	237 (72.9)	238 (74.4)	239 (75.2)	206 (64.2)	213 (65.7)	217 (67.6)
AAS7, in AAS7>0	57.1 (29.99)	52.0 (29.15)	54.9 (28.24)	50.2 (28.63)	51.5 (28.67)	51.7 (27.81)
DLQI Score	16.0 (7.34)	15.5 (7.13)	15.6 (7.13)	14.2 (7.11)	14.4 (7.02)	14.3 (7.11)

Mean (SD) unless otherwise indicated; full analysis set

*Patients treated with omalizumab at approved doses for at least 3 months and whose symptoms never responded or who responded initially but symptoms subsequently returned, or who discontinued omalizumab due to intolerance

Efficacy Results

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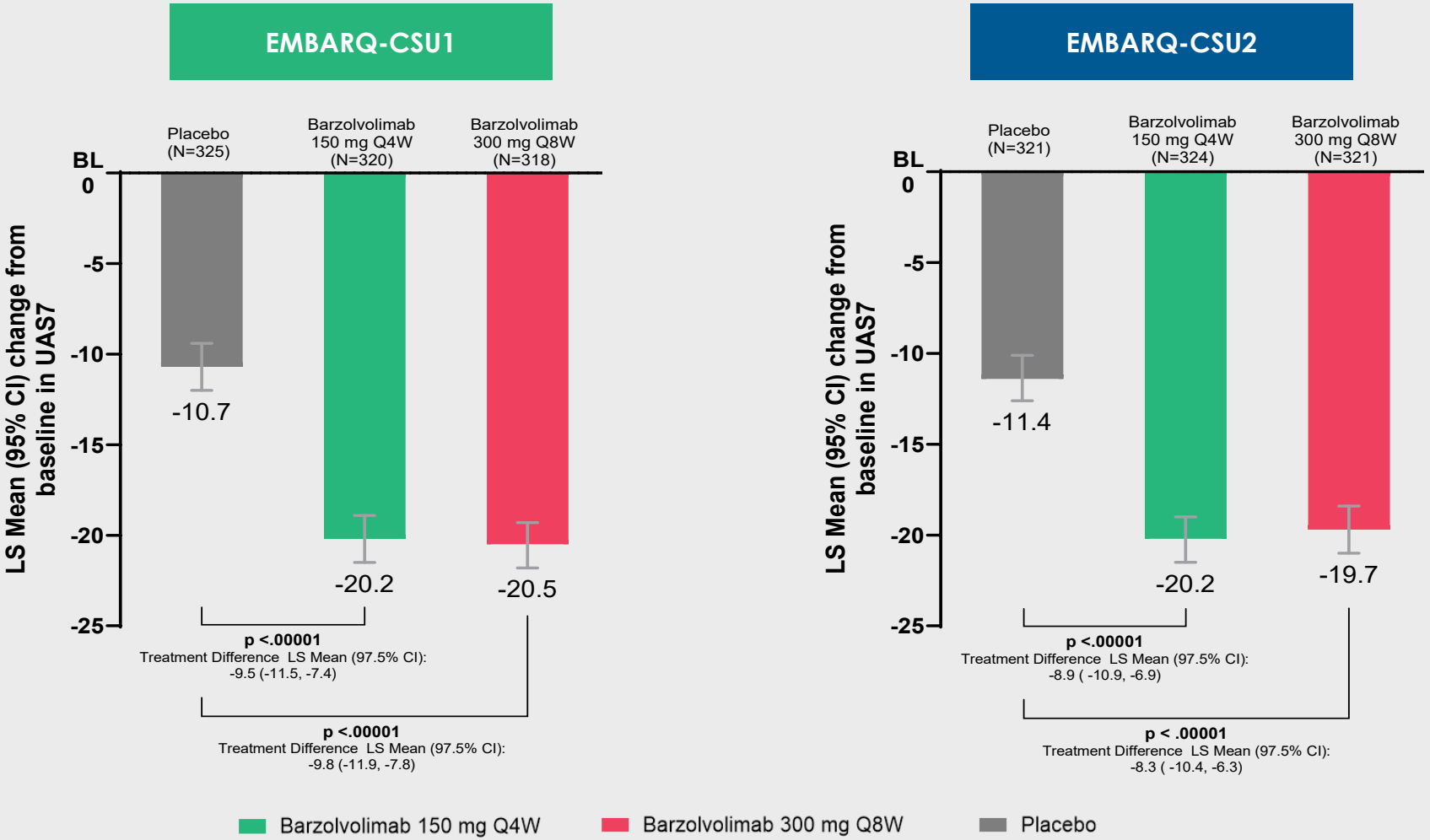
Primary Endpoint: Clinically Meaningful and Highly Statistically Significant Improvement in Mean Change from Baseline in UAS7 Score at Week 12



Full analysis set; imputed data and MMRM model

All Key Secondary Endpoints Met at Week 12: Clinically Meaningful and Highly Statistically Significant

Consistent with Phase 2 Experience

Trials met key secondary endpoints of high importance to patients and physicians

- Proportion of patients with complete response (UAS7=0)
- Proportion of patients with UAS7=0 in patients with CSU refractory to omalizumab
- Proportion of patients with AAS7=0 who have AAS7>0 at baseline

Trials met key additional secondary endpoints demonstrating consistent and deep responses to barzolvolimab

- Mean change from baseline in ISS7 and HSS7
- Mean change from baseline in UAS7 in patients refractory to omalizumab
- Proportion of patients with UAS7≤6

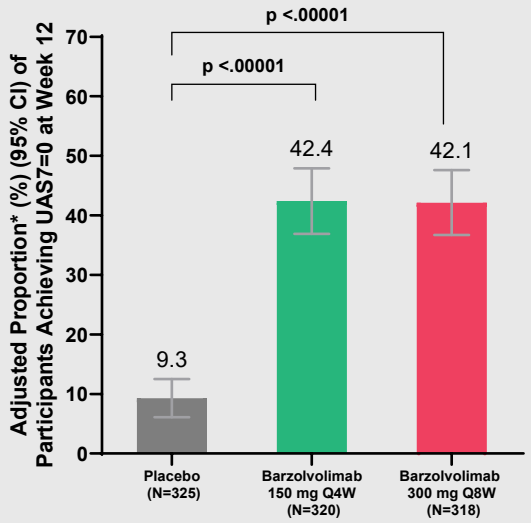
Efficacy sustained or deepened from Weeks 12 to 24 across primary and all key secondary endpoints

Complete Response (UAS7=0) Results Show Potential to Set New Treatment Standard

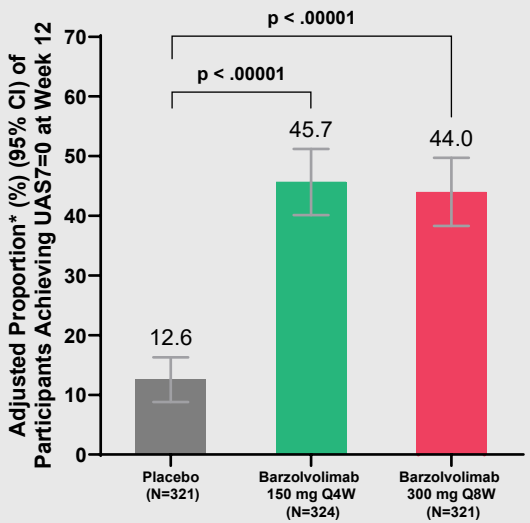
Complete Absence of Disease Activity Sustained or Deepened Over 24 Weeks

Week 12

EMBARQ-CSU1

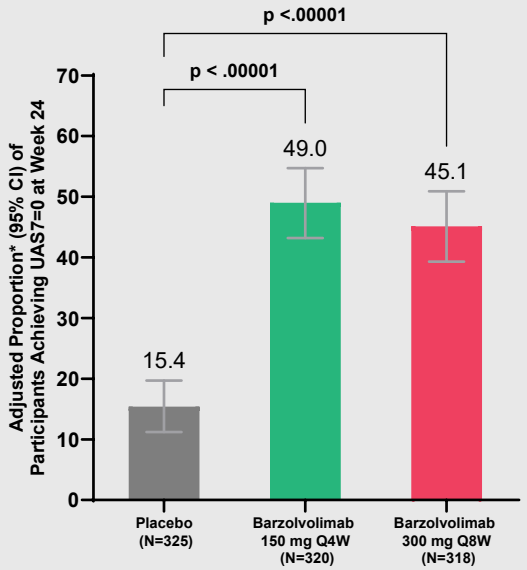


EMBARQ-CSU2

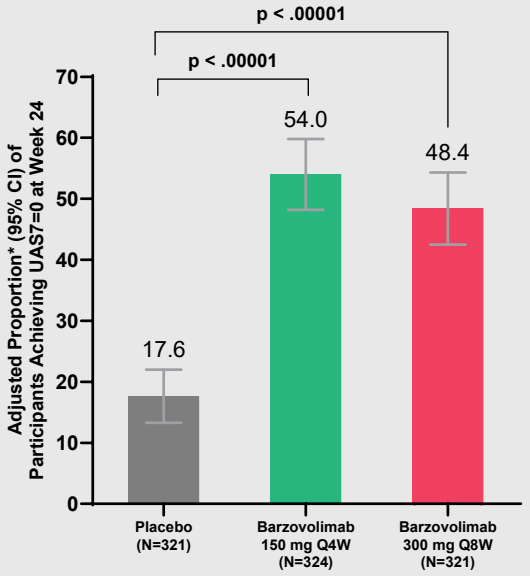


Week 24

EMBARQ-CSU1



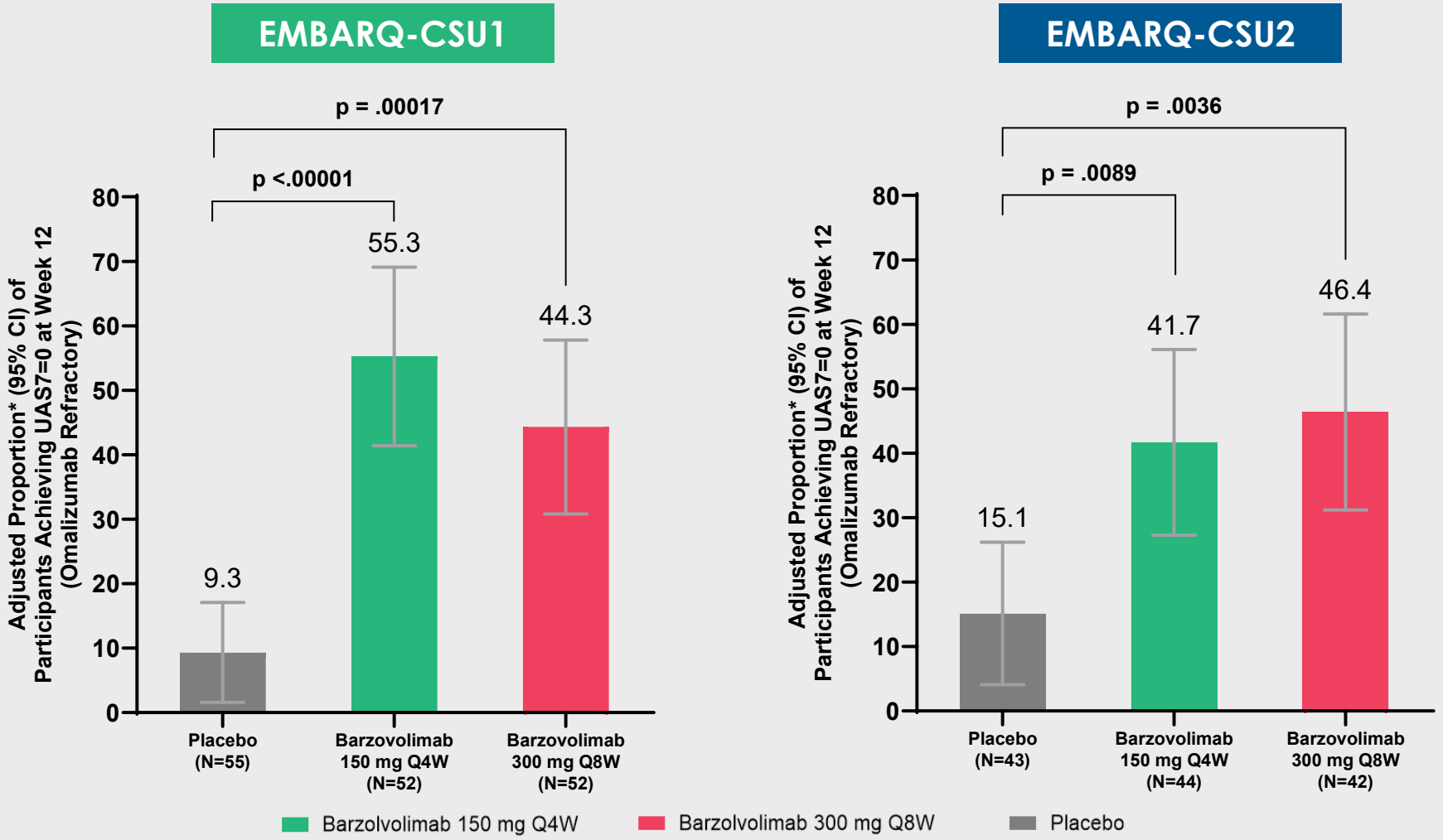
EMBARQ-CSU2



Barzolvolimab 150 mg Q4W Barzolvolimab 300 mg Q8W Placebo

*Adjusted proportions are based on logistic regression model with multiple imputation method.

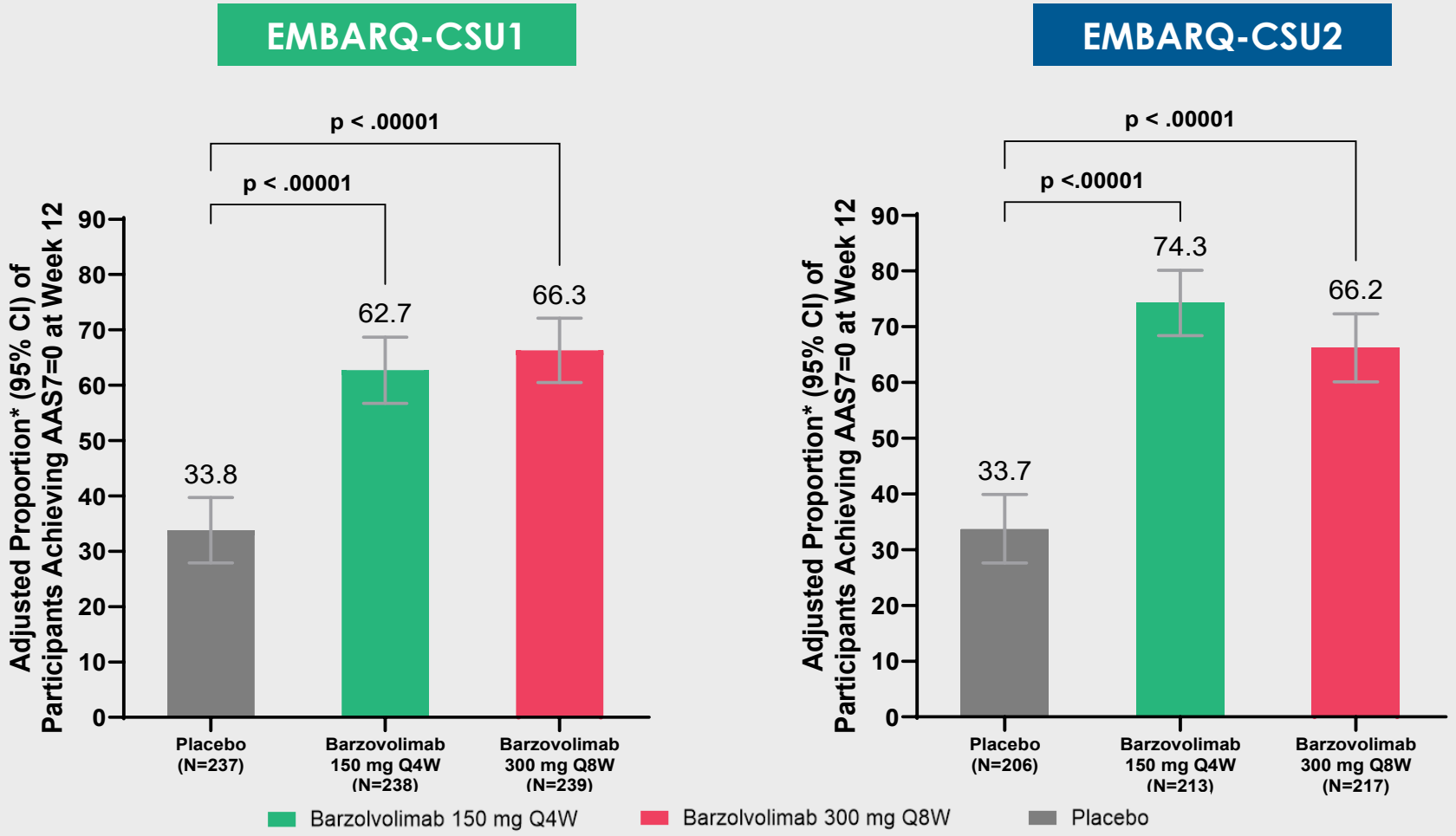
Statistically and Clinically Significant Higher Complete Response Rates (UAS7=0) Achieved in Omalizumab-Refractory CSU at Week 12, a Population of High Unmet Need



*Adjusted proportions are based on logistic regression model with multiple imputation method.

Majority of Patients Who Have AAS7>0 at Baseline Achieved Complete Angioedema Control (AAS7=0) at Week 12

Potential to Set New Standard in Angioedema Control



*The adjusted odds ratios and the proportions are based on logistic regression model with multiple imputation method.

Safety Results

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Favorable Safety Profile Consistent with Prior Experience

Adverse Events Through 24 Week Placebo Controlled Period (AEs observed in > 3% of patients)

	Pooled EMBARQ-CSU1 and EMBARQ-CSU2		
N (%)	Placebo Q4W (N=645)	Barzolvolimab 150 mg Q4W (N=648)	Barzolvolimab 300 mg Q8W (N=641)
Patients with ≥1 AE	340 (52.7)	490 (75.6)	492 (76.8)
Adverse Events in ≥ 3% of Patients			
Hair color changes	29 (4.5)	292 (45.1)	330 (51.5)
Skin Hypopigmentation	16 (2.5)	71 (11.0)	64 (10.0)
Neutropenia	4 (0.6)	59 (9.1)	75 (11.7)
Skin Hyperpigmentation	5 (0.8)	59 (9.1)	58 (9.1)
Dysgeusia	9 (1.4)	44 (6.8)	63 (9.8)
Hypogeusia	10 (1.6)	33 (5.1)	53 (8.3)
Nasopharyngitis	36 (5.6)	41 (6.3)	40 (6.2)
Anemia	4 (0.6)	20 (3.1)	20 (3.1)
Serious Adverse Events			
Patients with SAE(s)	15 (2.3)	6 (0.9)	14 (2.2)
Treatment Related SAEs	1 (0.2)	3 (0.5)	4 (0.6)
Anaphylaxis Adjudicated as Probable (G4)	0	2	1 (occurred after placebo dose)
Other	1[A]	1[B]	3[C]

- On barzolvolimab, the vast majority of AEs are mild to moderate
- As anticipated, on barzolvolimab most of the common AEs are KIT-mediated and expected to be reversible
- Rate of SAEs similar across treatment groups

[A]G3 anaphylaxis adjudicated as unlikely
[B]G2 angioedema/throat tightness/urticaria
[C]G3 anemia/neutropenia;
G2 malaise/dyspnea/chest pain;
G3 anaphylaxis after placebo administration adjudicated as unlikely

Barzolvolimab Did Not Lead to Increased Rate of Infections

Neutropenia Not Associated with Increased Incidence of Infections

No increased rates of infection in barzolvolimab vs placebo treatment groups

- Placebo: 23.9%
- 150 mg Q4W: 24.4%
- 300 mg Q8W: 23.6%

Rates of neutropenia in Phase 3 were consistent with Phase 2

- Placebo: 0.6%
- 150 mg Q4W: 9.1%
- 300 mg Q8W: 11.7%

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Bringing Barzolvolimab to Patients

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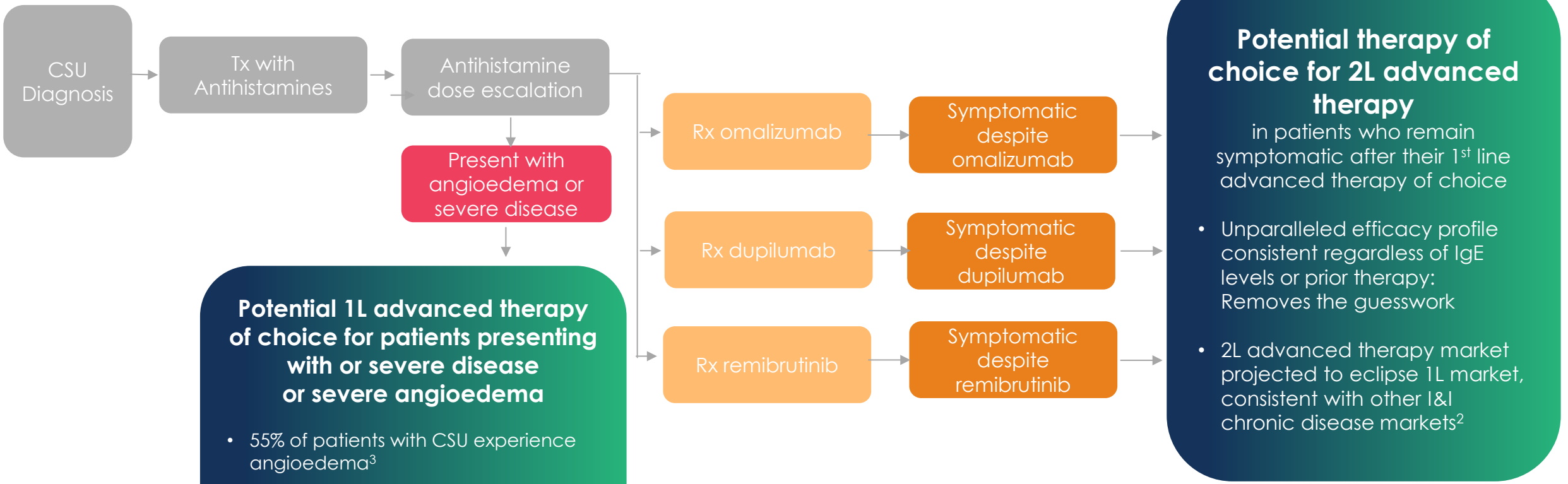
Phase 3 Data Support Barzolvolimab Potential to Uniquely Address Two Large CSU Populations With Significant High Unmet Need

Potential Future CSU Treatment Paradigm[1]



[1] Simplified for illustration; [2]Celldex data on file; [3]Weller at al., Urticaria Voices: Real-World Experience of Patients Living with Chronic Spontaneous Urticaria, Dermatol Ther, Feb 28 2025. [4]Weller at al., Urticaria Voices Study: Physicians' Perspectives on the Real-World Patient Burden, Treatments and Outcomes in Chronic Spontaneous Urticaria. Published online Aug 8, 2025

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EMBARQ Phase 3 Results Support Barzolvolimab Potential to Deliver Transformational Patient Impact & Commercial Success

- Barzolvolimab is a novel, first and only-in-class antibody with an MOA that addresses the root cause of CSU
- Favorable consistent safety and tolerability profile across multiple studies
- Phase 3 results demonstrated highly differentiated efficacy built on a foundation of Complete Response (no itch/no hives)
- Potential to address significant populations of unmet need within CSU, including severe disease and/or angioedema, and those refractory to advanced therapies

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Results Support Barzolvolimab's Potential to be a Life-Changing Therapy in CSU

- Results offer new hope for patients, physicians and CSU community
- Both Phase 3 trials met all primary and key secondary endpoints with high statistical significance at both dose levels
- Favorable safety profile consistent with Phase 2 experience
- Results support planned BLA submission in 2027
- Additional 24-week Phase 3 results anticipated in February 2027

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Questions
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