Barzolvolimab Phase 2 CSU 76 Week Data

7 MONTHS POST ACTIVE THERAPY

EAACI 2025

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01

Introduction

Anthony Marucci, President & CEO

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Barzolvolimab Best in Disease for All Patients[1]

CSU is a disease of misery, impacting all facets of patients' lives

- Highest rate of complete response at all time points[2]
- Rapid complete response (UAS7=0), as early as 2 weeks
- Deepening response over 52 weeks of treatment
- Durable complete response 7 months post treatment

Patient **quality of life** is **directly tied** to achieving **complete response (UAS7=0)**

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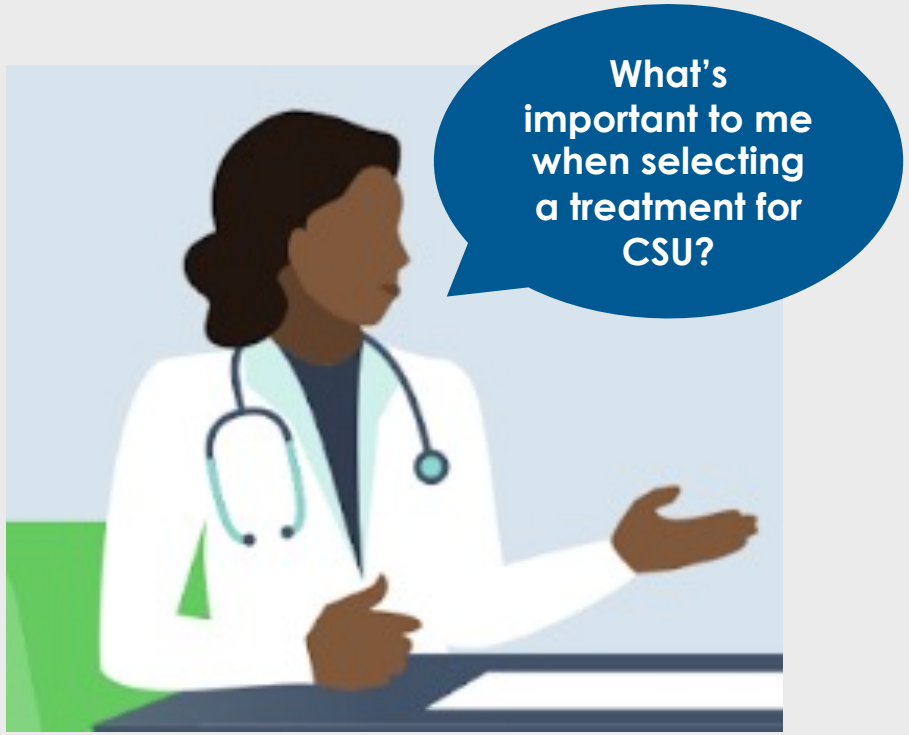
[1]Based on Phase 2 results; [2]Across reported studies, not based on head-to-head comparisons

Market Research Highlights HCPs Prioritize Efficacy and Quality of Life When Selecting Treatments For CSU

Allergists, dermatologists and NP/PAs in either specialty (n=205) ranked characteristics tied to efficacy as the most important when choosing a treatment for their CSU patients



01 Improves patients' quality of life

02 Has a strong efficacy profile

03 Completely eliminates my patient's symptoms

04 Has sustainable, lasting effects

05 Proven long-term safety profile

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Notes: Quantitative research done by external market research group in February 2025. A total of 205 providers were included in this research (n=75 US allergists, n=75 US dermatologists, n=55 NP/PAs with either allergy or dermatology specialty). HCP was asked (1) Select the characteristic that is most important to you when choosing a treatment for CSU.

92% of Patients Report Moderate to High Impact from CSU on their Daily Life[1]

Impacts all Aspects of Life[2,3]

Current clinical guidelines recommend complete response (UAS7=0) as the goal of treatment[4]

Patients report CSU has no impact on their quality of life when they achieve complete response[5]

Patients with CSU **need new options** to obtain **complete response** of their symptoms and **regain control of their lives**

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[1]Winders, TA, et al. EADV 2024; [2]Maurer, et al. Allergy, 2017; [3]Kolkhir P, et al. JACI, 2025; [4]Zuberbier T, et al. Allergy, 2022; [5]Kolkhir P, et al. JACI, 2023

Phase 2 CSU Data Continues to Impress

93% of treated patients had a clinically meaningful response on study

12 Weeks: Primary Endpoint Met (mean change in UAS7)

51% of patients (150 mg Q4W) had complete response compared to placebo rate of only 6%

48 Weeks: Patients Received Last Dose

52 Weeks: Response continued to Deepen

Highest rate of complete response observed in a well controlled study in CSU with 71% of patients (150 mg Q4W) achieving a complete response at Week 52

76 Weeks: 7 Months Post Active Therapy

Patients sustained treatment benefits on UAS7 were apparent over 76 weeks. Complete response was observed in 41% of patients (150 mg Q4W) 7 months following the last dose of barzolvolimab

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02

CSU 76 Week Results

DIANE YOUNG, SENIOR VICE PRESIDENT, CHIEF MEDICAL OFFICER

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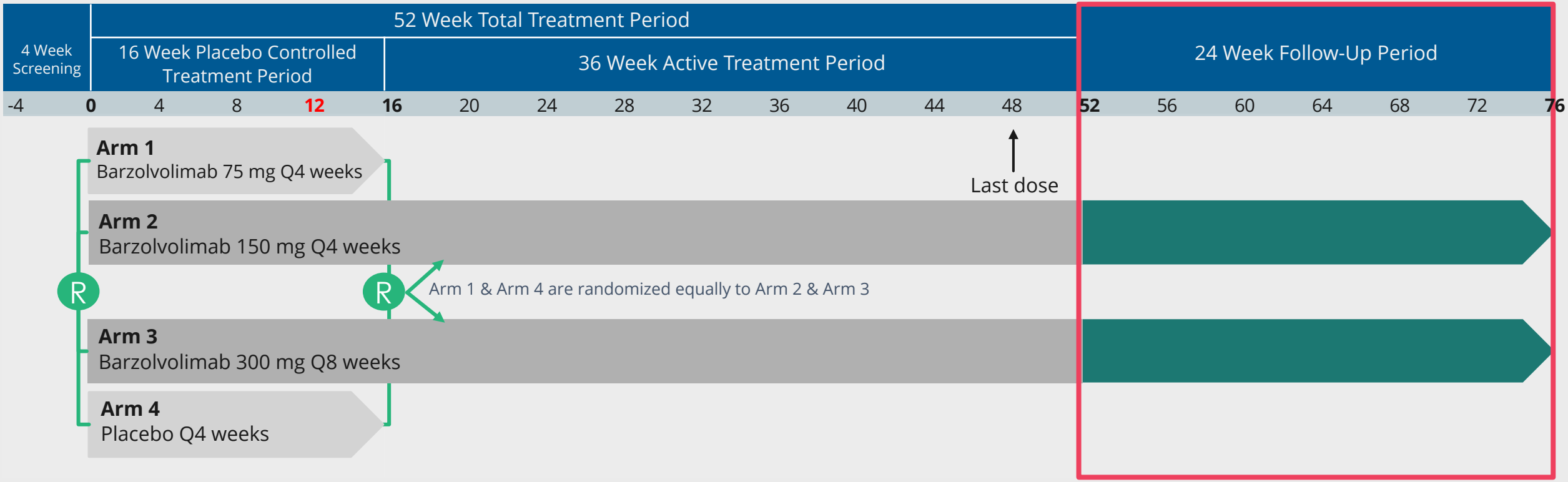
Randomized, Double-Blind Placebo Controlled Study

- **Moderate to severe CSU;** symptomatic despite treatment with up to **4X labeled antihistamine dose**; includes patients with **prior biologics**
- **207 treated patients**
- Primary Endpoint: **Mean change from baseline UAS7** (Urticaria Activity Score) at Week 12
- Final patient visit December 2024



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~70% Patients had Severe CSU (UAS7≥28) at Baseline

High UAS7/angioedema rates & prior omalizumab experience make efficacy even more impressive

	Barzolvolimab 75 mg Q4W (n=53)	Barzolvolimab 150 mg Q4W (n=52)	Barzolvolimab 300 mg Q8W (n=51)	Placebo (n=51)
Age (years)	42.2 (18-69)	46.0 (21-81)	47.2 (20-80)	44.4 (20-76)
Female, n (%)	40 (76%)	39 (75%)	41 (80%)	36 (71%)
Weight (kg)	77.5 (50-129)	80.9 (55-169)	85.7 (47-163)	83.8 (51-143)
UAS7 score	30.3 (14-42)	30.8 (12-42)	31.3 (17-42)	30.0 (13-42)
UAS7, severe disease n (%)	34 (64%)	36 (69%)	39 (76%)	33 (65%)
DLQI score	15.9 (3-30)	15.7 (3-30)	17.4 (1-30)	17.0 (3-30)
Angioedema at baseline, n (%)	40 (75%)	35 (67%)	42 (82%)	32 (63%)
Previous experience to omalizumab, Yes n(%)	11 (21%)	11 (21%)	11 (22%)	8 (16%)

Data shown are mean (range), unless otherwise specified

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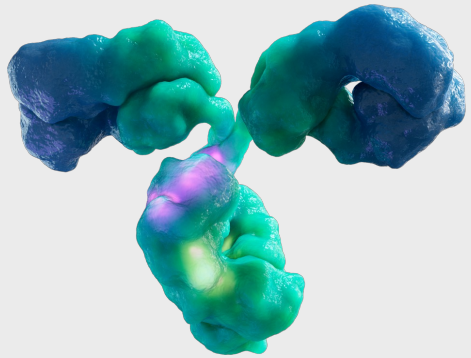
Barzolvolimab is Well Tolerated

Large Phase 2 experience reinforces a very well tolerated, long-term safety profile

Unique Allosteric MoA and Engineering



Designed to be highly potent with exquisite specificity, extended half-life and to eliminate potential for mast cell activation

Predictable mild, KIT-mediated effects are well understood and reversible

Most adverse events are mild (Grade 1), KIT-mediated effects and reversible during follow-up period

- Decreases in neutrophils resolve on treatment; no association with infections
- Hair color and skin hypopigmentation resolve following discontinuation of treatment

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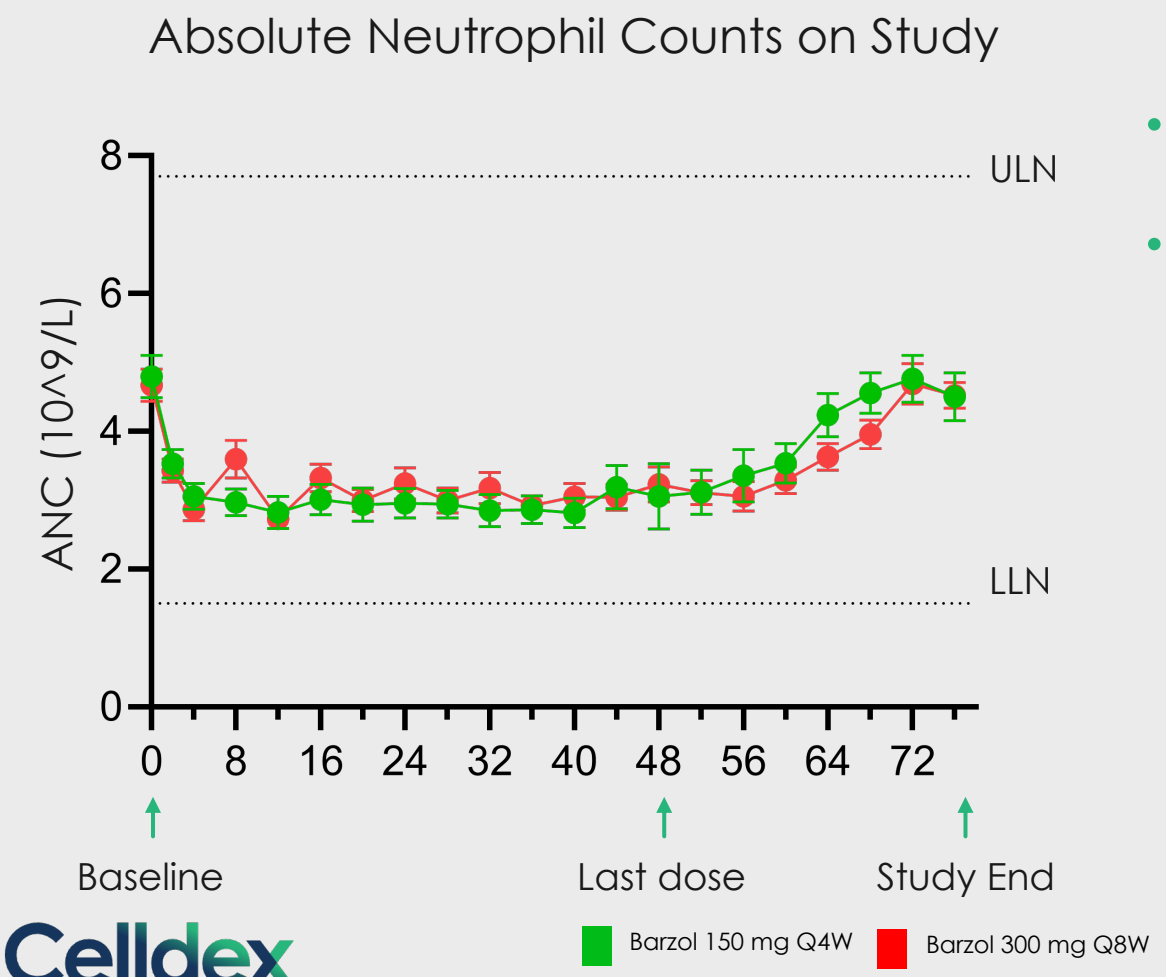
Neutrophil Count Changes – No Clinical Significance

Changes in laboratory values



- Initial neutrophil cell count drop with no progressive decline with additional treatment
- Patients that start at lower end of normal range for neutrophil counts can have transient lab values below the normal range
  - 28 patients on study had an AE of decreased neutrophil count/neutropenia; only 14 were confirmed
  - All resolved rapidly while on treatment
  - None associated with infection
  - Neutrophil counts return to baseline levels during follow-up

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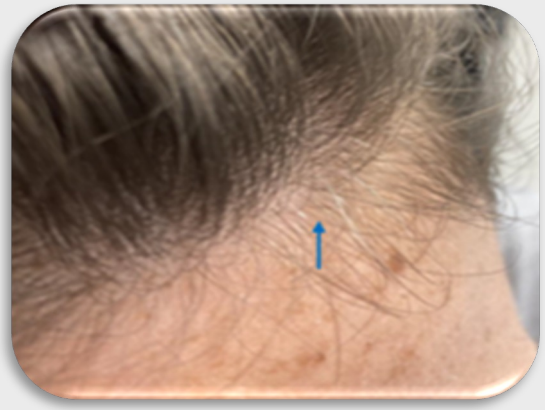
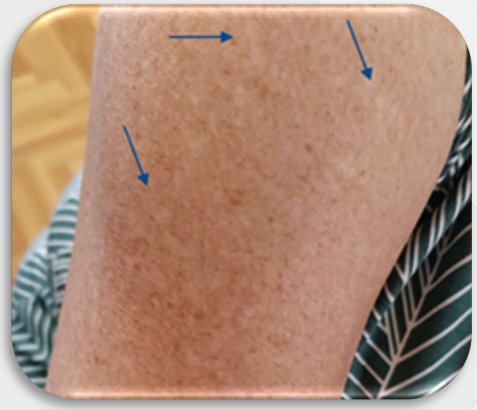
Hair/Skin Pigmentation Change are Mild and Reversible

Patients experience same level of QOL improvement



- Localized hair color changes/lightening in 48 patients (46 G1; 2 G2) through 52 weeks of treatment
- >90% already resolved at study closure; 4 ongoing
- Median onset: 3.4 months
- Median age: 42 years (18-80)
- 1 additional case (G1) during follow-up; resolved



- Small areas of hypo-pigmentation in 30 patients (28 G1; 2 G2 through 52 weeks of treatment
- >70% already resolved at study closure; 7 ongoing
- Median onset: 8 months
- Median age: 37 years (18-62)
- 6 additional cases during follow-up (G1); 1 ongoing

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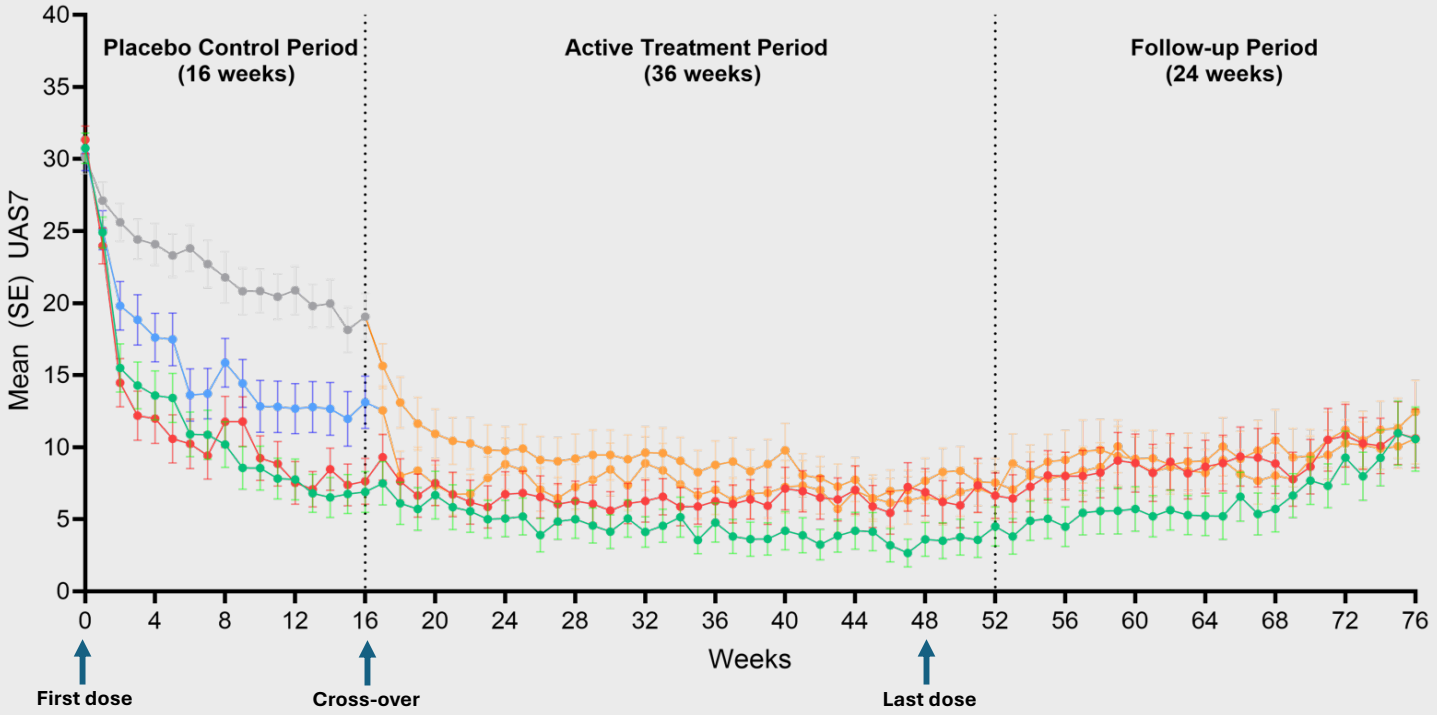
Rapid, Profound Improvements in UAS7; Sustained 7 Months Post Final Dose



Modified intent to treat; observed data.

UAS7 Mean Change from Baseline at Week 76 (SE):

-20.42 150 mg Q4W
-21.10 300 mg Q8W

	150 mg Q4W	300 mg Q8W	Placebo
Week 12	-23.61	-23.22	-9.02
Week 52	-27.24	-24.86	
Week 76	-20.42	-21.10	

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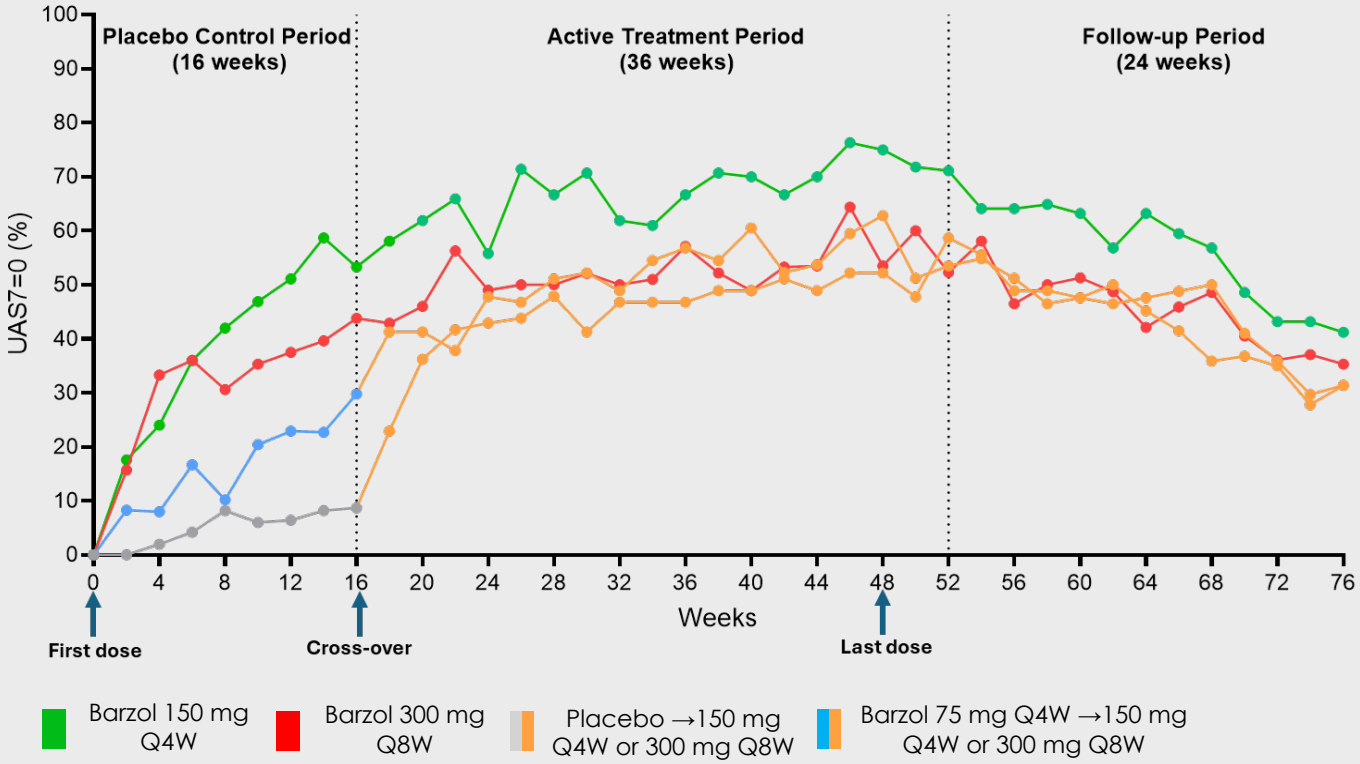
Rapid Complete Responses, Improving to Week 52; Sustained 7 Months Post Final Dose

Complete response is UAS7=0



Modified intent to treat; observed data.

35% - 41% barzolvolimab patients had a complete response at Week 76

	150 mg Q4W	300 mg Q8W	Placebo
Week 12	51%	38%	6%
Week 52	71%	52%	
Week 76	41%	35%	

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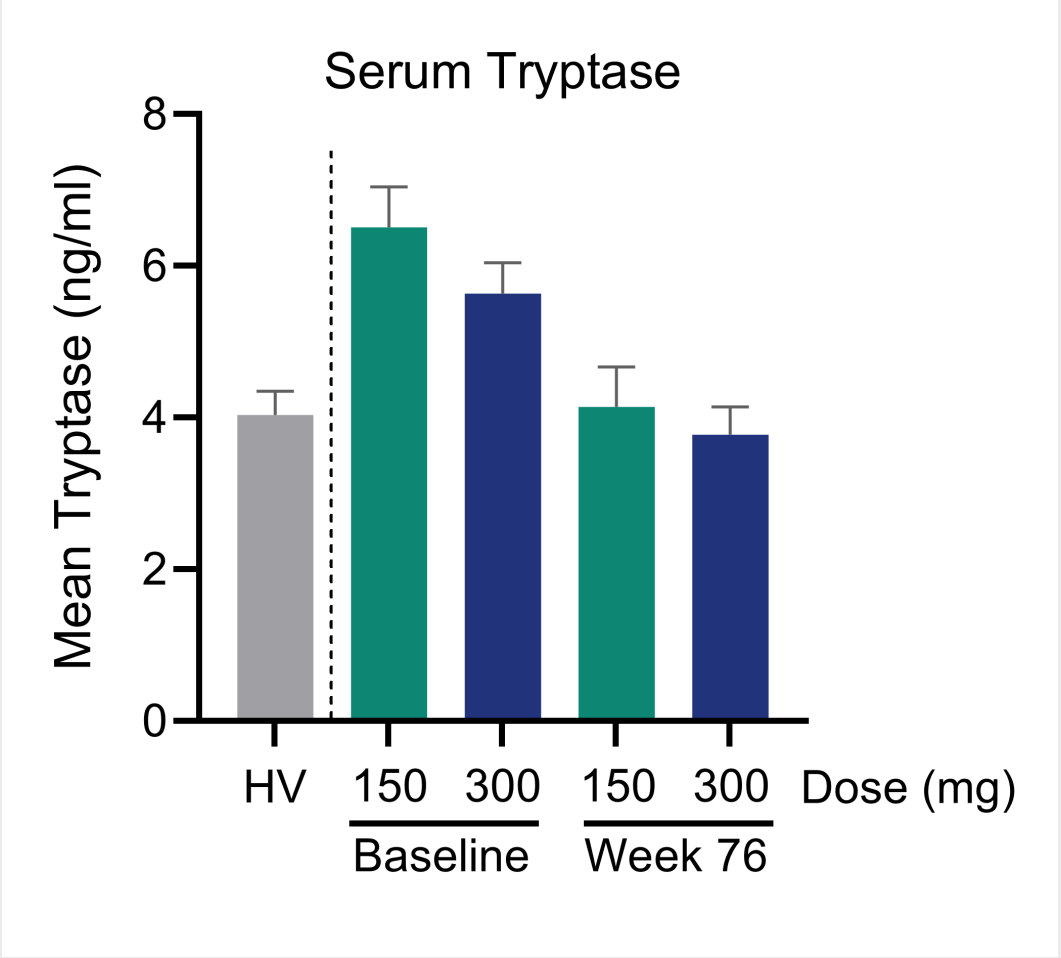
Complete Responses Sustained 7 Months Post Final Dose Even With the Return of Mast Cells

- Systemic KIT saturation waning 12 weeks post last dose; barzolvolimab fully cleared by 24 weeks
- Tryptase recovery suggests normal mast cell load 24 weeks post last dose



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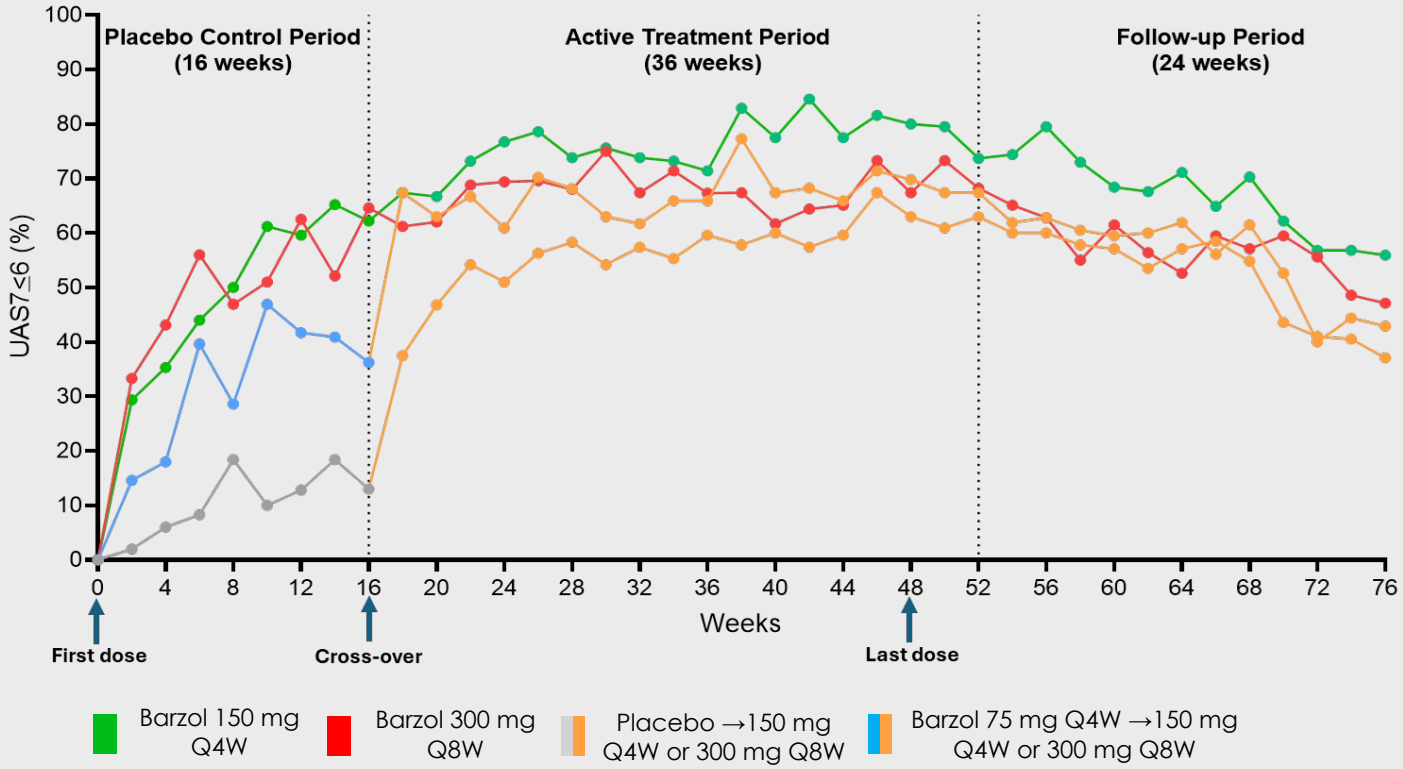
Rapid Well Controlled Disease also Improving to Week 52; Sustained 7 Months Post Final Dose

Well controlled disease is UAS7≤6



Modified intent to treat; observed data.

47% - 56% barzolvolimab patients had well controlled disease at Week 76

	150 mg Q4W	300 mg Q8W	Placebo
Week 12	60%	63%	13%
Week 52	74%	68%	
Week 76	56%	47%	

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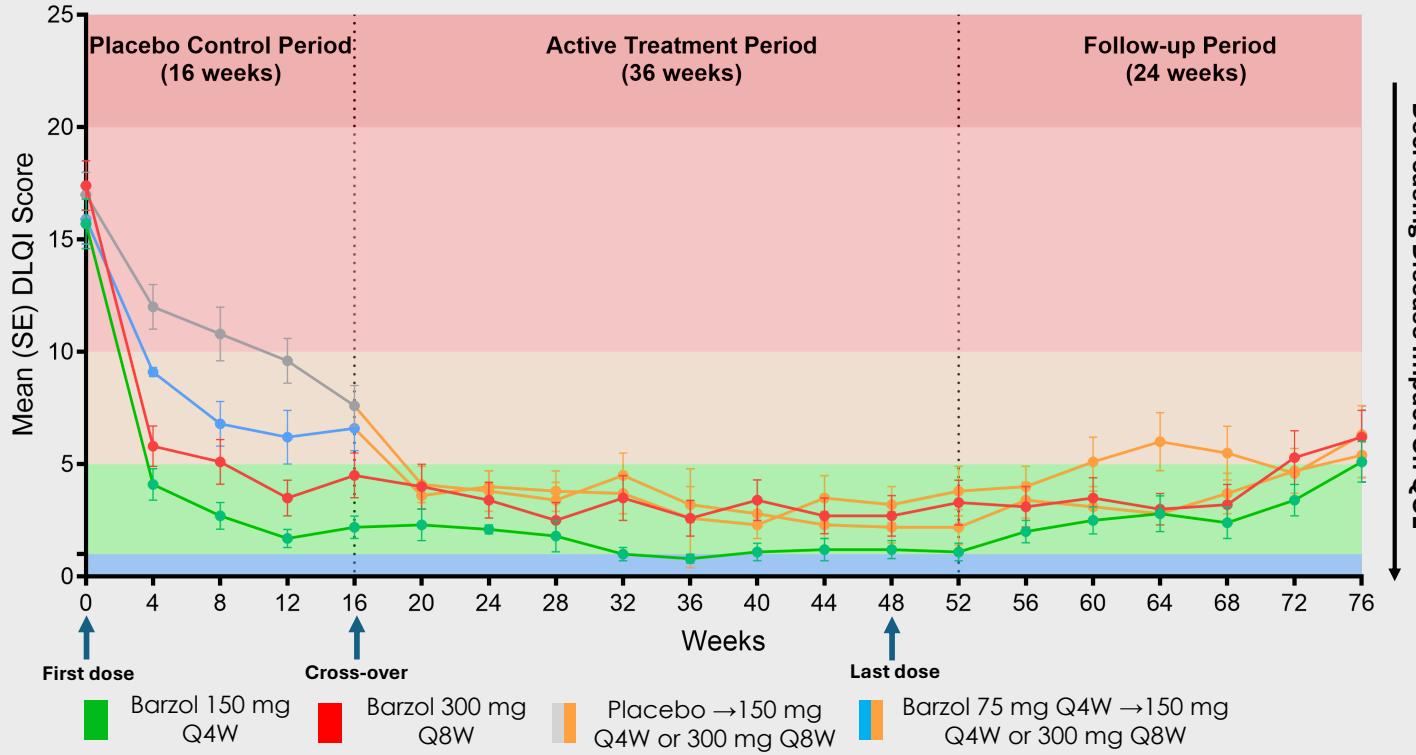
Rapid and Sustained Improvements to Patient Quality of Life; Sustained 7 Months Post Final Dose

Complete disease response is correlated with meaningful improvements in QOL[1,2]



40% - 48% patients on barzolvolimab reported CSU had **no impact** (0-1) on QOL at Week 76

	150 mg Q4W	300 mg Q8W	Placebo
Week 12	67%	57%	10%
Week 52	82%	72%	
Week 76	48%	40%	

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[1]Kolkhir P, et al. JACI, 2023, [2]Bernstein J, et al. Journal of Clinical Medicine, 2023

Patients Need New Options to Ensure Complete Response and Regain Control of their Lives

Current clinical guidelines recommend complete disease control as the goal of treatment[1]

Patients report minimal or no impact on their quality of life when they achieve complete disease control[2]

Barzolvolimab has highest rate of complete response at all timepoints[3]

51% Week 12
71% Week 52
41% Week 76

Patients treated with barzolvolimab reported CSU had no impact on QOL

67% Week 12
82% Week 52
48% Week 76

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[1]Zuberbier T, et al. Allergy, 2022; [2]Kolkhir P, et al. JACI, 2023; [3]Across reported studies, not based on head-to-head comparisons

Barzolvolimab Offers New Hope For All Patients

Patients with CSU need new options to obtain complete response of their symptoms

5 + years of clinical results demonstrate[1]…	…barzolvolimab's best in disease profile[2]
Unparalleled complete response rate	Patients experience complete resolution of symptoms - goal of therapy
Responses are rapid and prolonged, even 7 months post dosing	Patients see very fast benefit and unprecedented long-term results
Efficacy correlated with meaningful, dramatic improvements in QOL	Patients see transformative impact…path to living a normal life again
Same level of response in patients with prior omalizumab	Omalizumab refractory patients now have a potential treatment option
Well tolerated with demonstrated safety profile to date	Physician and patients recognize the clear benefit to risk profile

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[1]Based on Phase 2 results; [2]Across reported studies, not based on head-to-head comparisons

03

Impressions on data

MARTIN METZ, PROFESSOR, DEPARTMENT OF DERMATOLOGY AND ALLERGY,
HEAD OF TRANSLATIONAL RESEARCH, DEPUTY HEAD OF CLINICAL TRIALS

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Pioneering new horizons in immunology to deliver life-changing therapies

Q&A

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