
Pioneering new horizons in immunology to deliver life-changing therapies.
NASDAQ: CLDX
MARCH 2026
Celldex

# Safe Harbor Statement

This communication contains "forward-looking" statements within the meaning of the Private Securities Litigation Reform Act of 1995. All statements other than statements of historical fact are statements that could be forward-looking statements. You can identify these forward-looking statements through our use of words such as “may,” “will,” “can,” “anticipate,” “assume,” “should,” “indicate,” “would,” “believe,” “contemplate,” “expect,” “seek,” “estimate,” “continue,” “plan,” “point to,” “project,” “predict,” “could,” “intend,” “target,” “potential” and other similar words and expressions of the future. These forward-looking statements are subject to risks and uncertainties that may cause actual future experience and results to differ materially from those discussed in these forward-looking statements. Important factors that might cause such a difference include, but are not limited to, the timing, cost and uncertainty of obtaining regulatory approvals for product candidates; our ability to develop and commercialize products before competitors that are superior to the alternatives developed by such competitors; the validity of our patents and our ability to avoid intellectual property litigation, which can be costly and divert management time and attention; and the other factors listed under “Risk Factors” in our filings with the SEC, including Forms 10-K, 10-Q and 8-K. Celldex does not undertake any obligation to release publicly any revisions to such forward-looking statement to reflect events or circumstances after the date hereof or to reflect the occurrence of unanticipated events.

# Proven Leaders in Antibody Development

**Team brings significant experience in getting important drugs approved & successfully to market, including I&I**

## Barzolvolimab: *First-in-Class, Best-in-Disease, Franchise-in-a-Molecule Potential*

- Novel mast cell targeting MOA delivering unprecedented data across multiple indications
- Phase 3 CSU program enrollment completed 6 months ahead of guidance, topline data expected Q4 26, BLA filing planned for 2027
- Phase 3 ColdU/SD study initiated Dec 2025
- Phase 2 study in PN fully enrolled; topline data expected summer 26
- Phase 2 AD study fully enrolled; topline data expected late 26

## Next Generation Programs in Inflammatory Diseases

- Robust mAb/bsAb antibody platform supported by in-house manufacturing

## CDX-622 (TSLP & SCF)

- Phase 1 HV study fully enrolled; data expected Q3 26
- Phase 1 Proof of Mechanism study in asthma initiated Jan 26

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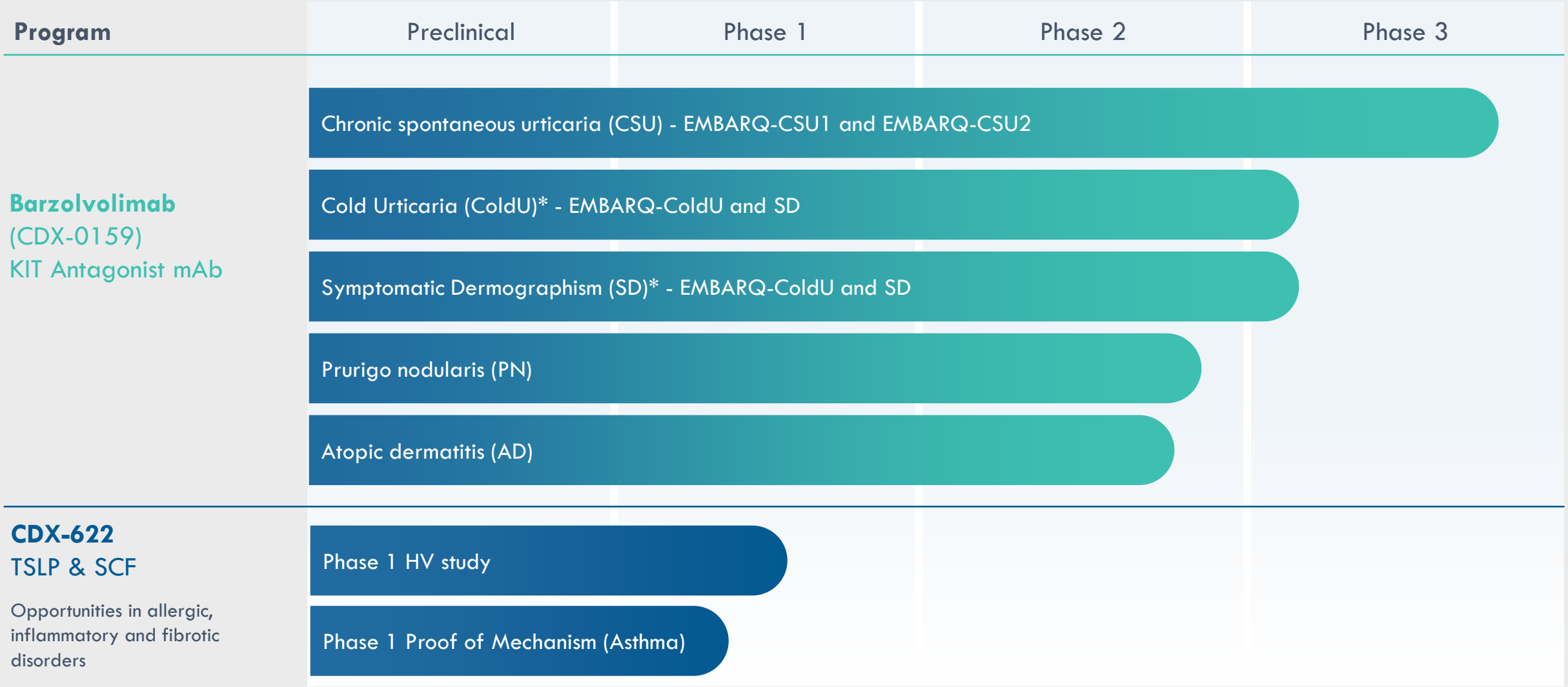
# Strong, Late Stage Clinical Pipeline with Near-Term Inflection Points




*ColdU and SD are subtypes under the global Phase 3 CIndU (Chronic Inducible Urticaria) program

# Significant Recent Accomplishment: *Enrollment Completed Six Months Ahead of Guidance In Phase 3 CSU Program*

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EMBARQ|CSU

**Completed enrollment 6 months ahead of guidance**

## *Important Study Highlights*

Two Phase 3 trials—EMBARQ-CSU1 and EMBARQ-CSU2

- 1,939 patients, 43 countries, 500 sites
- Largest program conducted in antihistamine refractory CSU, also includes patients with advanced therapy experienced/refractory CSU
- ~75% of patients had no prior biologic experience demonstrating tremendous unmet need in CSU and the desire of patients and treating physicians to access barzolvolimab
- 25% of patients enrolled in the US, consistent with recent Phase 3 CSU trials
  - Majority (53%) of US patients enrolled by dermatologists, supporting growing awareness/adoption in this community

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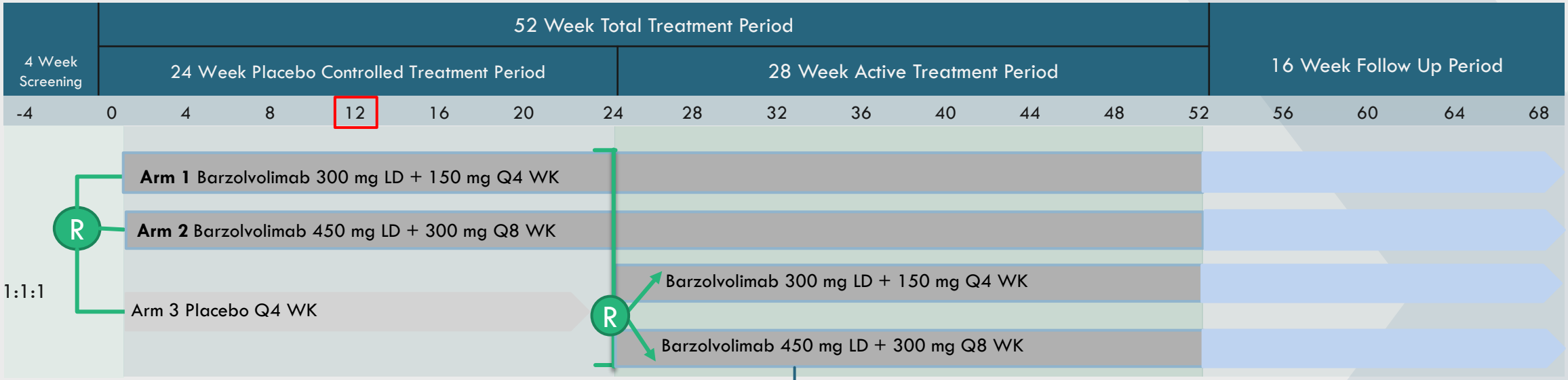
# EMBARQ CSU

# Phase 3 CSU Registration Program - Topline Data Q4 26




## 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
- 915 patients per study; ~40 countries; 250 sites per study

## 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 in participants who have AAS7> 0 at baseline
- Mean change from baseline in UAS7 in participants refractory to omalizumab treatment
- Proportion of participants with UAS7=0 in participants refractory to omalizumab treatment

# Barzolvolimab Opportunity is Vast

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# Barzolvolimab Opportunity is Vast

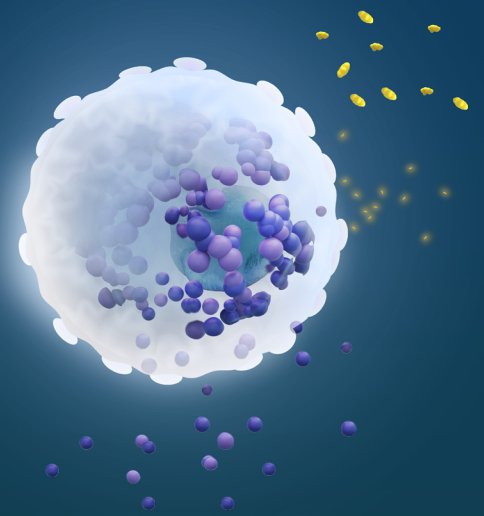
- Celldex is leading in the development of **highly differentiated treatments for mast cell diseases,** starting with chronic urticarias and extending to PN, AD and additional mast cell driven diseases.
- Target addressable population for identified mast cell driven diseases with **high unmet need is >10.5M people.**
- CSU has **tremendous headroom for advanced therapy growth** with less than 1/3 of the 1.8M US patients currently diagnosed and treated.
- The arrival of new advanced therapies will drive changes in the CSU treatment paradigm. These changes create **tailwinds for barzolvolimab**.
- **Barzolvolimab uniquely positioned for two large CSU populations of unmet need that are expected to grow**: 1st line advanced therapy for severe/angioedema & therapy of choice for 2nd line advanced therapy.
- I&I analogues reinforce the opportunity for **clinically differentiated therapies to significantly expand advanced therapy utilization**, and **the opportunity for second line+ advanced therapy markets to eclipse markets for 1st line therapies**.

**Barzolvolimab's unparalleled efficacy in CSU positions us well to be a leader in this under-penetrated, high-growth market.**

# Barzolvolimab: Raising the Bar in Mast Cell Driven Diseases

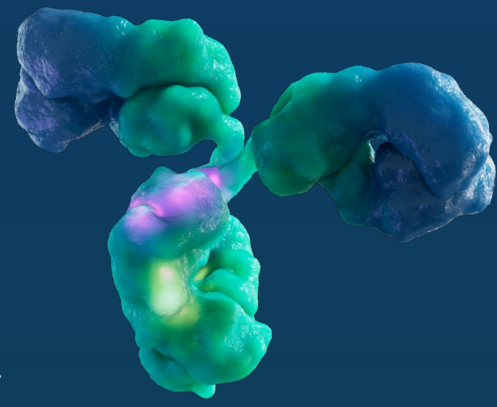
- Mast cells mediate inflammatory responses such as hypersensitivity and allergic reactions, across a broad array of conditions/diseases

**The Mast Cell**



- Novel mechanism of action targets mast cells by binding with high specificity to a unique part of the KIT receptor and potently inhibiting its activity.
- The KIT receptor is abundantly expressed by mast cells and critical for their function and survival.

**Barzolvolimab**



**IgG1k with modified Fc**

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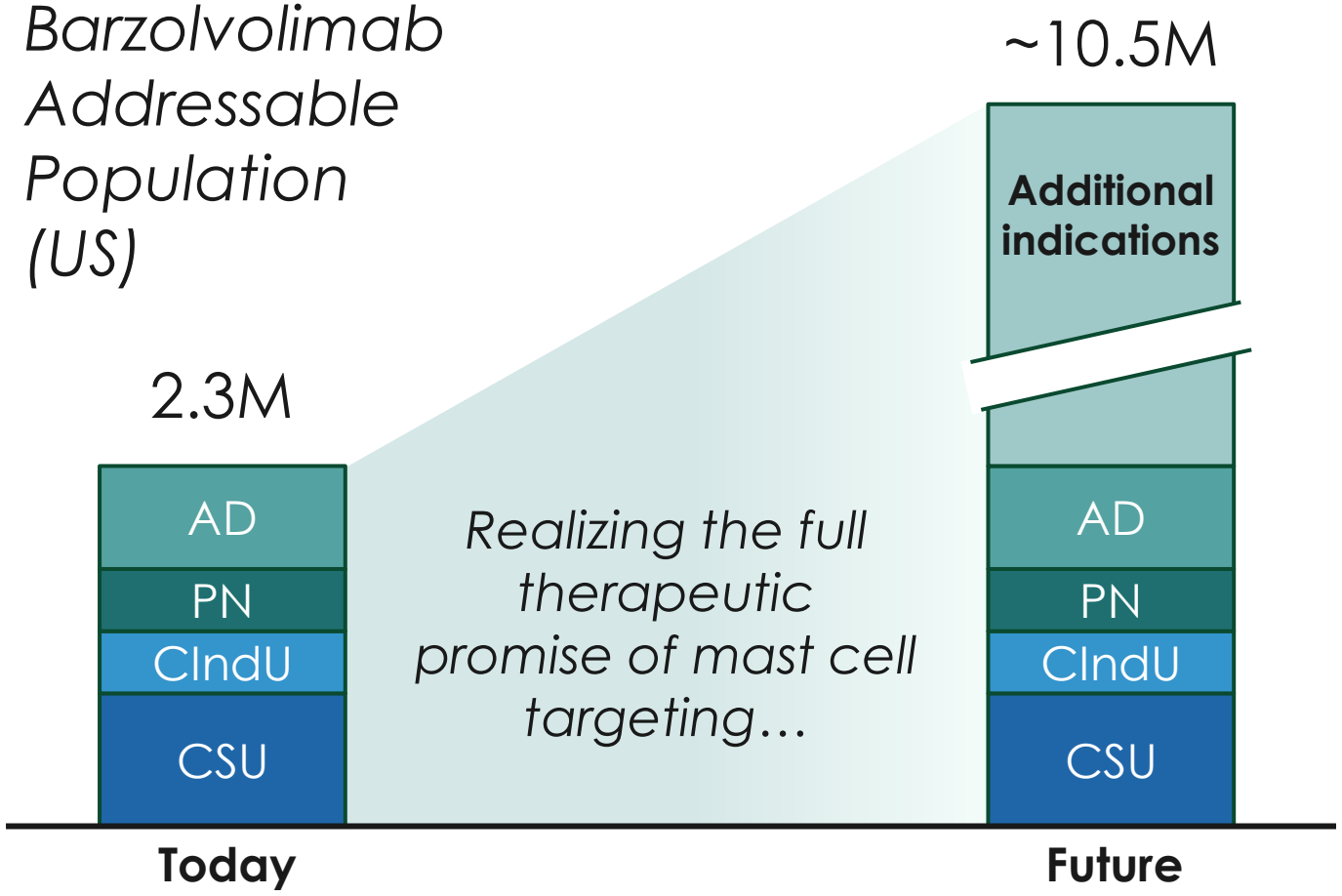
# From Mast Cell Science To Category Creation

*Barzolvolimab Addressable Population (US)*




**Additional Mast Cell Driven Diseases Of Interest**

**Severe Allergic Rhinitis** (uncontrolled) *~500k-2M*

**Severe Asthma** (2L+ AT) *~470k*

**BP** (biologics eligible) *~27k*

**CPUO** (Severe) *110k*

**CRSwNP** (mod-severe) *~147k*

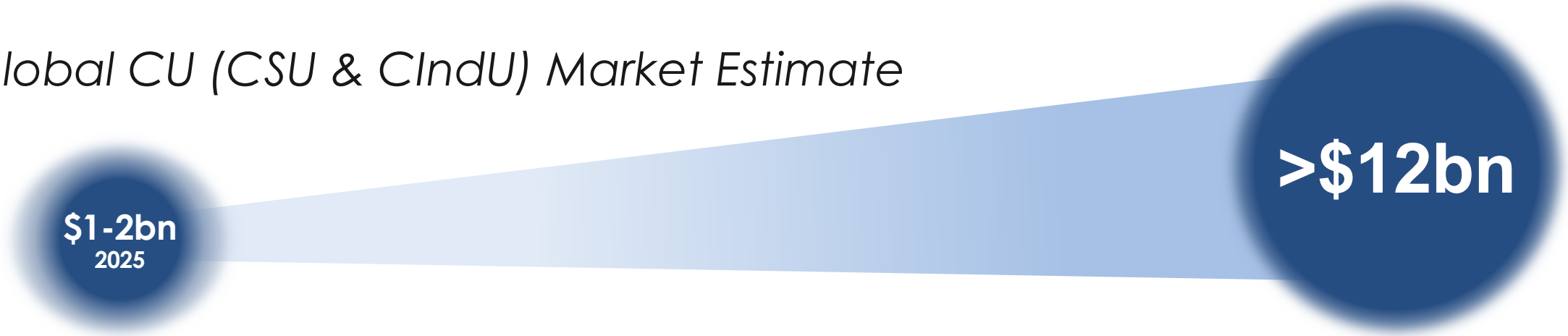
**Adult Food allergy** (mod-severe) *~4-5M*

**Hidradenitis Suppurativa** (mod-severe) *200-400k*

Source: Celldex analysis.

# The Chronic Urticaria Market Is Entering A New Growth Phase

*Global CU (CSU & CIndU) Market Estimate*




## Today

- Xolair Omalizumab — IgE inhibitor, Roche
- Dupixent (dupilumab) — IL-4/IL-13 inhibitor, Sanofi/Regeneron
- Rhapsido — BTK Inhibitor, Novartis

## Discontinued *during development*

- *Siglec-6*
- *Siglec-8*
- *TSLP*
- *Reversible BTKi*
- *MRGPRX2*
- *JAK1*

## Future

**barzolvolimab**

KIT inhibitor
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**Precision KIT inhibition** with differentiated efficacy and safety

**Strong and complete durable** symptom control

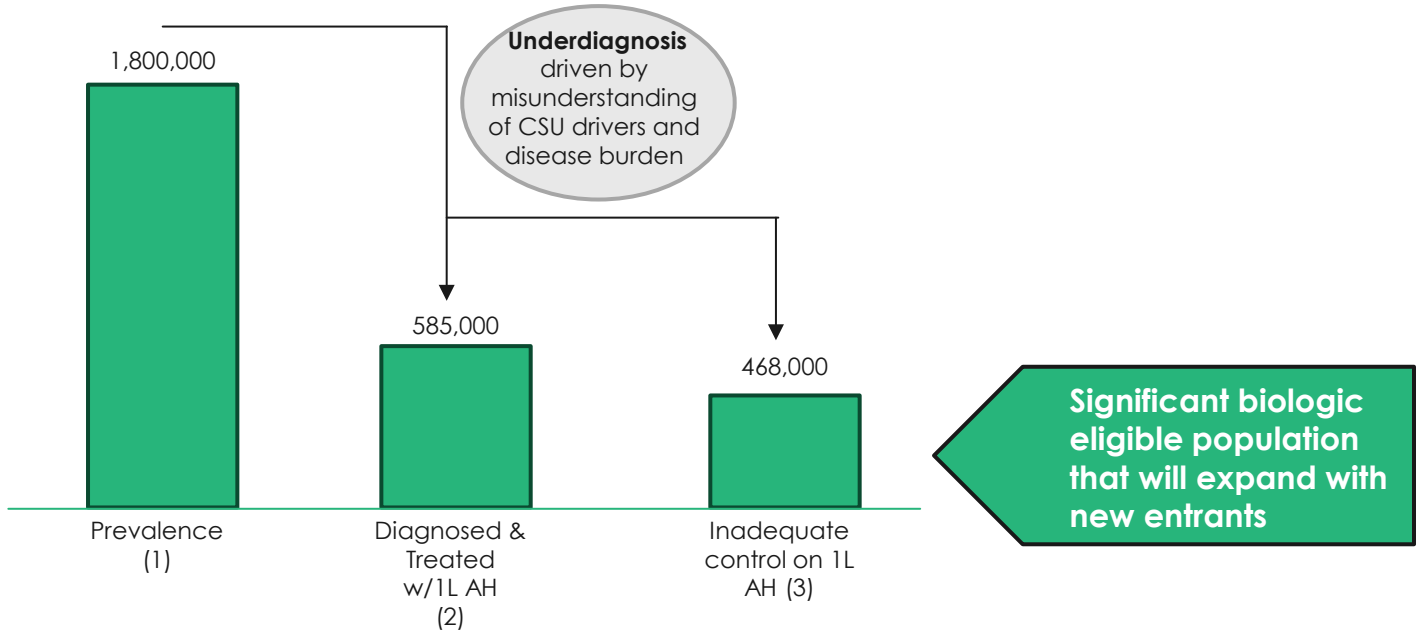
Source: Company press releases, Celldex analysis.

# CSU US Market Has Tremendous Headroom for Advanced Therapy Growth

**Market Poised for Significant Expansion With New Treatment Options**

- Increased rates of diagnosis and treatments
- Accelerated timing of diagnosis and treatment
- Expanded adoption of advanced therapies (more HCP treaters)
- Faster progression to, and through, advanced therapies to deliver desired treatment outcomes

## US Adult CSU Patient Number Estimates 2024-2025




Sources

(1) Census.gov; Maurer M, Weller K, Bindslev-Jensen C, et al. Unmet clinical needs in chronic spontaneous urticaria. A GA²LEN task force report. Allergy. 2011;66:317-330; Celldex analysis.
(2) Census.gov; Celldex analysis.
(3) Bernstein et al. Urticaria voices: Real World Treatment Patterns and Outcomes. April 22, 2025 80% report inadequate control despite 1IAH

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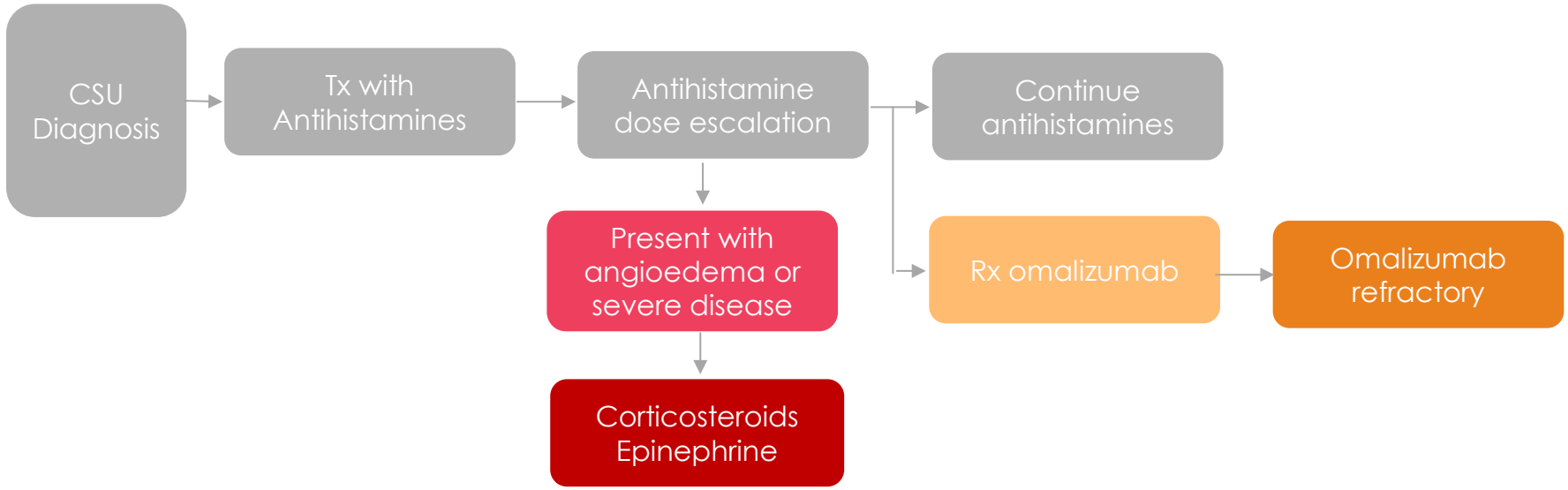
# Historical CSU Treatment Paradigm: Severely Limited Use of the Only Approved Advanced Therapy

## Treatment Paradigm 2014-2025



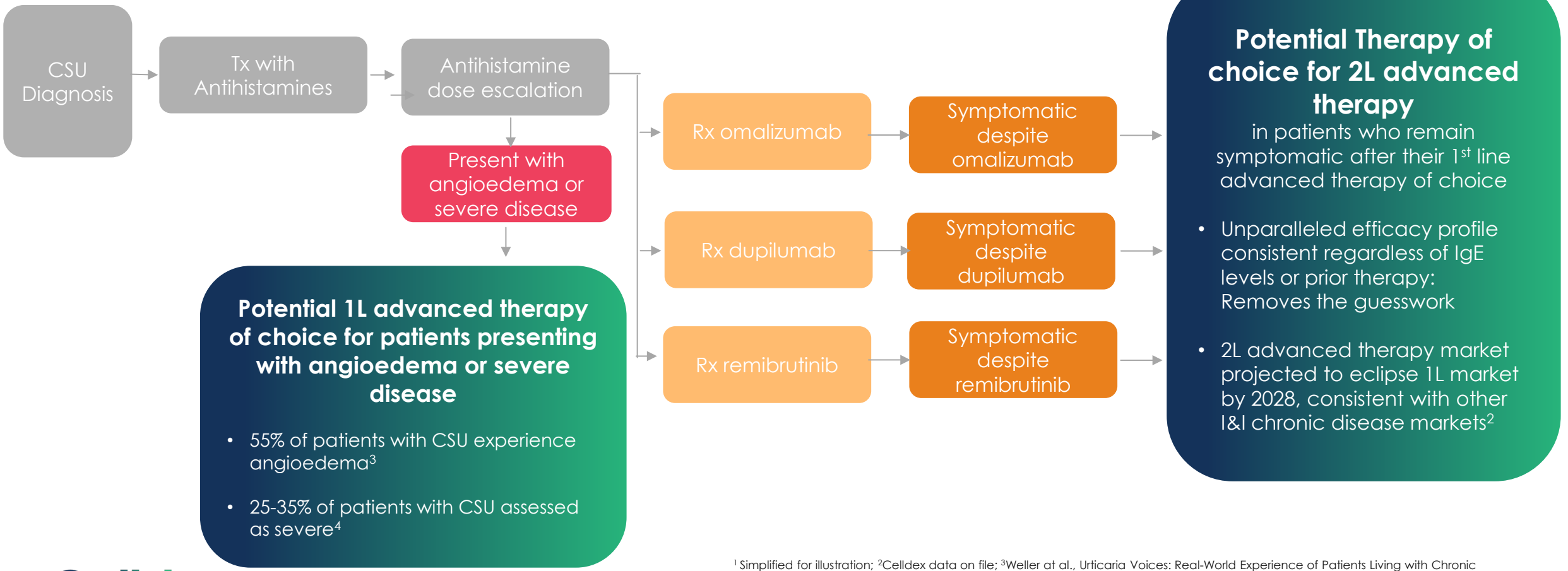

**Historical Treatment Paradigm**

- A single advanced therapy that was underutilized
- Underinvestment and limited treatments reinforced slow and low diagnosis rates
- Lack of an advanced therapy treatment pathway
- Patients presenting with angioedema routinely receiving multiple doses of corticosteroids
- Despite these limitations, omalizumab has generated $1.0-$1.5B in estimated US CSU sales[1]

[1]Komodo Claims Database; IQVIA, Celldex data on file.

# Barzolvolimab in CSU Uniquely Positioned for Two Significant Populations of Unmet Need Expected to Grow with Availability of New Treatments

## 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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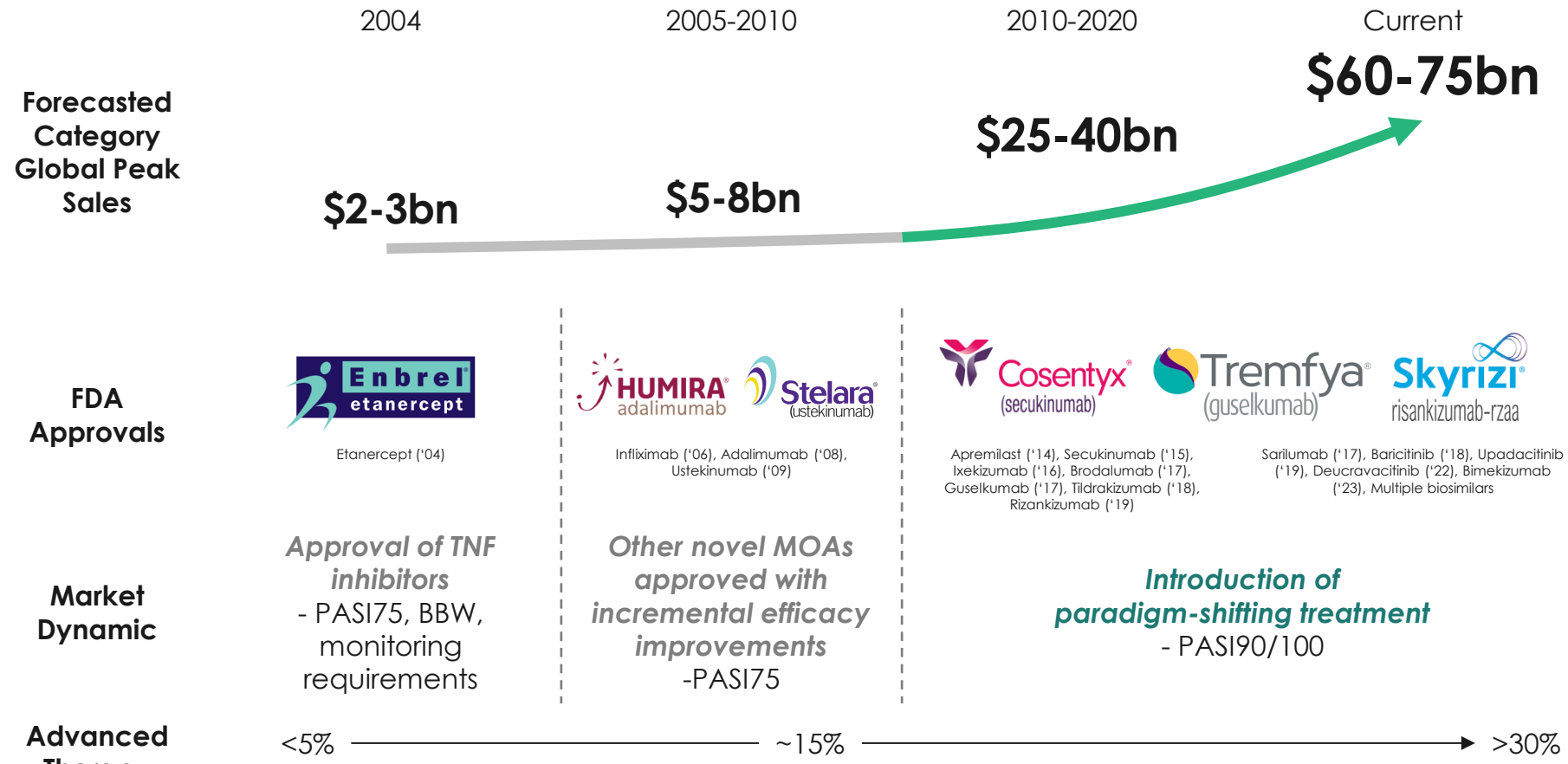
# Psoriasis Market Analogue May Be Instructive in CSU

## New, more effective entrants accelerated advanced therapy (AT) use



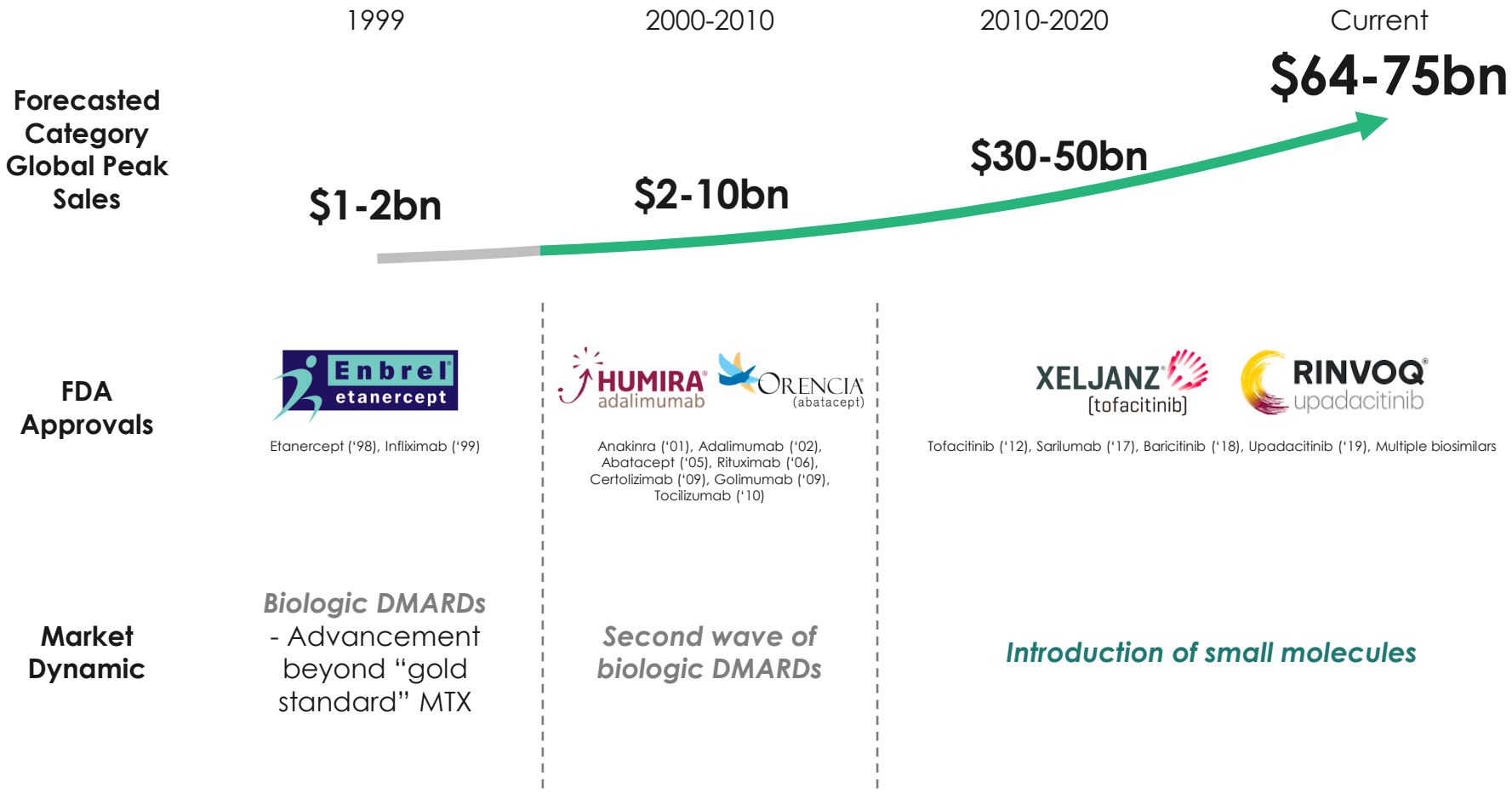

**More Patients Treated With AT As The Number Of Better Therapies Were Approved**

- Initial market under-forecasted
- Provider willingness to adopt more effective therapies was under-estimated
- IL-23 inhibitors were the 1st therapies to deliver PASI100 (completely clear skin) to majority of patients
- Despite step-edits placing IL23i's at 2L+, revenue eclipsed earlier line therapies by 4th year on market, as HCPs sought better treatment for patients who remained symptomatic despite 1L therapies
- AT utilization rates doubled since IL23 introduction

Sources: IQVIA, Evaluate Pharma Data Monitor; Celldex date on file

# RA Market Analogue May Be Instructive in CSU

## Utilization continued to deepen with more effective therapies; 2L+ AT eclipsing 1L AT




**More Patients Treated With AT As The Number Of Better Therapies Were Approved**

- Despite uniformity in the 1L gold standard, there has been continued growth in the market size of RA with the introduction of several therapeutic advancements
- ~50% of patients fail their first DMARD therapy within the first year of treatment[1,2]
- For the RA Market 2016-2025, ~180-190k 1L AT treated annually for a total reported revenue of $51.2B for the period vs. ~370-380k 2L+ AT treated annually for a total reported revenue of $99.8B

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Sources: IQVIA, Evaluate Pharma Data Monitor; Celldex data on file, (1) Murray K et al. Arthritis Res Ther 2021; 23(1):25. (2) Rosenberg V et al. Adv Ther 2023; 40(10):4504-4522

*"…targeting wild-type c-KIT has been a sort of holy grail of the industry for decades…"*

- Large Pharma Head of R&D, Company Webcast

# Chronic Urticaria Overview: *Mast Cell Driven Diseases of Misery*

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# "A Disease of Misery…Impacts on Every Aspect of Life…"

Significant medical need with **limited or no treatment options**
Patients suffer both physically and psychologically with impaired quality of life

"…severely disturbing disease to have, devastating, long-lasting and basically impacts on every aspect of life; sleep, interpersonal relationships, performance at work and school, hobbies, traveling, sports, all of these patients have stories to tell where their disease dominated their life…" - Marcus Maurer, MD

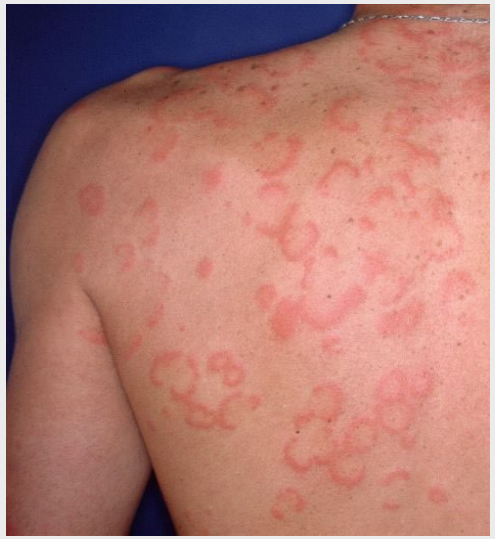
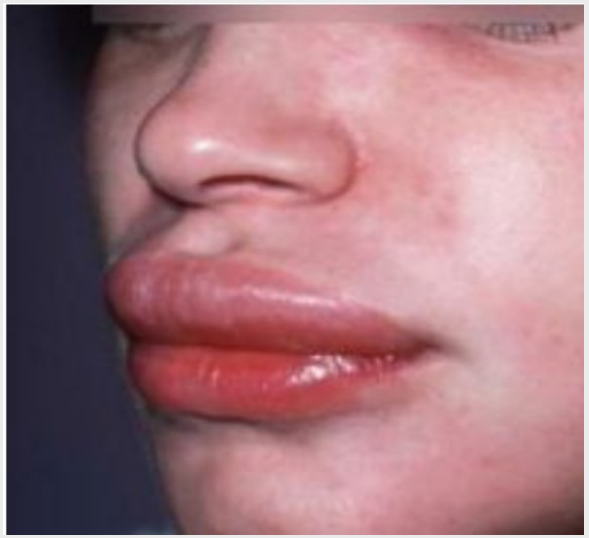
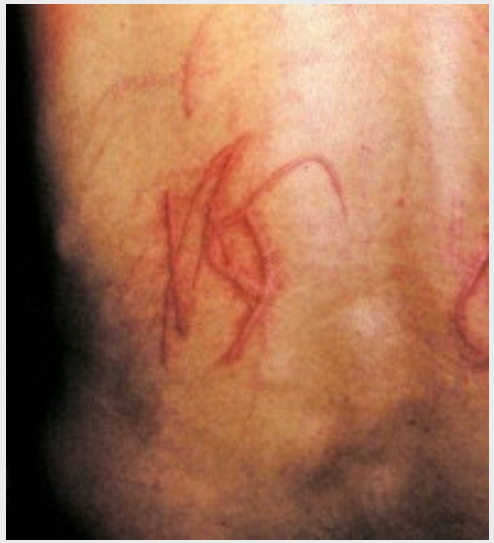
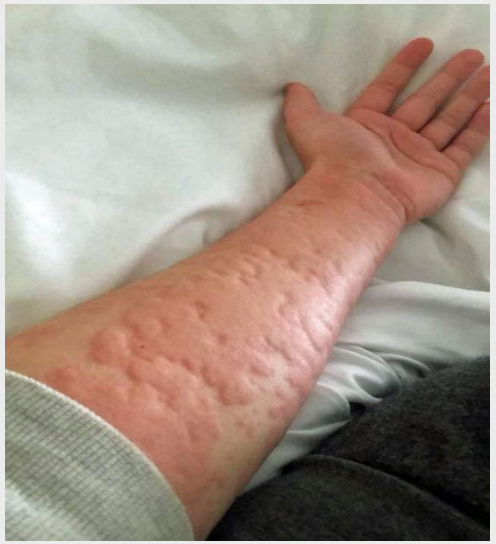

**Image** Sources: https://dermnetnz.org/topics/dermographism, https://www.bbc.co.uk/bbcthree/article/d7ae42f3-b3ae-47ae-9464-eb8c328fe3dc

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*Marcus Maurer, MD, Professor of Dermatology and Allergy, Charité – Universitätsmedizin, Berlin: Commentary from 7/12/21 data update call*

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

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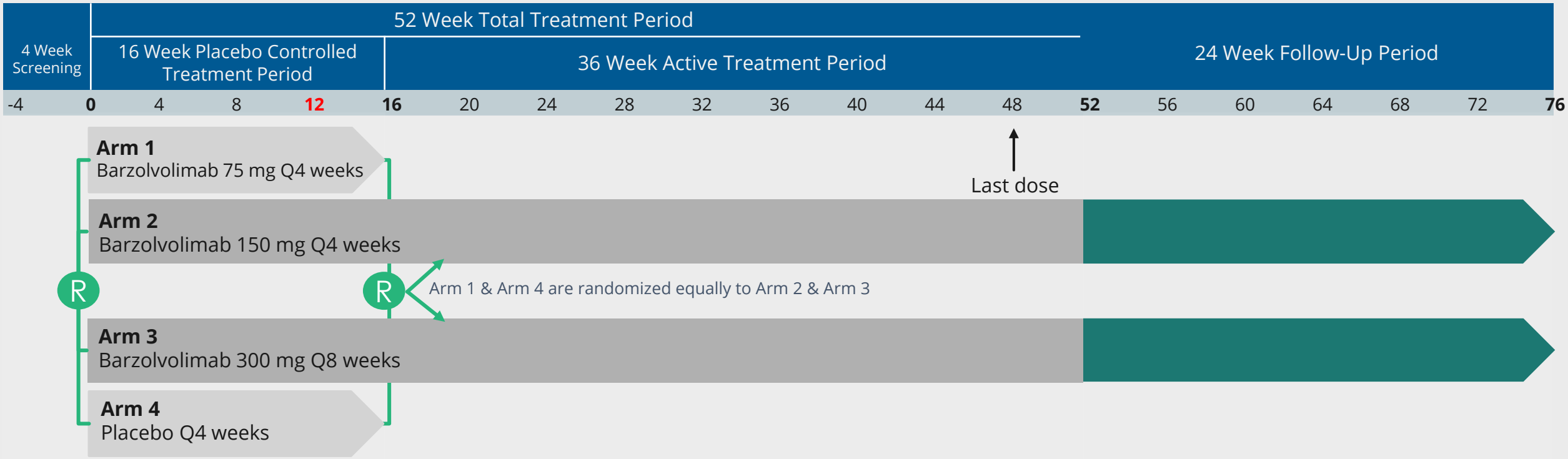
[1]Weller, et al. Dermatol Ther, 2025; [2]Maurer, et al. Allergy, 2017; [3]Kolkhir P, et al. JACI, 2025

# Phase 2 CSU Study Design (Completed)




- **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: 80% power to detect a 9 point improvement in UAS7 for each arm versus placebo

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*Primary endpoint

# Barzolvolimab Phase 2 CSU Data Raises the Bar

**Rapid, profound** and **durable efficacy** that is **unparalleled in CSU, with 93% of patients achieving clinically meaningful response**[1]

1

**Highest rate of complete response at all reported timepoints**[2]

51% Week 12
71% Week 52

*7 months after final dose*
41% Week 76

2

**Patients report CSU had no impact on QOL**[2]

67% Week 12
82% Week 52

*7 months after final dose*
48% Week 76

3

**Patients report they are angioedema free**[2]

65% Week 12
77% Week 52

*7 months after final dose*
52% Week 76

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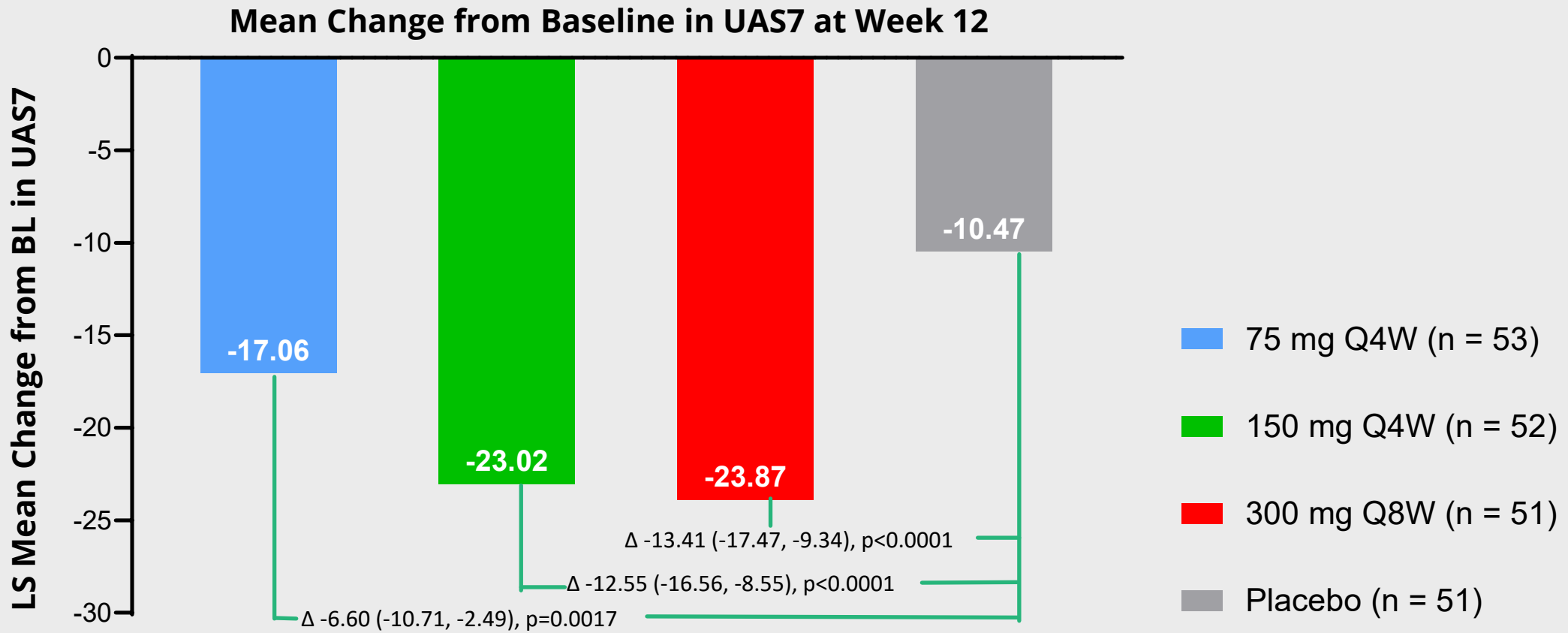
[1]As reported by Minimal Change in Disease (MCID). [2]Across reported studies, not based on head-to-head comparisons. Cross study comparisons are limited given differences in the design of the included trials, such as variations in statistical methods, patient populations and dosing schedules, among other factors. Reported data from 150mgQ4 arm.

# Best-in-Disease Improvement (UAS7 at Week 12: Primary Endpoint) in Established Regulatory Endpoint

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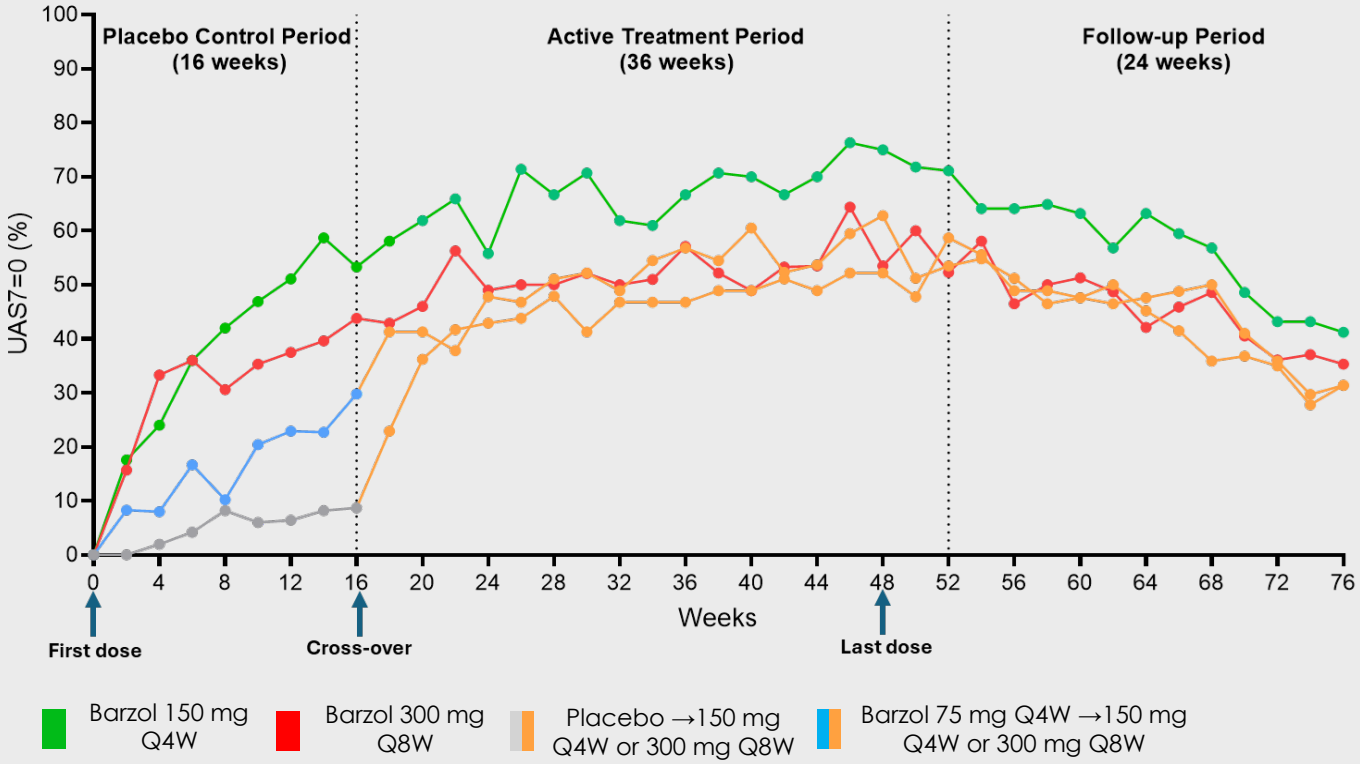
Data were analyzed using ANCOVA model and multiple imputation. Benjamini-Hochberg were used for multiplicity adjustment
Δ treatment difference LS mean (95% CI)
CI, confidence interval; LS, least squares; n, number of patients who received at least one dose of study drug, UAS7-weekly Urticaria Activity Score

# 1 Rapid, Profound Complete Responses, Sustained 7 Months Post Final Dose

**Complete response is UAS7=0**




Modified intent to treat; observed data.

**35% - 41% barzolvolimab patients remained in complete response 7 months after last dose (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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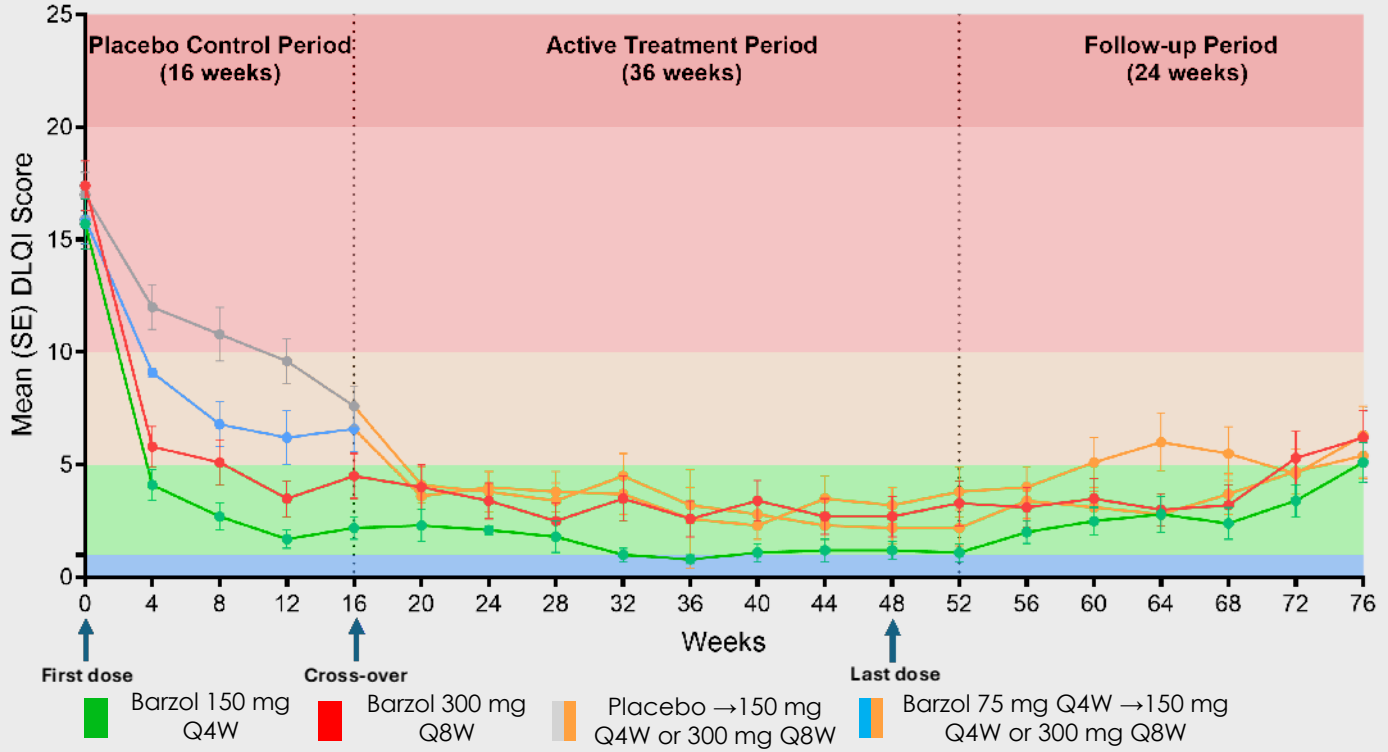
# 2 Rapid, Profound QOL Improvements; Sustained 7 Months Post Final Dose

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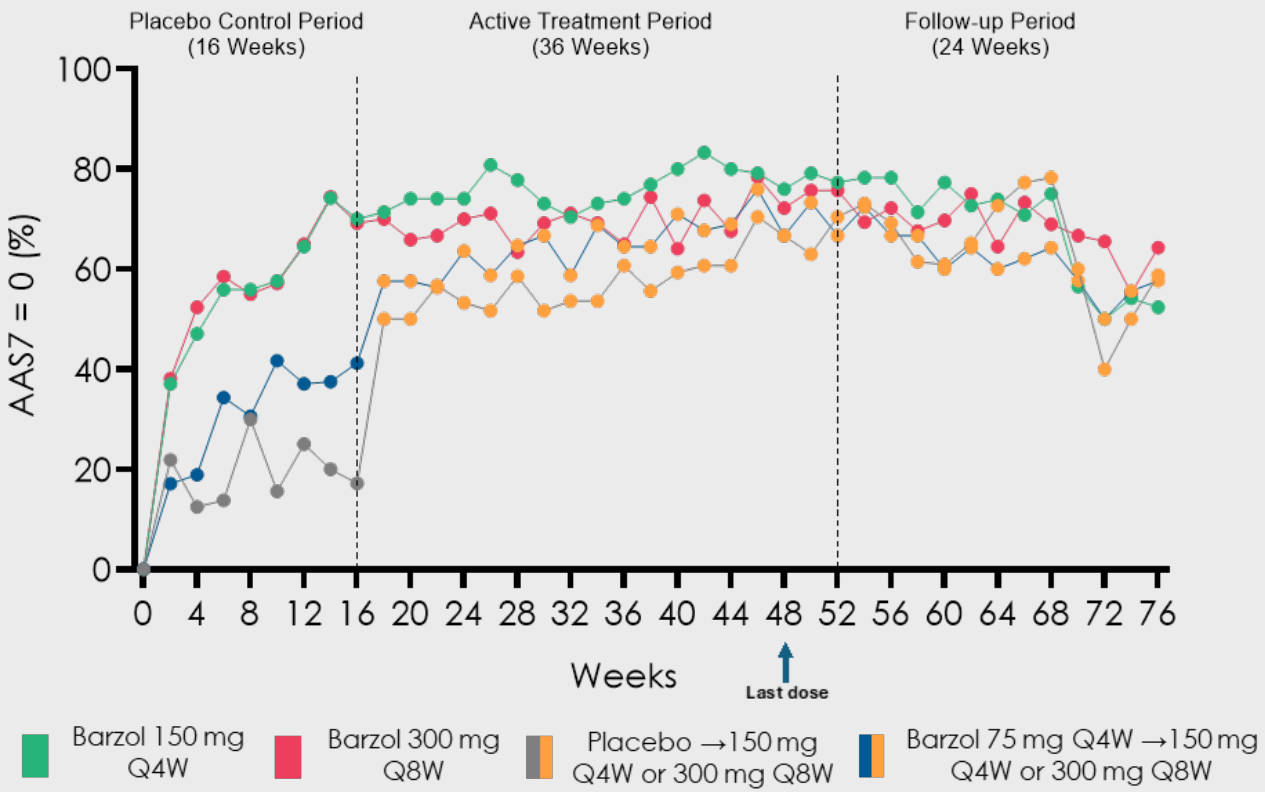
[1]Kolkhir P, et al. JACI, 2023, [2]Bernstein J, et al. Journal of Clinical Medicine, 2023

# 3 Rapid, Profound Improvement in Angioedema; Sustained 7 Months Post Final Dose




**52% - 64% barzolvolimab patients remained angioedema free 7 months after last dose (Week 76)**

| | 150 mg Q4W | 300 mg Q8W | Placebo |
|---|---|---|---|
| **Week 12** | 65% | 65% | 25% |
| **Week 52** | 77% | 76% | |
| **Week 76** | 52% | 64% | |

% of patients with AAS7=0 (Patients who were AAS7 positive at baseline)

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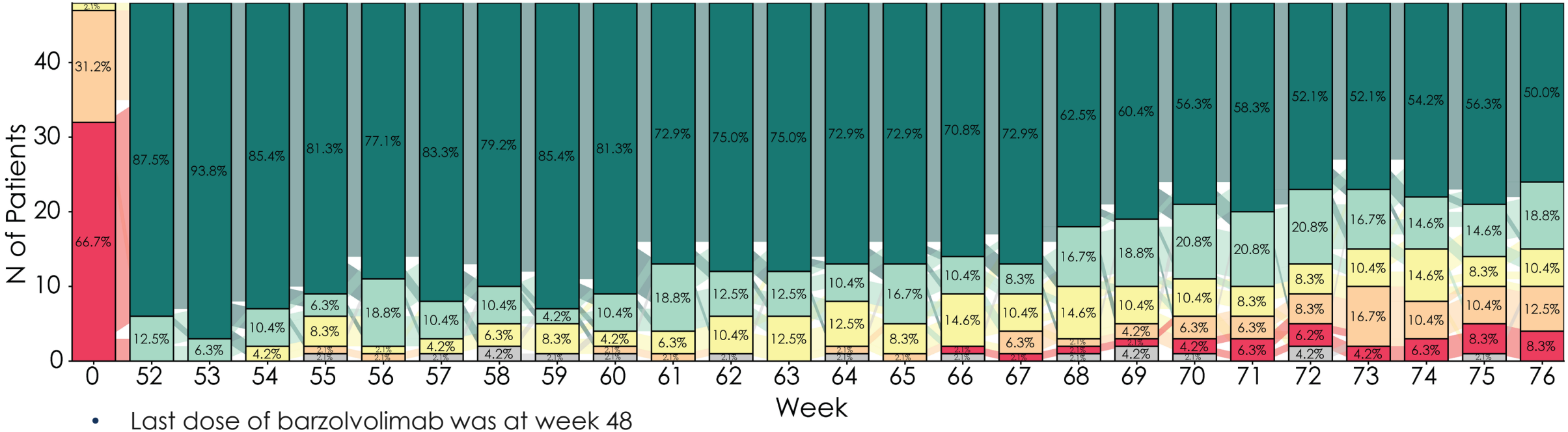
# Sustained Well Controlled Disease 7 Months After Last Barzol Dose in 69% of Patients who Achieved Well Controlled Disease at Week 52




- Last dose of barzolvolimab was at week 48

**UAS7 = 0** Complete Response

**UAS7 ≤ 6** Well Controlled Disease

**UAS7 = 7-15** Mild Disease

**UAS7 = 16-27** Moderate Disease

**UAS7 = 28-42** Severe Disease

UAS7 score-based health states were used to describe CSU disease activity throughout the 24-week follow-up period (W52 – W76)

Based on: Stull D, et al. Br J Dermatol 2017;177(4):1093-1101.

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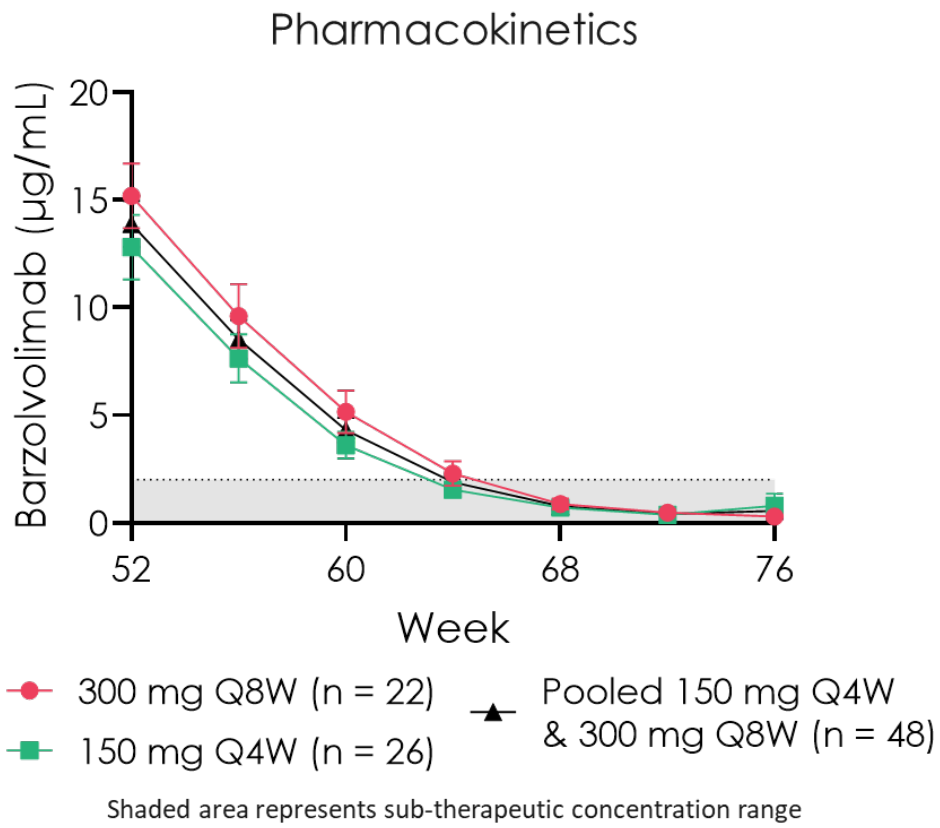
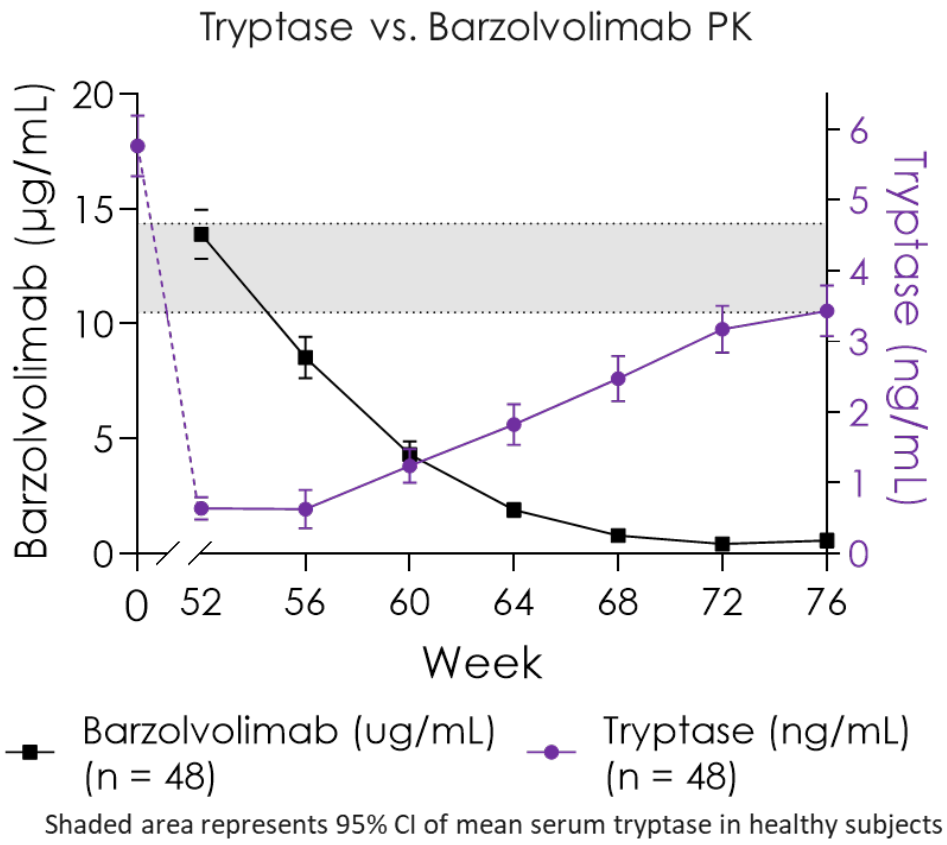
# UAS7 Scores (mean) Remain Low Despite Decreasing Barzol Concentration and Tryptase Recovery

**Concentration of barzolvolimab falls below therapeutic levels by week 64**




Shaded area represents sub-therapeutic concentration range

**Tryptase recovers towards range of healthy subjects by week 76 indicating normal mast cell numbers**




Shaded area represents 95% CI of mean serum tryptase in healthy subjects

# Barzolvolimab Phase 2 Data Raise the Bar for the Treatment of CSU

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

| **5 + years of clinical results demonstrate[1]…** | **…barzolvolimab's potential best-in-disease profile[2]** |
|---|---|
| Unparalleled complete response rate | Patients experience complete resolution of symptoms - goal of therapy |
| Responses are rapid and durable, even 7 months post dosing | Patients see very fast benefit and unprecedented long-term results, as evidenced by up to 41% complete response rate 7 months after last dose |
| Meaningful, dramatic improvements in angioedema and QOL | Patients see transformative impact…freedom from their disease/restored QOL |
| Same level of response in patients with prior omalizumab | Omalizumab/advanced therapy experienced/refractory patients now have a potential treatment option |
| Strong safety and tolerability profile | Physicians and patients recognize the clear benefit to risk profile |

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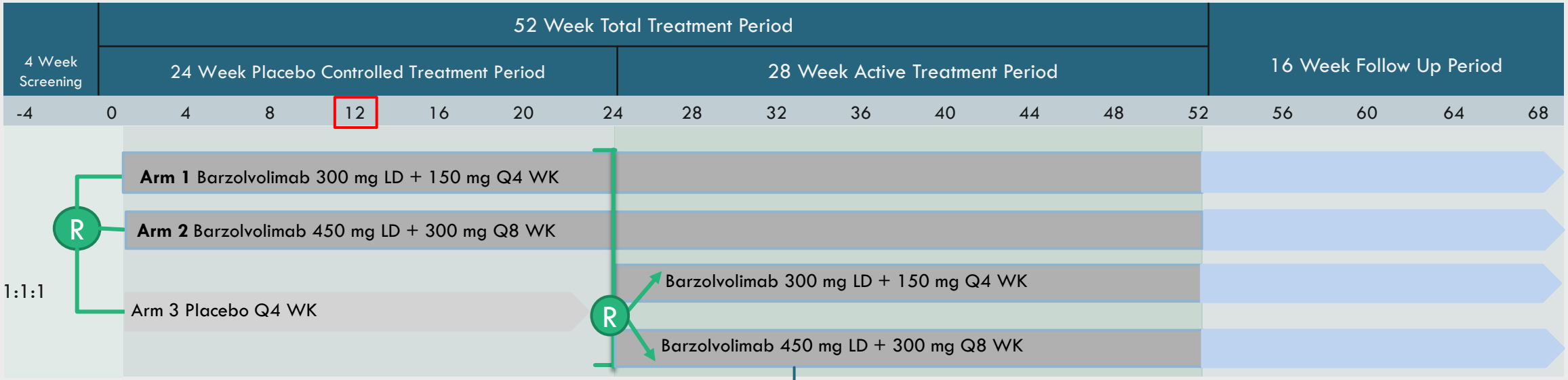
[1]Based on Phase 2 results; [2]Across reported studies, not based on head-to-head comparisons. Cross study comparisons are limited given differences in the design of the included trials, such as variations in statistical methods, patient populations and dosing schedules, among other factors.

# EMBARQ CSU

# Phase 3 CSU Registration Program - Topline Data Q4 26




## 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
- 915 patients per study; ~40 countries; 250 sites per study

## 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:

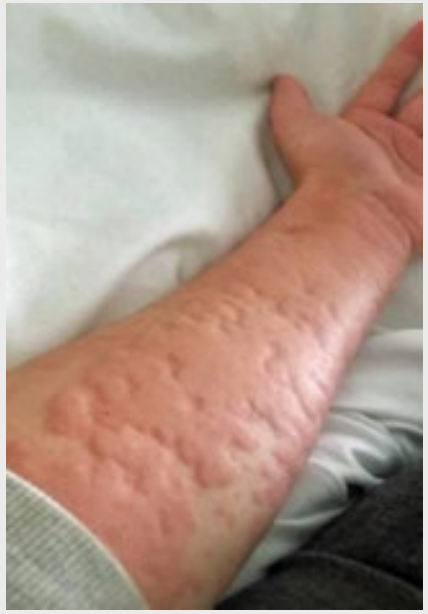
- Mean change from baseline in ISS7 and HSS7
- Proportion of participants with UAS7=0
- Proportion of participants with UAS7≤6
- Proportion of participants with AAS7=0 in participants who have AAS7> 0 at baseline
- Mean change from baseline in UAS7 in participants refractory to omalizumab treatment
-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

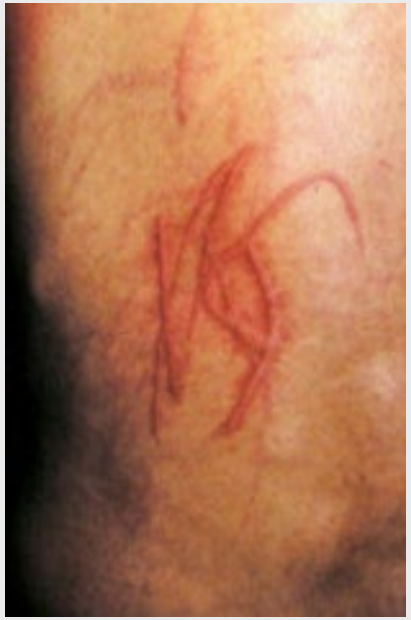
# Barzolvolimab Phase 2 Data Sets the Bar in ColdU and SD: *Complete Disease Control and Improved Trigger Thresholds*

Celldex

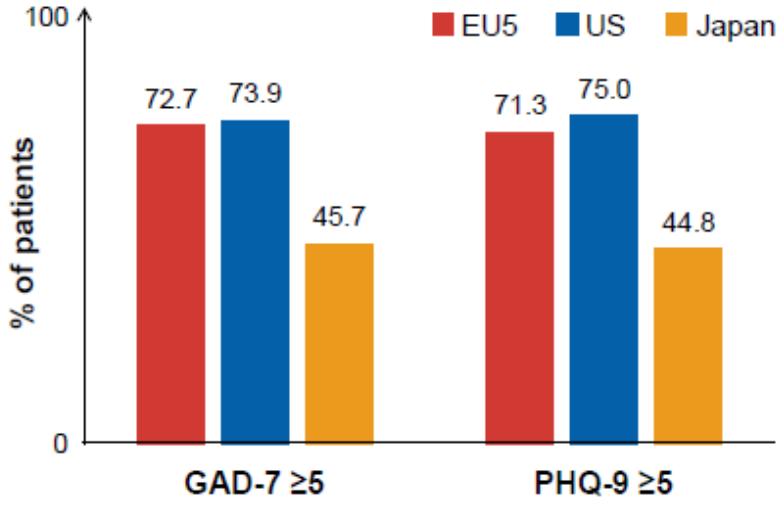
# Chronic Inducible Urticaria is a Disease of Misery: Hard to Treat Condition, Impairs Patient's QoL, and with No Approved Treatment to Date

- Patients have poorly controlled disease, history of mental comorbidities & high medical resource use[1]
- Respond poorly to commonly prescribed doses of antihistamines (AH); low rates of spontaneous remission[2]
- No approved therapies after AH





**Patients with CIndU experience high rates of anxiety (GAD-7 ≥5) and depression (PHQ-9 ≥5)**




GAD-7: General anxiety disorder-7; PHQ-9: Patient health questionnaire-9

**Patients with CIndU have high healthcare utilization (over 6 months*)**

| | EU5 (N=275) | US (N=272) | Japan (N=116) |
|---|---|---|---|
| **Any HCP** | | | |
| Visited, % | 94.5 | 94.5 | 89.0 |
| Number of visits, mean [SD] | 8.8 [23.2] | 8.2 [12.1] | 10.9 [12.6] |
| **ER visits** | | | |
| Visited, % | 39.6 | 51.8 | 8.6 |
| Number of visits, mean [SD] | 1.2 [2.3] | 1.9 [3.8] | 0.3 [1.1] |
| **Hospitalization** | | | |
| Visited, % | 32.0 | 46.7 | 14.7 |
| Number of visits, mean [SD] | 0.8 [2.0] | 2.7 [10.6] | 0.3 [1.2] |

*Percent of patients who had visits; mean number of visits for patients with visits

ER: emergency room; GP: general practitioner; HCPs: healthcare providers; SD: standard deviation

1. EADV poster: Prevalence, clinical profile and burden of chronic inducible urticaria in EU5, US and Japan, Sep 2022. 2. Jain & Mullins, JEADV May 2016; 2. Munoz et al, Current Allergy and Asthma Reports June 2024

CIndU Image Sources: https://dermnetnz.org/topics/dermographism, https://www.bbc.co.uk/bbcthree/article/d7ae42f3-b3ae-47ae-9464-eb8c328fe3dc

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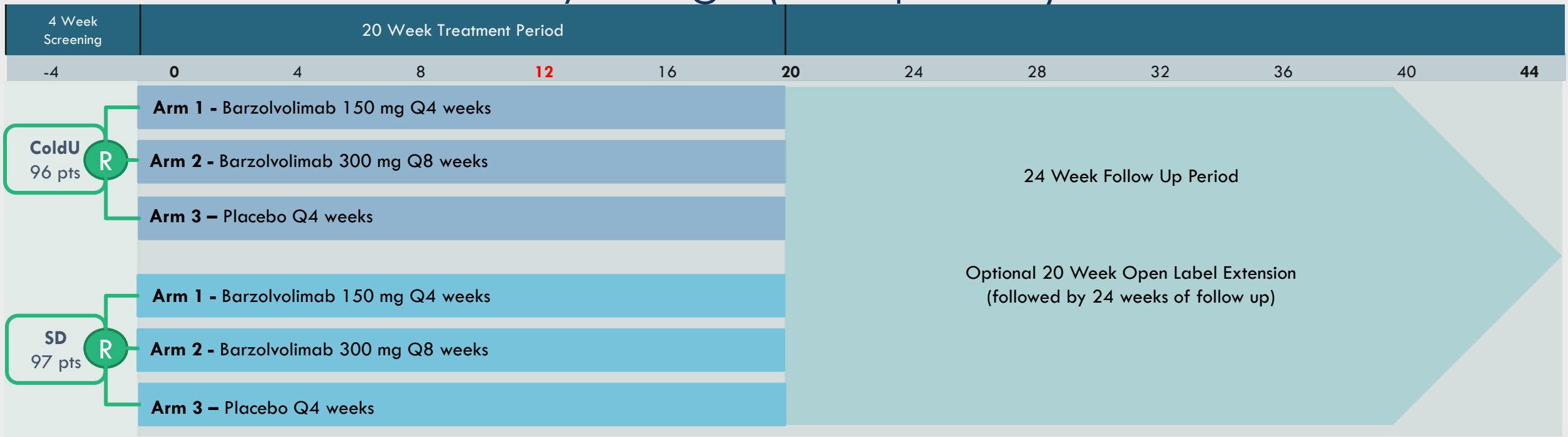
# Phase 2 ColdU/SD Study Design (Completed)




- **ColdU and SD symptomatic despite AH treatment; Poorly controlled disease** on initial provocation testing
- **193 treated patients**
- Primary Endpoint: % **patients with negative provocation test at Week 12**: ColdU (TempTest®) & SD (FricTest®): 80% power to detect a 35% difference for each subgroup between each barzol arm and placebo

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*Primary endpoint



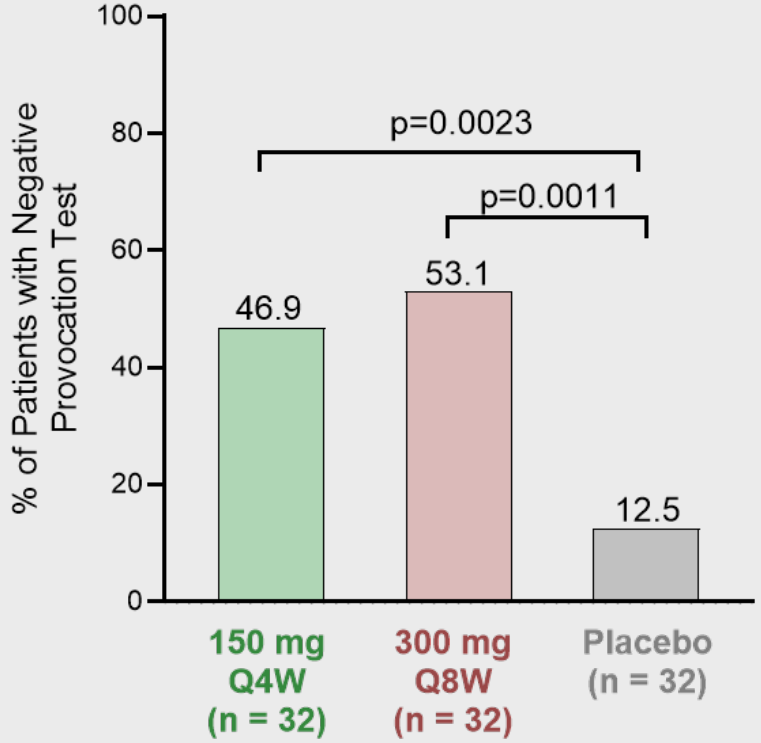
Data cut off: July 3, 2024

# Best in Disease[1]: Statistically Significant Improvement in Rate of Complete Response at Week 12 (primary endpoint)

- Up to 53% of patients with ColdU and 58% with Symptomatic Dermographism treated with barzolvolimab had a Complete Response

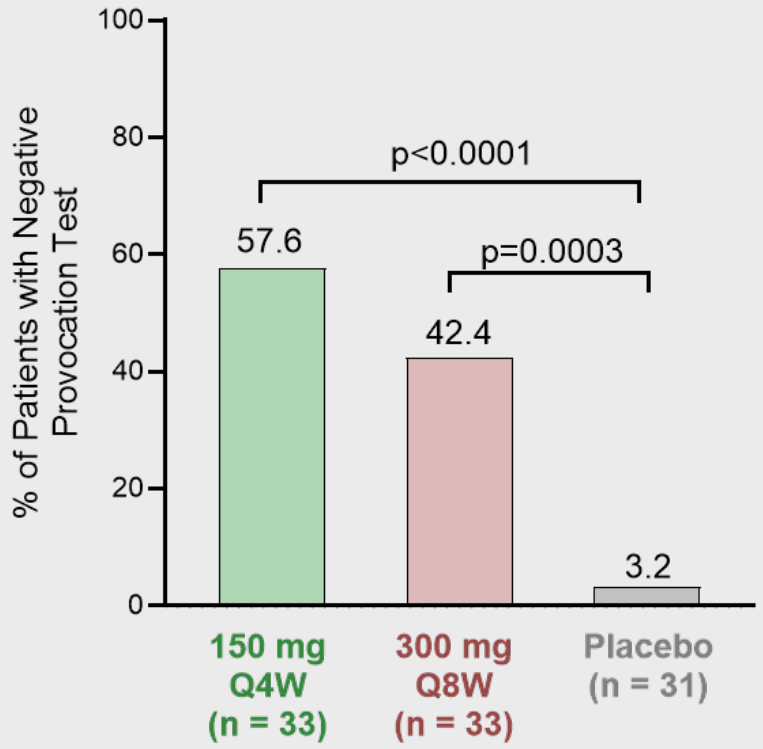
**Cold Urticaria**

**% of patients with negative provocation test**




**Symptomatic Dermographism**

**% of patients with negative provocation test**



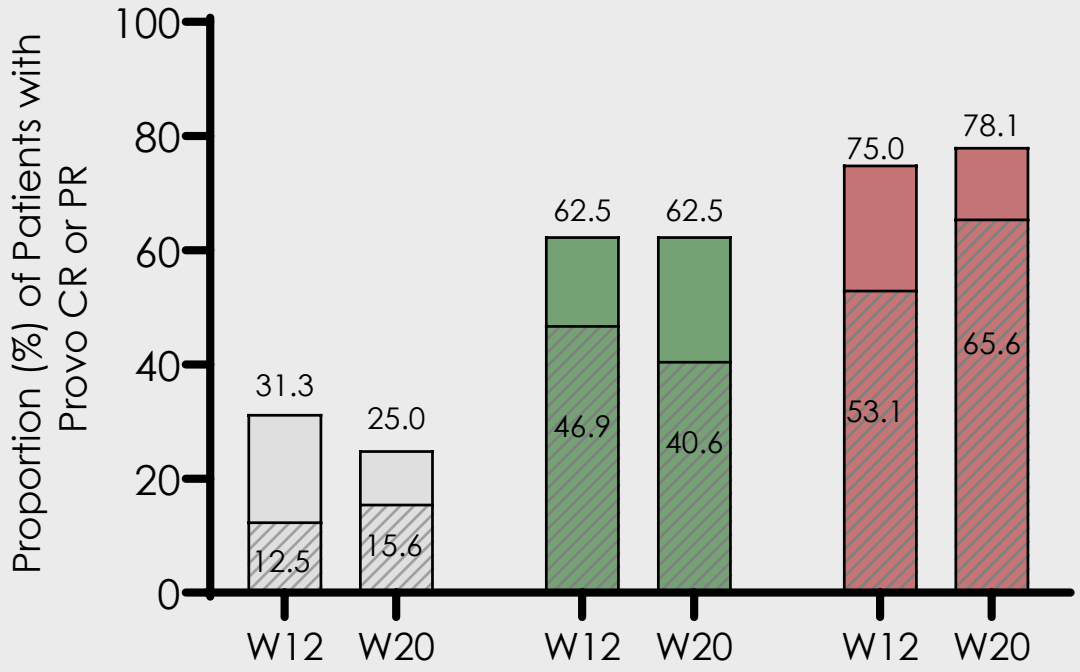

ColdU: Complete Response (CR) =negative provocation test at ≤4°C
Symptomatic Dermographism: CR=0 pins
Non-responder imputation approach; mITT population

[1]Based on reported results

# Up to 78% of Patients with ColdU and 58% of Patients with SD Obtained a Partial or Complete Response at Week 20

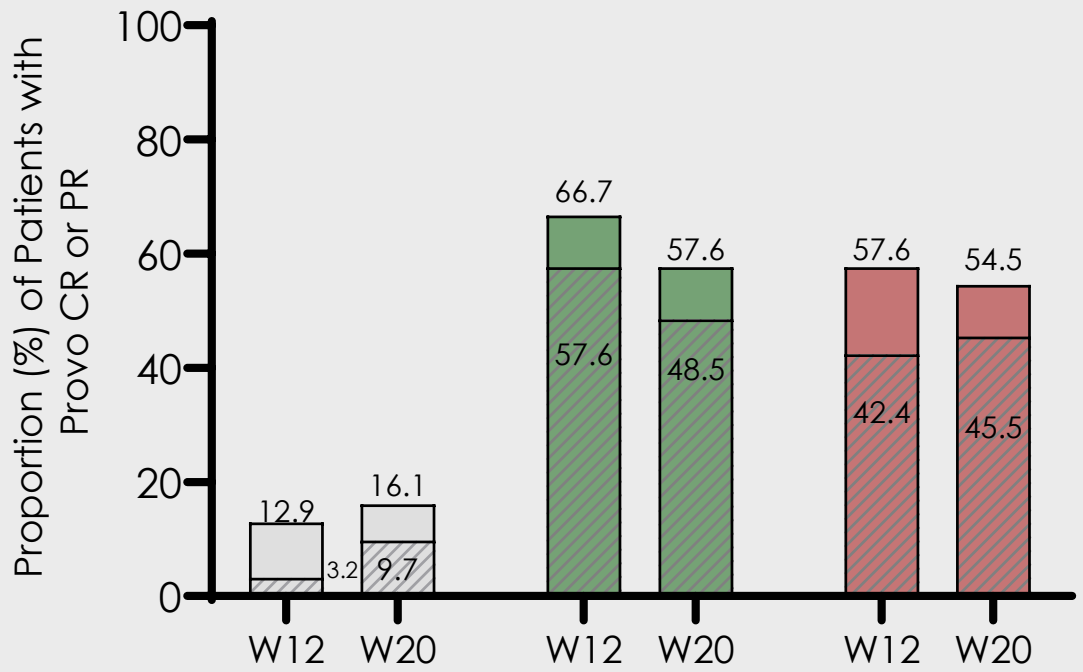
**Cold Urticaria**

% of patients with a complete response to provocation




**Symptomatic Dermographism**

% of patients with a complete response to provocation




Partial or Complete Response: Placebo; 150 Q4W barzolvolimab; 300 Q8W barzolvolimab

Complete Response: Placebo; 150 Q4W barzolvolimab; 300 Q8W barzolvolimab

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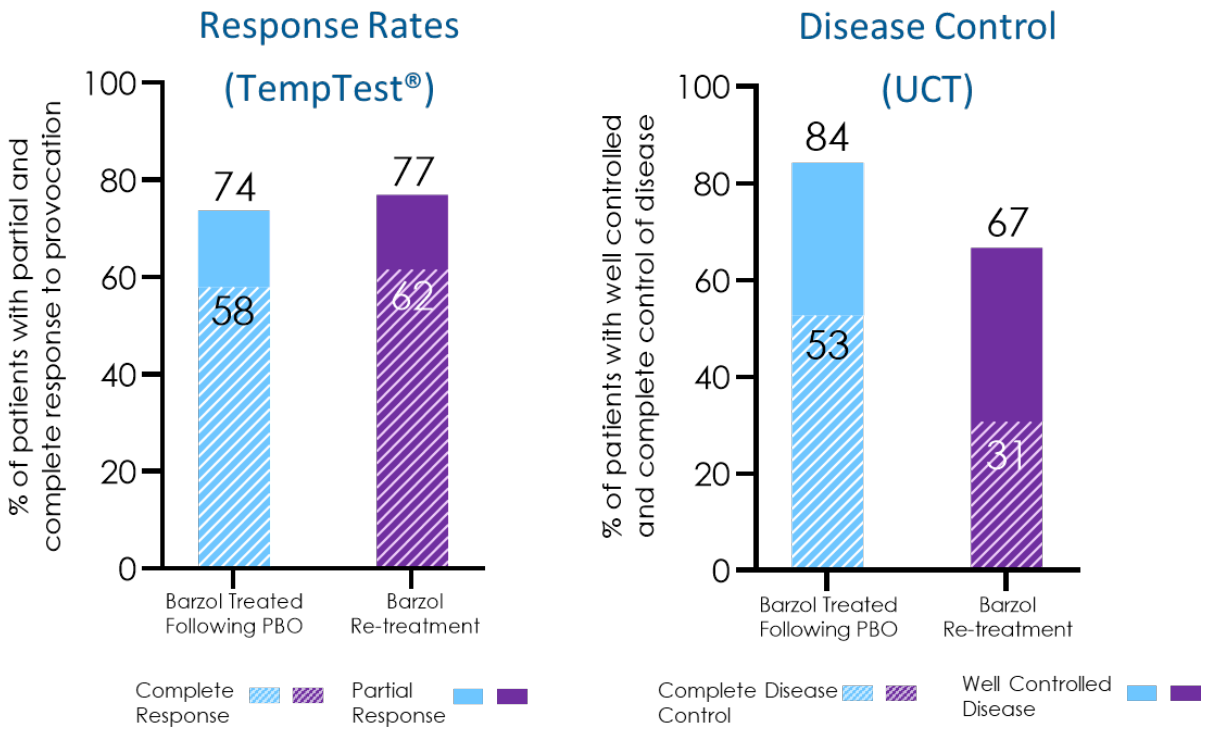
A non-responder imputation approach was used for calculating proportions of participants with complete and partial responses. ColdU: Complete Response: negative test at 4 °C, Partial Response: ≥ 4 °C improvement. SD: Complete Response: 0 pins, Partial Response: ≥ 2 pin improvement

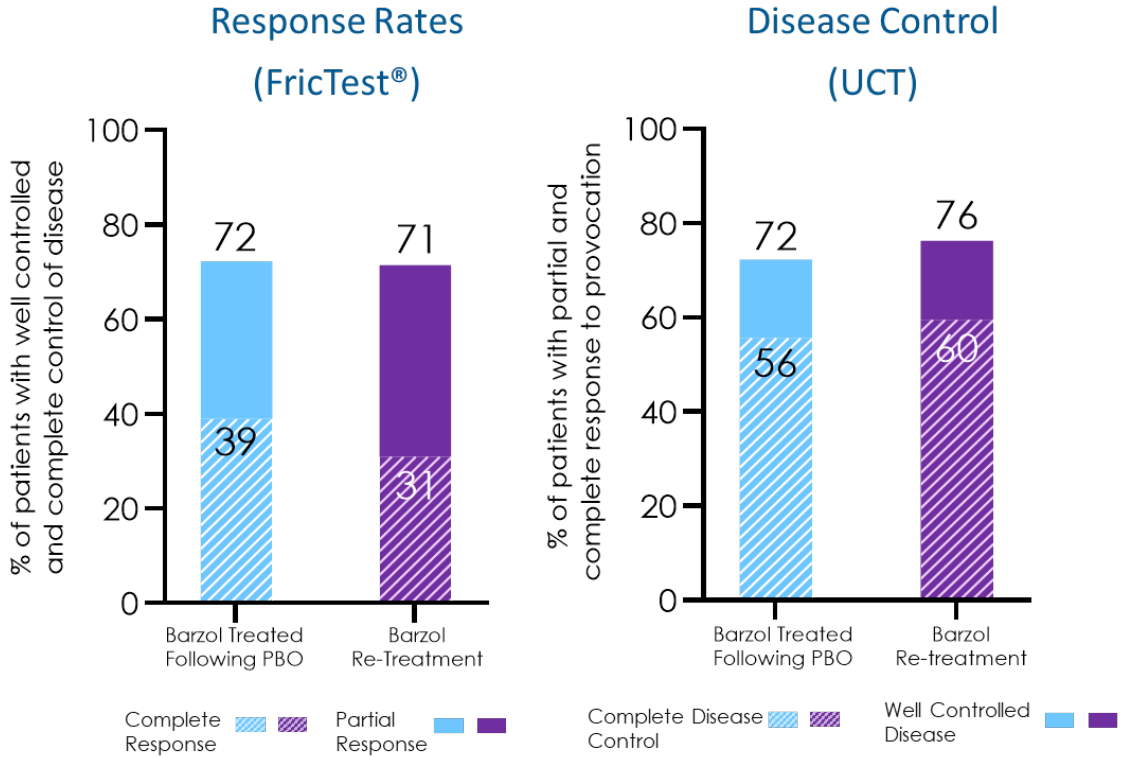
# OLE Retreatment: Similar Profound Efficacy to First Exposure

## Cold Urticaria: Week 20 Results




- ColdU CR rates in the OLE were 55%, 68%, and 58% for patients who originally received 150 mg Q4W, 300 mg Q8W and PBO in the main study, respectively

## Symptomatic Dermographism: Week 20 Results




- SD CR rates in the OLE were 52%, 68%, and 56% for patients who originally received 150 mg Q4W, 300 mg Q8W and placebo in the main study, respectively

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# Barzolvolimab Phase 2 Data Set the Bar for Patients with ColdU and SD

- First large, randomized, placebo-controlled study to demonstrate clinical benefit in ClndU
- Study met all primary and secondary endpoints at Week 12—statistically significant, clinically meaningful improvements compared to placebo
- Improvement was marked, rapid and sustained through 20 weeks across multiple endpoints
- Results achieve the goal of treatment for ColdU and SD
  - Improve trigger thresholds, enabling patients to regain control of their lives
  - Provide fast acting, durable treatment option that offers a meaningful opportunity for complete disease control
  - OLE data demonstrate that retreatment achieves similar profound efficacy to first exposure
- Phase 3 in ColdU and SD initiated in Dec 2025

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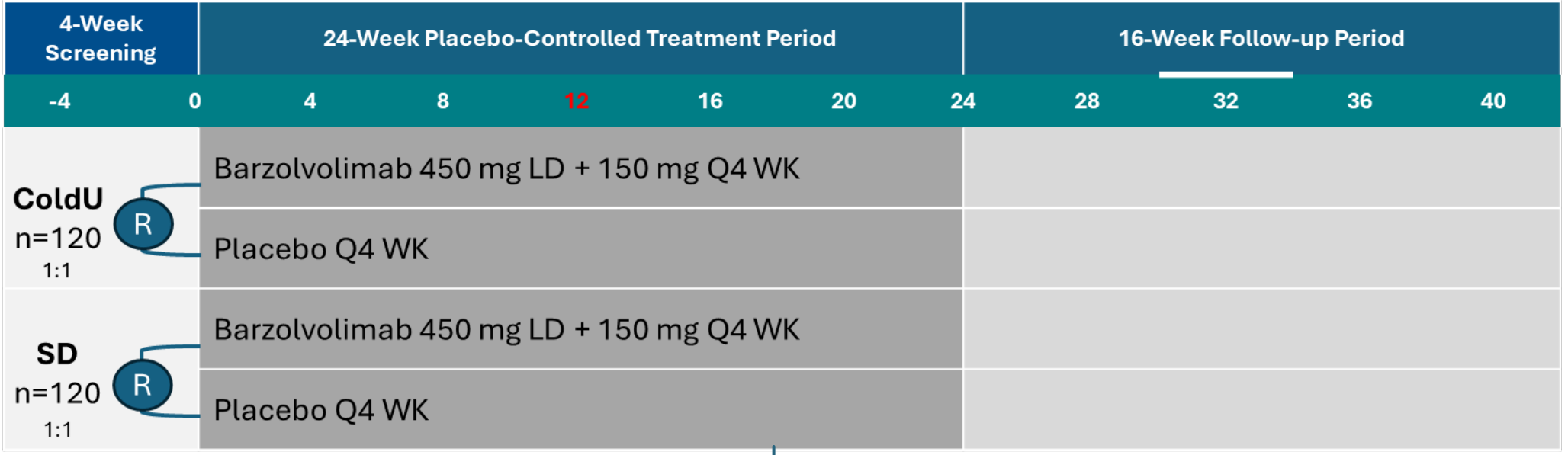
# Phase 3 ColdU and SD Study Initiated Dec 2025




## Study Overview

Randomized, double-blind, placebo-controlled, parallel group study

Diagnosis of ColdU or SD for at least 3 months; recurrent wheals despite stable AH regimen. Prior biologics permitted

- ColdU: Critical Temperature Threshold (CTT, TempTest) of ≥ 10 °C and < 37 °C and WI-NRSprovo of ≥ 3; positive ice cube test
- SD: Critical Friction Threshold (CFT, FricTest) of ≥ 3 and WI-NRSprovo of ≥ 3

240 patients across 7 countries; ~75 sites

## Primary Endpoint

% of patients with complete response (negative provo test) at Week 12

90% powered to detect a 28% difference between barzolvolimab and placebo in the CR rate in each subtype

## Key Secondary Endpoints

Mean change from baseline CTT and CFT at Weeks 4, 12 & 24

CR rate at Weeks 4 & 24

CFB in WI-NRS and WH-NRS at Weeks 12 & 24

CFB in WI-NRSprovo at Week 12

DLQI 0-1 at Week 12

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*Primary endpoint

# *Prurigo Nodularis (PN): Targeting Itch and Nodule Resolution*

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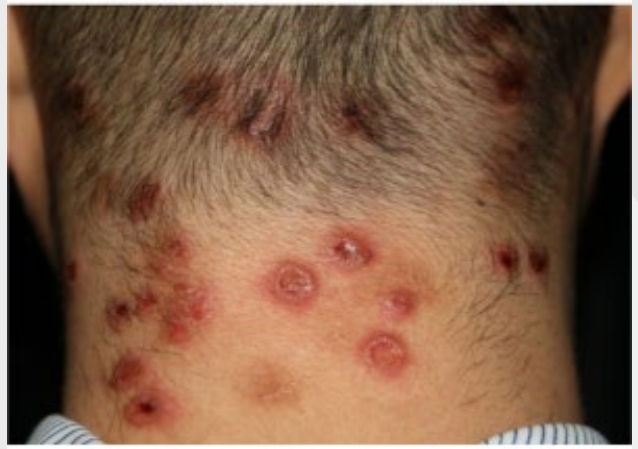
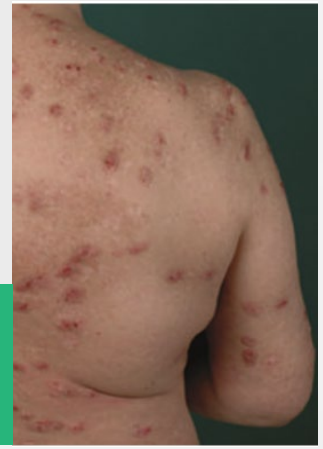
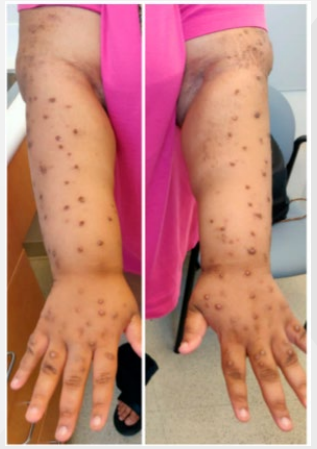
# Mast Cells Play an Important Role in Chronic Itch: Prurigo Nodularis (PN)

***Mast cells amplify chronic itch and neuroinflammation. PN study expands barzolvolimab development into chronic pruritic diseases and other indications driven by itch and neuroinflammation***

- Chronic disease - hard, itchy skin lesions; intense itching causes scratching to the point of bleeding/pain - scratching can cause more skin lesions perpetuating the disease cycle
- Significant QoL impact: sleep disturbance, psychological distress, social isolation, anxiety, depression
- Significant unmet need







**Phase 2 study fully enrolled; data expected in summer 26**

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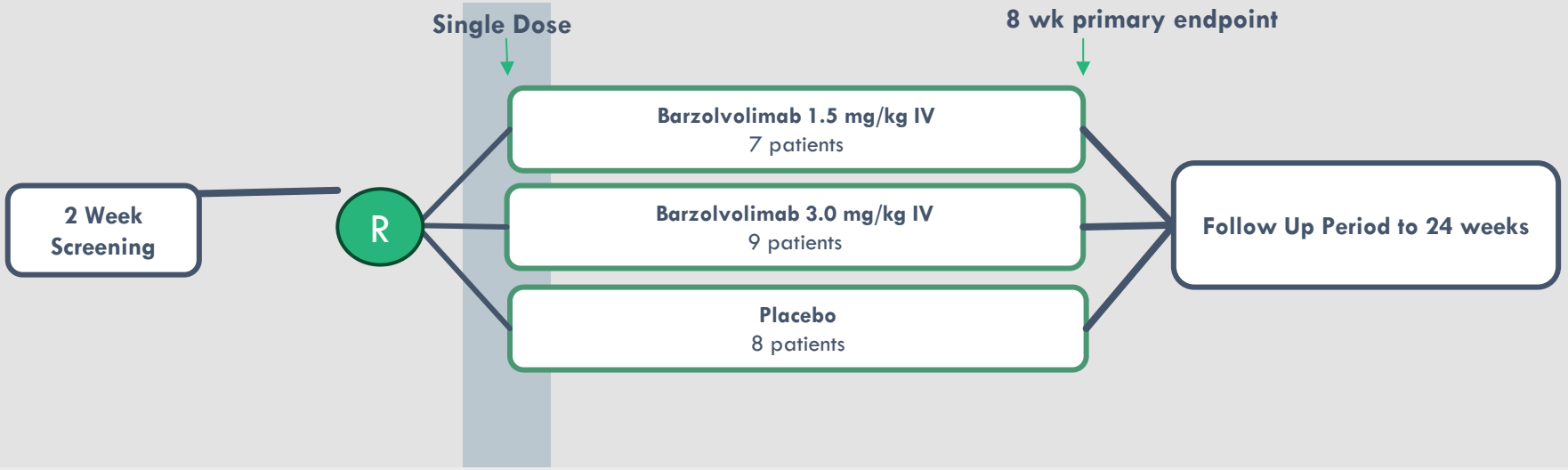
# Phase 1b PN Study Design (Complete)




- Randomized, double-blind, placebo-controlled, single dose study in adults with moderate to severe PN
- Primary endpoint—safety; secondary endpoints—changes from baseline in Worst Itch-Numerical Rating Scale (WI-NRS) & Investigator Global Assessment (IGA)
- 24 patients randomized (evaluable: n=23 safety; n=22 efficacy)

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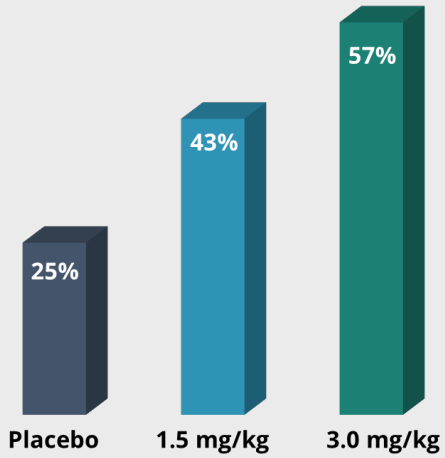
# Clinically Meaningful Reduction in WI-NRS & Lesion Clearing with a Single Dose

- Effect noted as early as the first clinic visit at week 2 and generally maintained out to week 16

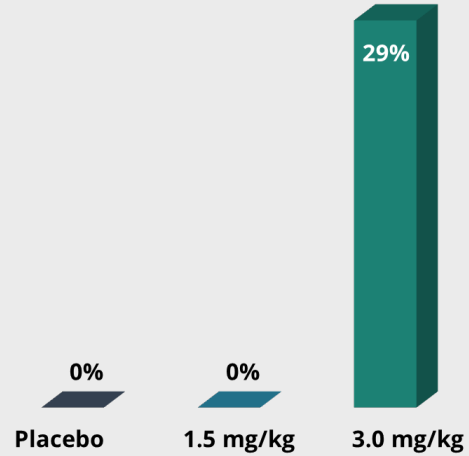
**WI-NRS at Week 8 (≥4-point)**




In 3.0 mg/kg arm, decrease in itch seen as early week 1 and reached a high of 71% of patients at week 6

| Dose | Week 01 | Week 02 | Week 03 | Week 04 | Week 05 | Week 06 | Week 07 | Week 08 |
|---|---|---|---|---|---|---|---|---|
| 1.5 mg/kg | 0 | 14 | 29 | 14 | 29 | 29 | 29 | 43 |
| 3.0 mg/kg | 14 | 29 | 29 | 29 | 57 | 71 | 57 | 57 |
| placebo | 0 | 0 | 13 | 13 | 25 | 38 | 38 | 25 |

**29% of patients (3.0 mg/kg) achieved clear/almost clear skin by week 8**




4 additional barzol pts (2 in 1.5, 2 in 3.0 mg/kg arms) and 1 PBO pt had IGA 0/1 between weeks 8 and 24

| Dose | Baseline | Week 2 | Week 4 | Week 8 |
|---|---|---|---|---|
| 1.5 mg/kg | 0 | 0 | 0 | 0 |
| 3.0 mg/kg | 0 | 14 | 14 | 29 |
| placebo | 0 | 0 | 0 | 0 |

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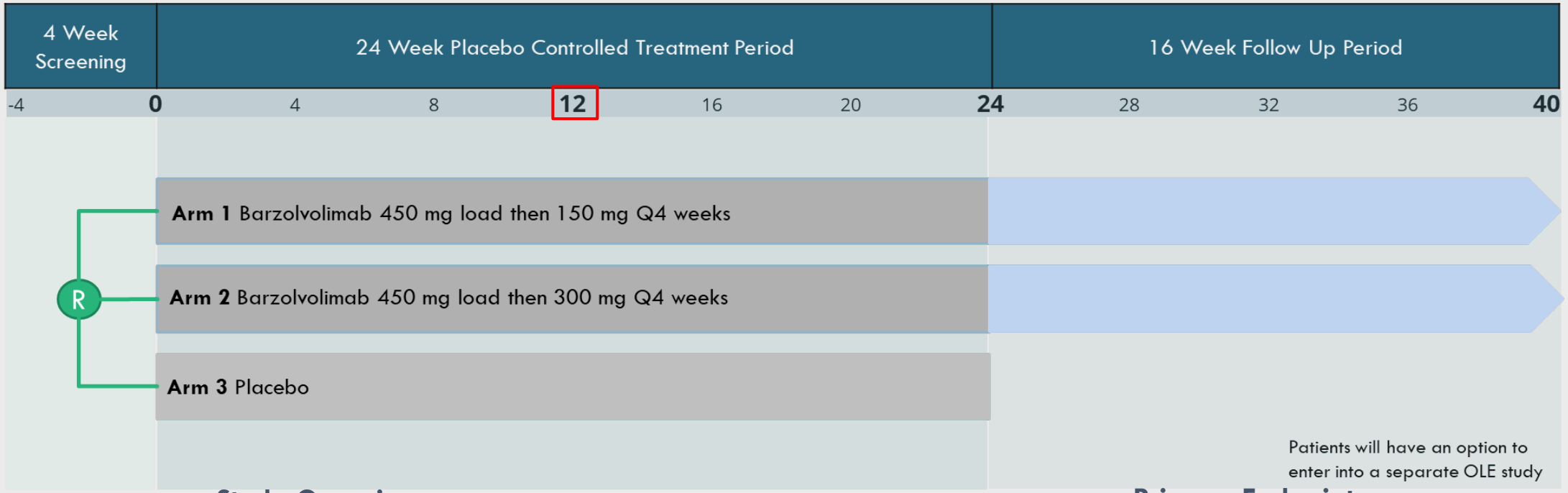
# Phase 2 Study Design in PN: Fully Enrolled with Data Expected Summer 26




## Study Overview

Randomized, double-blind, placebo-controlled parallel group study in adults with moderate-to-severe PN (≥ 20 PN nodules, WI-NRS ≥ 7, IGA-CNPG-S ≥ 3)

~120 patients, 3 arms (40 patients each), 5 countries, 55 sites

## Primary Endpoint

% pts with itch response (reduction in WI-NRS by ≥ 4) from baseline to Week 12

80% powered to detect a 25% difference between each of the active arms an placebo

## Key Secondary Endpoints

% pts achieving itch response (WI-NRS ≥4-pt reduction from BL) at Weeks 4, 24 and over time

% pts achieving IGA-CNPG-S response (0 or 1) at Weeks 4, 12 & 24

% pts achieving itch and IGV response at Weeks 4, 12 & 24

*Primary endpoint

# *Atopic Dermatitis (AD): Significant Unmet Need for Patients with Recalcitrant Moderate-to-Severe AD*

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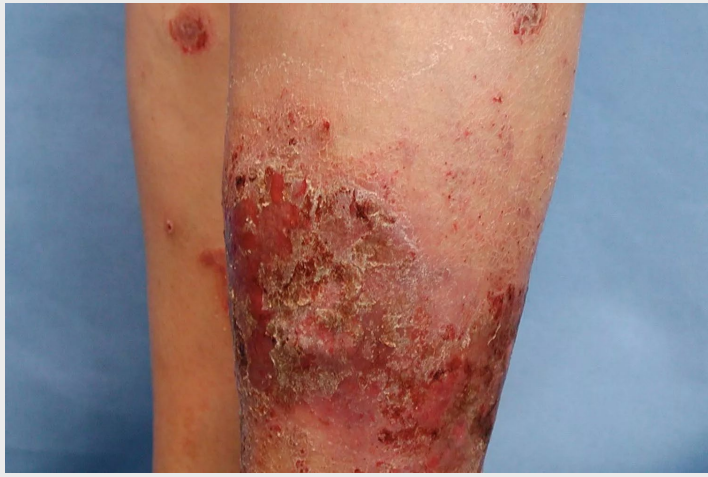
# Barzolvolimab Expands into Atopic Dermatitis (AD)

## Fifth Indication and Additional Disease Setting with Mast Cell Involvement

Most common chronic inflammatory skin disease, with a lifetime prevalence of up to 20% of the population and substantial impact on quality of life[1]

- Chronically relapsing skin disease, driven by Type 2 and neuroinflammatory processes that drive disease progression and itch
- Typical symptoms include areas of skin lesions that can appear red, scaly, dry and/or lichenified and burdensome pruritus:
  - 86% of patients experience itch daily; 61% assess itching as severe or unbearable[2]
  - Pruritus is a strong driver of poor QoL outcomes for patients with AD[3]
- Significant unmet need remains for patients with recalcitrant moderate-to-severe AD who require therapies with a rapid onset of action and convenient management of their pruritus and skin disease



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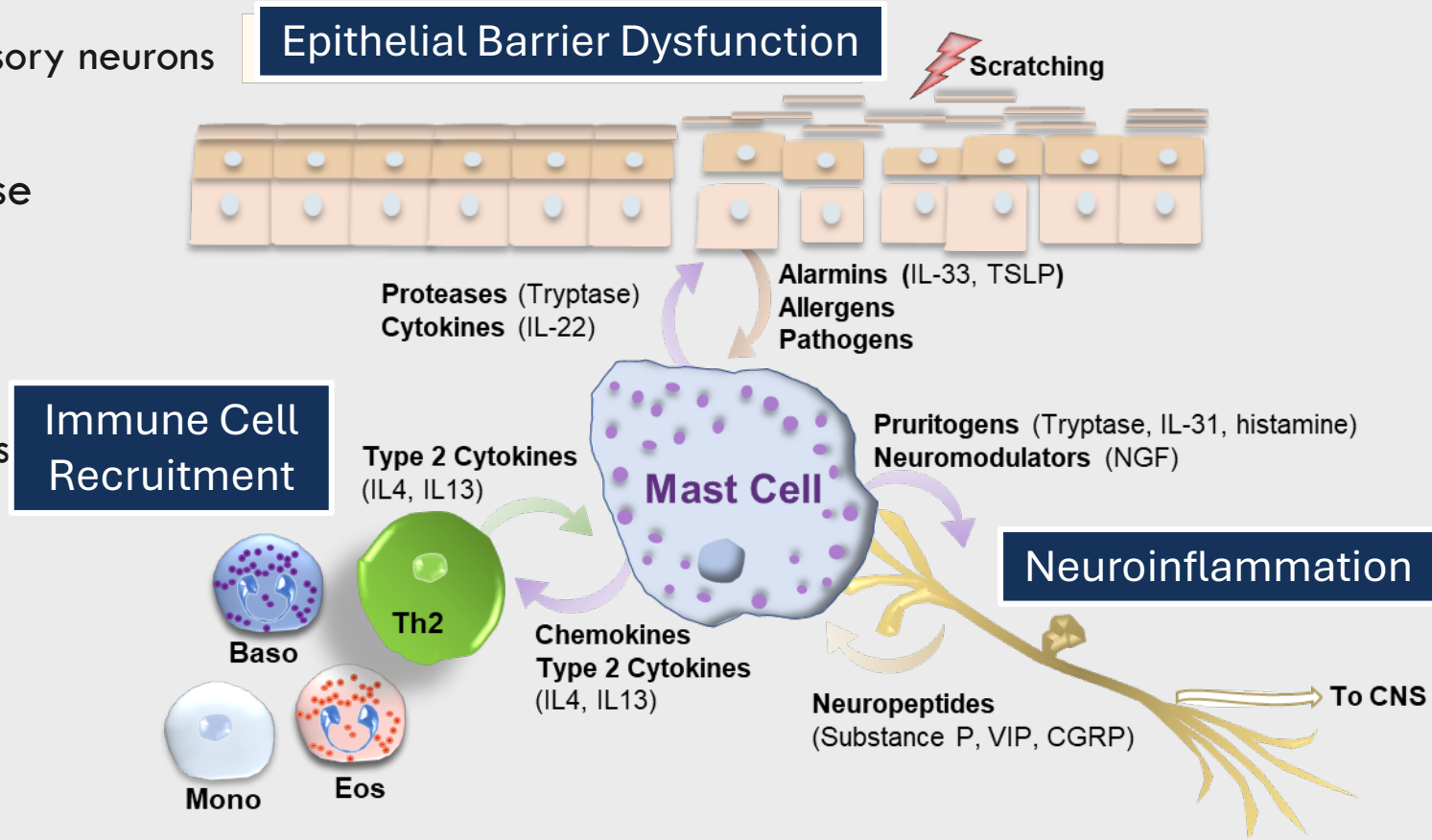
1. Weidinger S et al., Nat Rev Disease Primer, 2018; 4:1; 2. Simpson EL, et al., J Am Acad Dermatol., 2016, 74:491-498; Photos: Shutterstock and DermNet; [3]Kunhs, L., *Itch Descriptors in Atopic Dermatitis May Predict Disease Severity, QOL.* Dermatology Advisor, July 2025.

# Role of Mast Cells in AD Disease Pathology

- Mast cells (MCs) are naturally found in skin and act as first responders to injury and infection
  - Associated with stroma, vasculature and sensory neurons
  - Increased numbers in AD lesions[1]
- MC-associated factors correlate with disease severity in AD
  - Levels of SCF and the KIT receptor correlate with the exacerbation of the disease in AD patients, reducing upon effective treatment[2]
  - Increased IgE levels are found in AD patients and correlate with severity of disease[3]
- MCs strongly implicated in all facets of AD pathology:[4,5,6]
  - Epithelial barrier dysfunction
  - Immune cell recruitment
  - Neuroinflammation




- Barzolvolimab rapidly and profoundly depletes skin mast cells eliminating their role in AD pathophysiology

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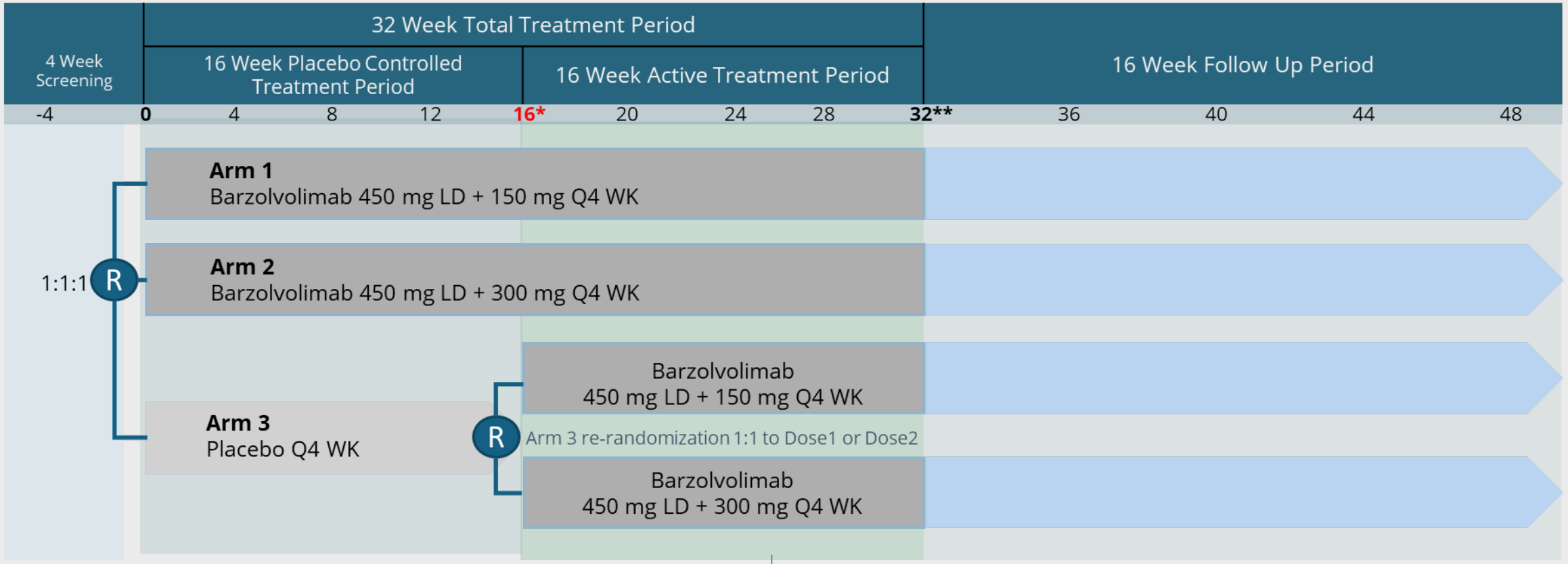
1. Theoharides T et al, Expert Rev Clin Immunol, 2019; 2. Kanbe, T. et al., Br. J. Dermatol., 2001, 144, 1148–1153; 3. Wollenberg, A. et al., World Allergy Org Journal, 2021, 14:100519; 4. Numata T et al, Front Immunol. 2022.; 5. Voss M et al. Int J of Mol Sci, 2021.; 6. Siiskonen et al; Front Cell Neurosci, 2019

# Phase 2 Study Design in AD: Fully enrolled with Data Expected Late 26




## Study Overview

Randomized, double-blind, placebo-controlled study in adults with moderate to severe AD who remain symptomatic despite treatment with TCS or TCI

~120 patients, 50 sites (U.S.)

## Primary and Key Secondary Endpoints

**Primary Endpoint:** PP-NRS at Week 16; 80% powered to detect a 30% difference between each of the active arms and placebo

**Key Secondary Endpoints:** CFB EASI score at W16; IGA 0 or 1 at W16

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*Primary endpoint

# *Barzolvolimab: Strong Safety and Tolerability Profile*

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# Strong Safety & Tolerability Profile, Consistent across Multiple Trials

- **Most common side-effects (≥10%) are grade 1 (mild), mechanism related (KIT-mediated) and reversible.**
  - Neutropenia events: transient, resolve on drug, not associated with infection
  - Hair/skin hypopigmentation: not associated with meaningful treatment discontinuation, demonstrated reversibility post treatment
- Reduction in sperm count observed preclinically; demonstrated reversibility post barzolvolimab clearance
- Hypersensitivity reactions consistent with other widely used I/I mAbs
- Safety profile consistent across multiple clinical trials

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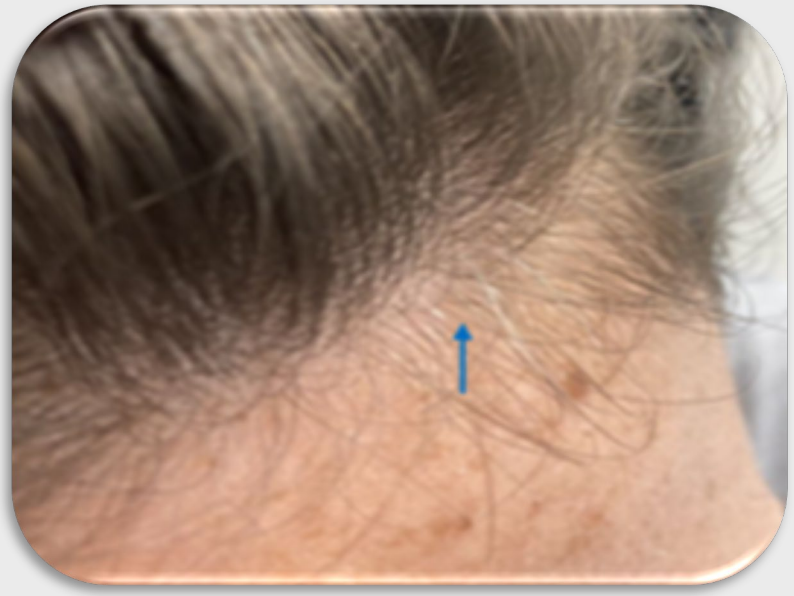
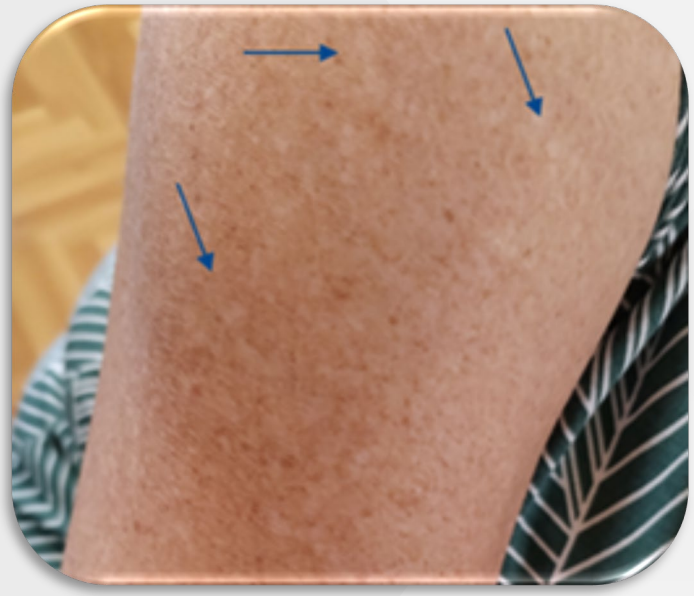
# Hair/Skin Hypopigmentation is Mild and Reversible

**Patients experience same level of QOL improvement**



- Localized hair color changes/lightening
- Median onset: 3.4 months of therapy



- Small areas of hypo-pigmentation
- Median onset: 8 months of therapy

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Through 52 weeks of treatment: localized hair color changes/lightening in 48 patients (46 G1; 2 G2) and small areas of hypo-pigmentation in 30 patients (28 G1; 2 G2)

# *Advancing Innovative Antibody Platform behind Barzolvolimab*

- *Build from the success and learnings with barzolvolimab*
- *Bispecific antibody approach broadens the opportunity to indications where mast cells contribute to disease but are not the only driver*

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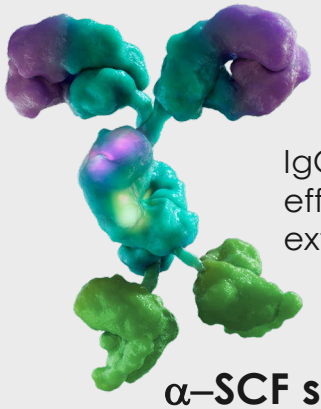
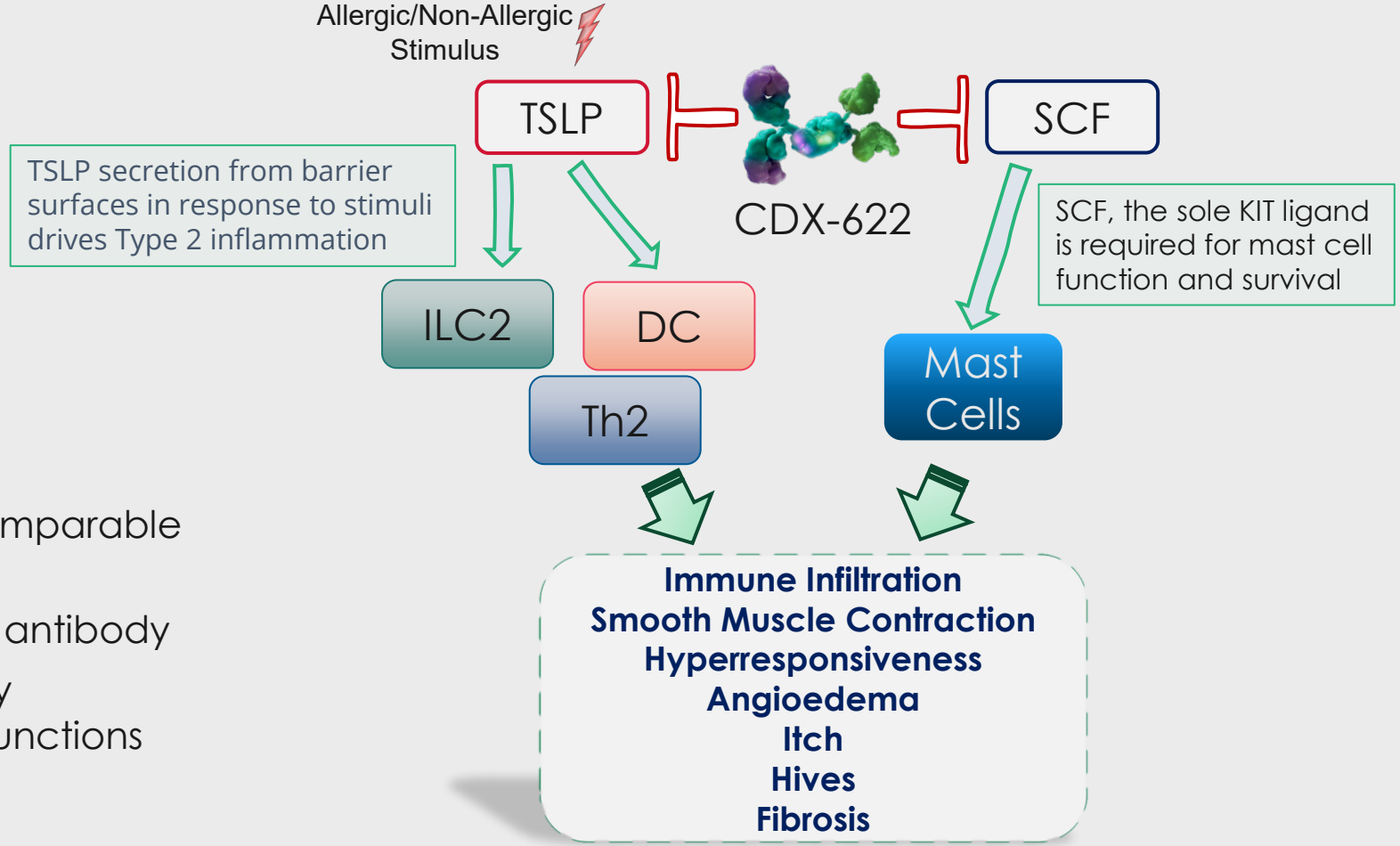
# CDX-622: Novel Bispecific Antibody that Neutralizes Two Independent Inflammatory Pathways, TSLP and Mast Cells

**α–TSLP mAb**



IgG1 engineered to disable effector function (AQQ) and extend half-life (YTE)

**α–SCF scFv**




- Potent TSLP and SCF neutralizing activity comparable to tezepelumab and barzolvolimab
- Incorporates first-in-human SCF neutralizing antibody
- Targets the soluble form of SCF, differentially impacting MCs over other KIT-dependent functions

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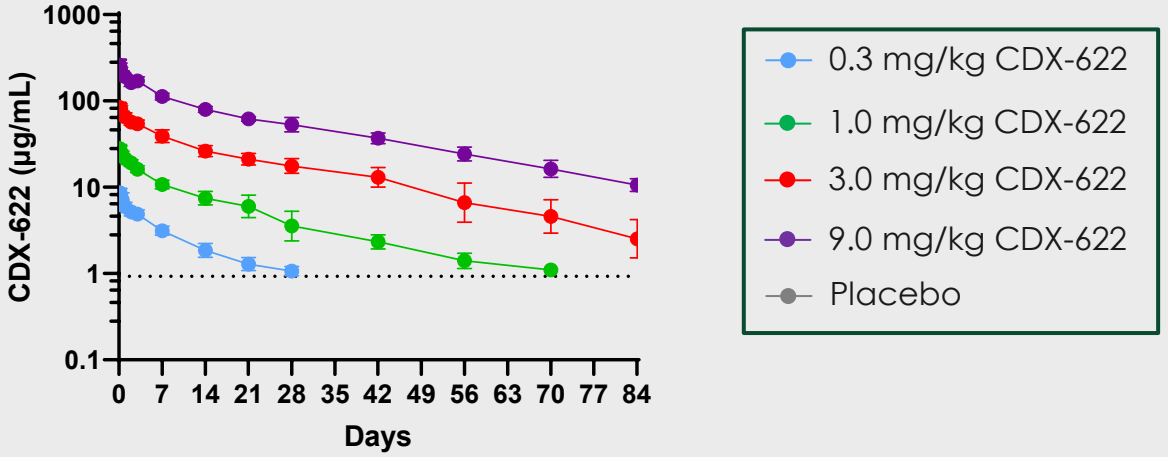
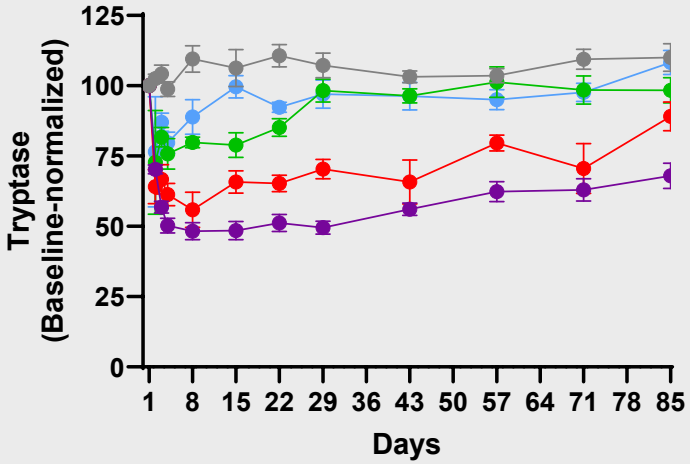
# CDX-622 Exhibits mAb-Like Pharmacokinetics and Significantly Reduces Serum Tryptase in Phase 1 SAD Study

## Pharmacokinetics




## Serum Tryptase



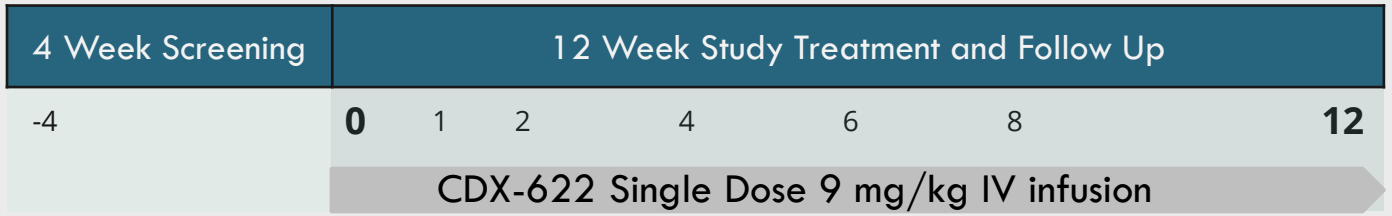

- Long serum half life (~24 days at 9 mg/kg) consistent with engineered half-life extension. No evidence of ADA to date.
- Dose-dependent, rapid and sustained decrease in circulating tryptase consistent with systemic mast cell inhibition
- Well tolerated with no emergent adverse events related to systemic KIT inhibition

**Phase 1 HV study fully enrolled including: MAD IV at 1 mg/kg, 3 mg/kg, 9 mg/kg Q2W (4 doses) SAD subcutaneous administration at 290 mg, 580 mg, 870 mg flat dose; Data in Q3 26**

# CDX-622: Phase 1b Proof of Mechanism Study in Asthma initiated Jan 2026

## Confirm the reduction in TSLP-dependent biomarkers and impact on lung mast cells

**Evaluating the safety, PD, and PK of CDX-622 in 12 adults with mild to moderate asthma**




### Study Overview

Participants followed over 12 weeks for safety and biomarker follow up visits. Visits at Weeks 1, 2, 4, 6, 8, 12

Biomarker analysis conducted on serum and induced sputum

Pulmonary function (FEV1) and asthma control (ACQ-6) evaluated

### Primary & Key Secondary/Exploratory Endpoints

Primary Endpoints: Safety and tolerability

Key Secondary & Exploratory Endpoints: FeNO levels, Absolute blood eosinophil count (AEC), tryptase, TSLP, PK

**Emerging data will inform additional development in asthma and other indications**

# *Upcoming Milestones & Financial Overview*

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# Driving Value Through Execution & Key Milestones

## Programs and Anticipated Milestones

### Barzolvolimab (CDX-0159)

- ✓ CSU Phase 3 enrollment completion – guided summer 2026; completed Feb 2026
- ✓ ColdU/SD retreatment data – AAAAI 2026
- Phase 2 PN topline data – expected summer 2026
- Phase 3 CSU topline data – expected Q4 2026
- Phase 2 AD topline data – expected late 2026

### CDX-622 (SCFxTSLP)

- ✓ Phase 1 SAD data
- ✓ Phase 1 asthma POM initiated Jan 2026
- Phase 1 HV data – expected Q3 2026

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# Financial Overview (as of 12/31/2025)

**Well-capitalized; clean balance sheet**

| $518.6M | $0.0 | 66.5M |
| --- | --- | --- |
| Cash | Debt | Shares Outstanding |

Cash runway through 2027

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*Targeted Antibody Therapeutics to Address Devastating Diseases*

*NASDAQ: CLDX*

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