Celldex therapeutics

Barzolvolimab Data Updates

Phase 2 Topline CSU & Phase 1b PN Data Results

NASDAQ: CLDX
November 6, 2023

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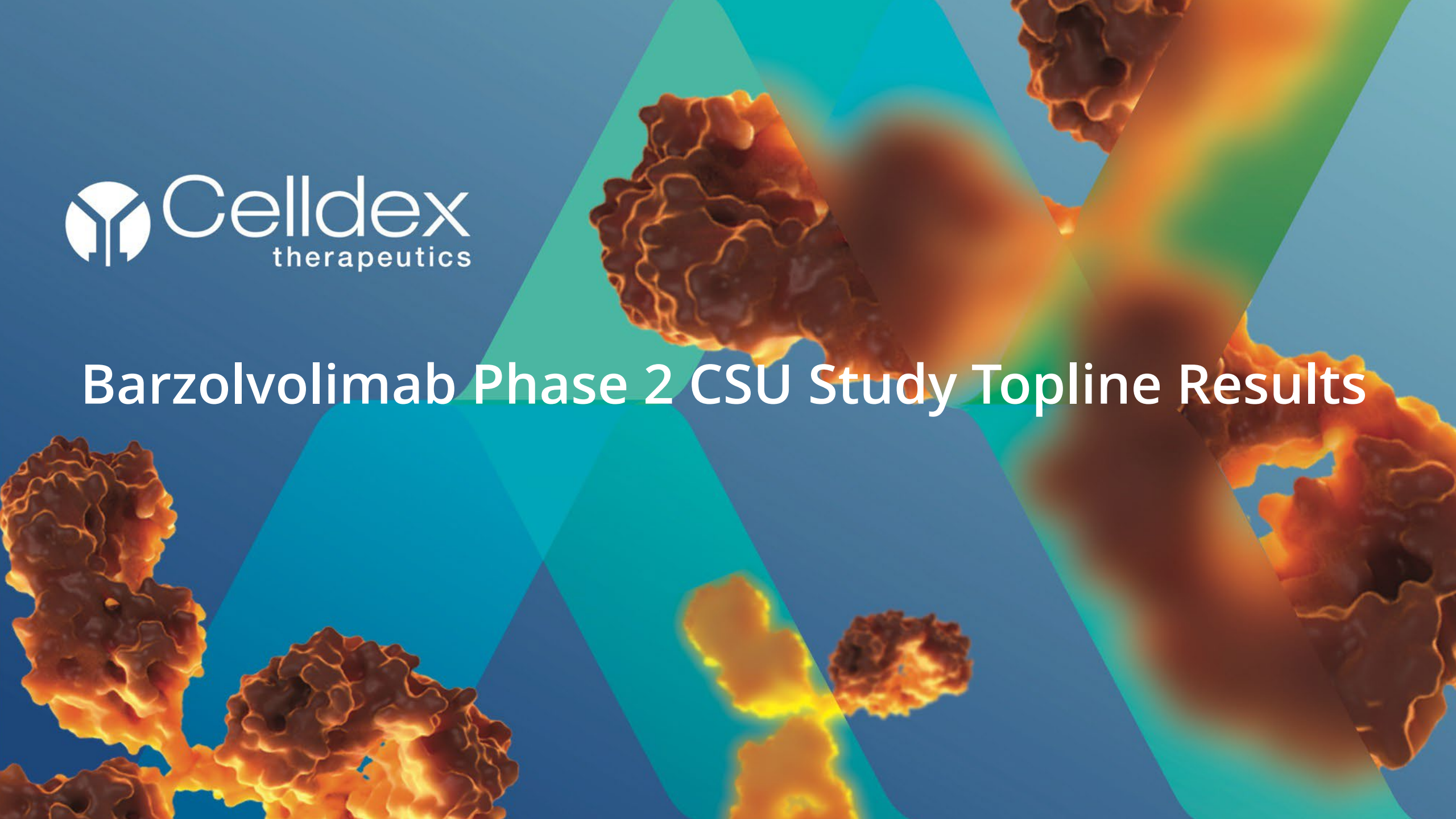
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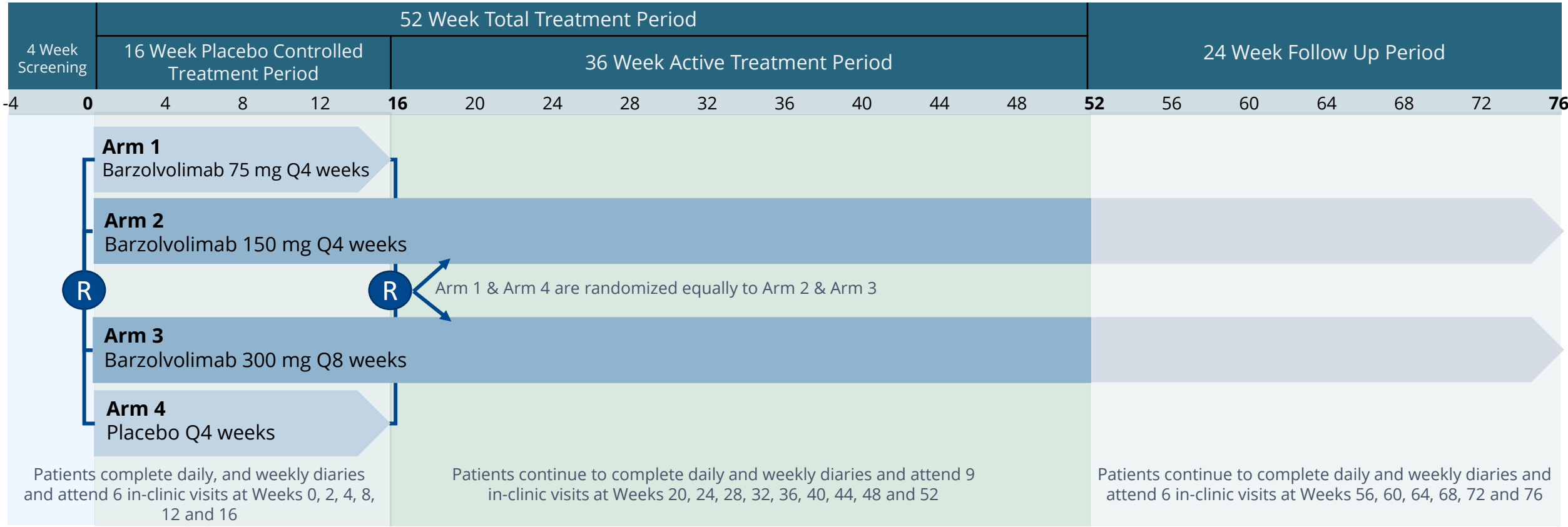
Barzolvolimab Phase 2 CSU Study Topline Results

Phase 2 CSU Study Design and Key Eligibility



Randomized, double-blind, placebo-controlled, dose-finding study

208 patients enrolled; 72 sites/8 countries

Biologic naive & experienced patients refractory to antihistamines

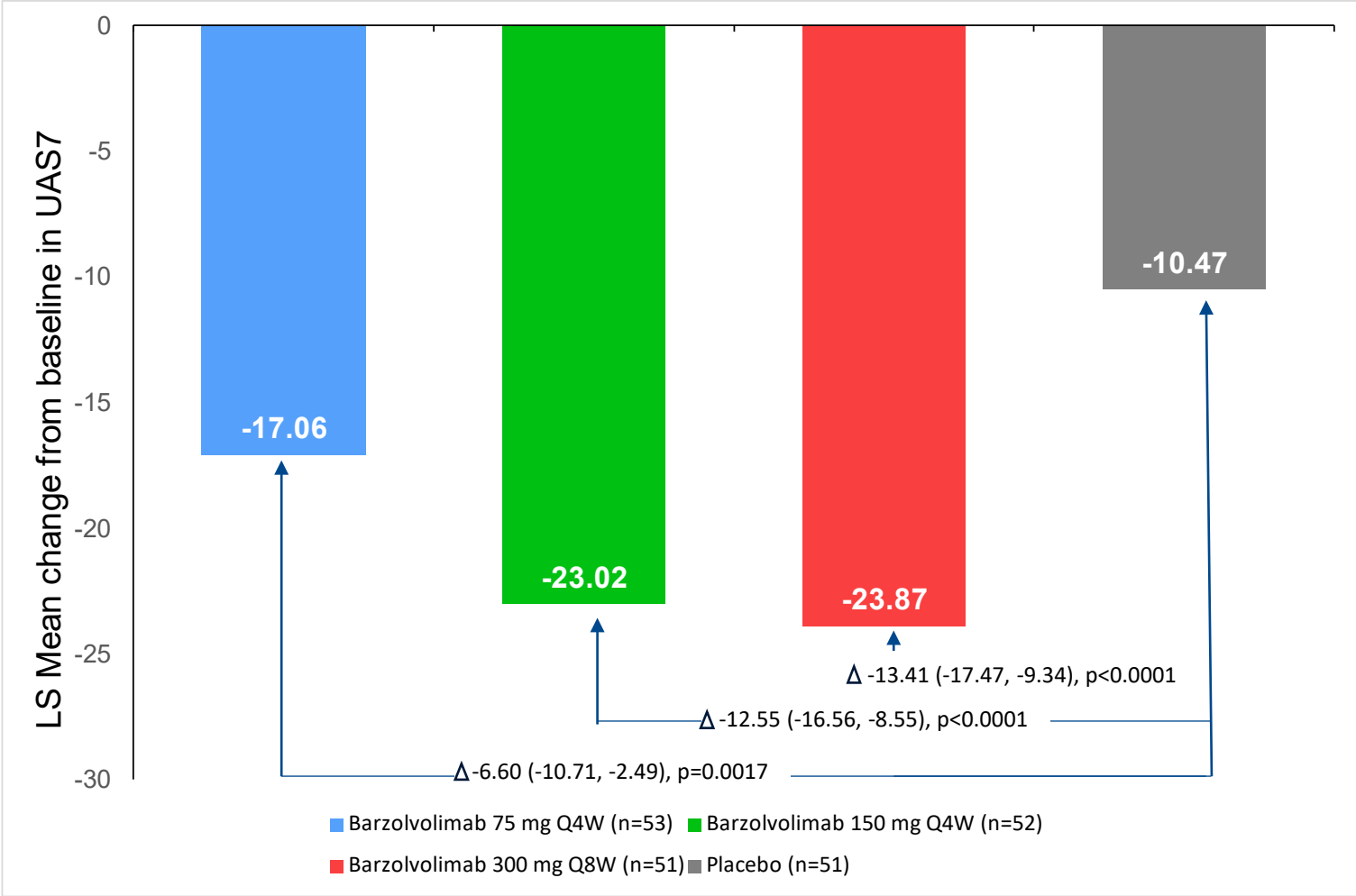
Primary Endpoints:
Mean change from baseline to Week 12 of UAS7 (Urticaria Activity Score)

Secondary Endpoints:
ISS7 (Itch Severity Score)
HSS7 (Hives Severity Score)
AAS7 (Angioedema Activity Score)
Safety

Data cutoff Oct 18, 2023

Profound Improvement in UAS7 in Patients with Moderate to Severe CSU at Week 12

Mean Change from Baseline in UAS7 at Week 12

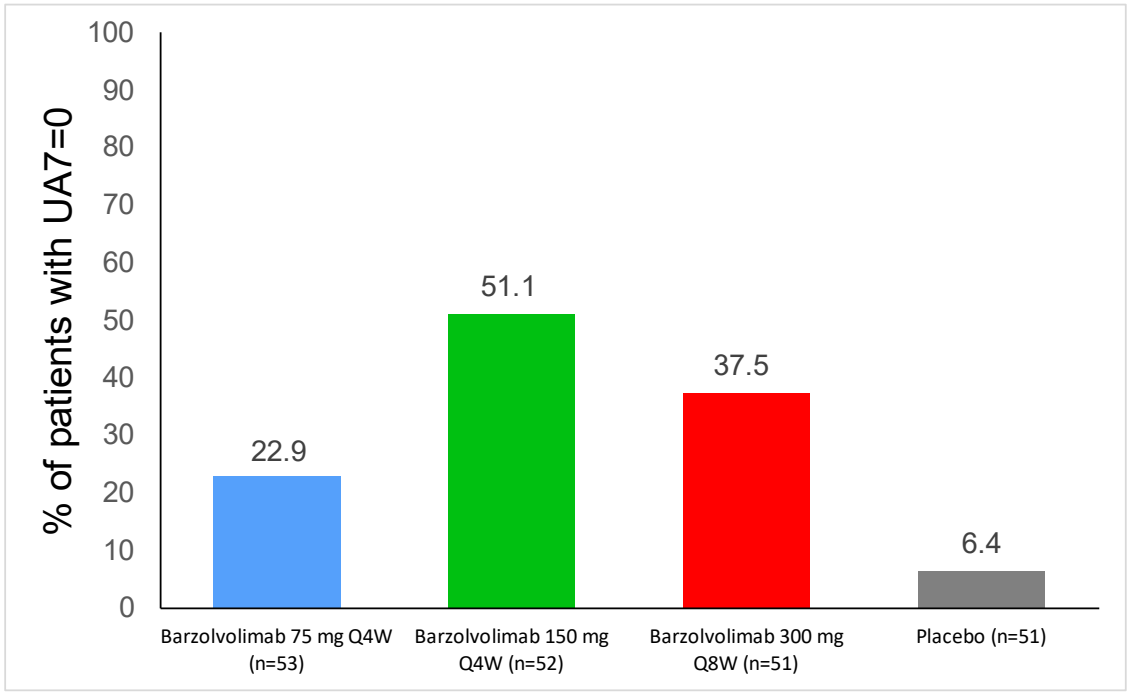


Data were analyzed using ANCOVA model and multiple imputation. Benjamini-Hochberg were used for multiplicity adjustment.
Δ treatment difference LS mean (95% CI)
CI, confidence interval; LS, least squares; n, number of patients who received at least one dose of study drug; UAS7, weekly Urticaria Activity Score
Data cutoff Oct 18, 2023

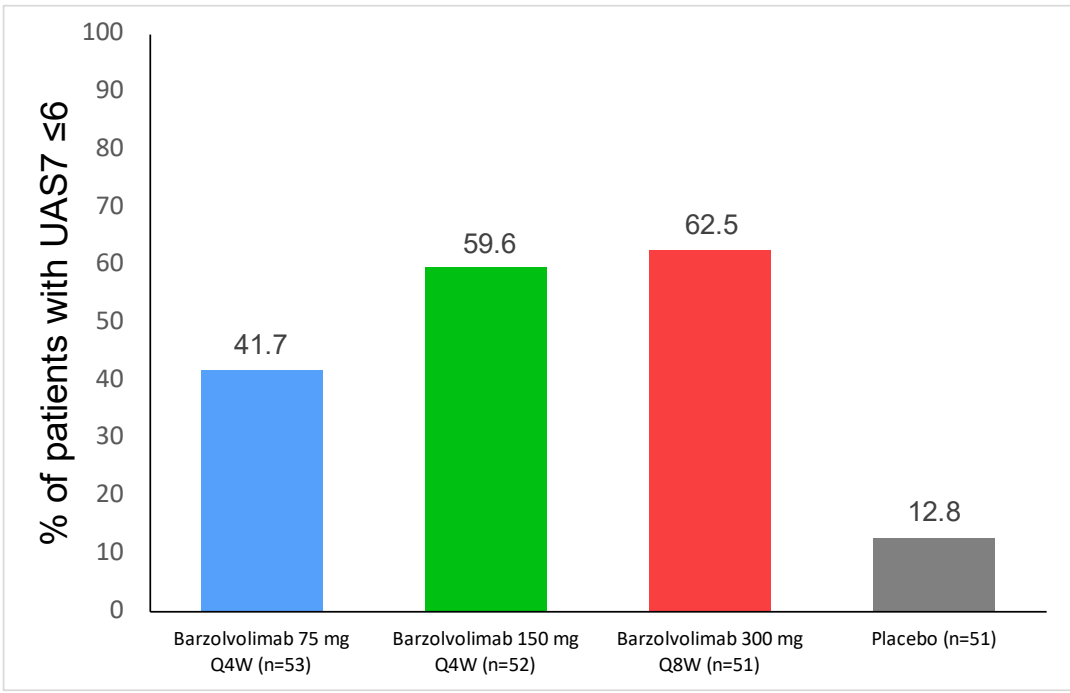
Barzolvolimab Achieves Clinically Meaningful Responses in Patients with CSU

- The majority of patients treated with 150mg or 300mg were well controlled at week 12

% of Patients with UAS7 = 0 Complete Control



% of Patients with UAS7 ≤ 6 Well Controlled



Data cutoff Oct 18, 2023

Barzolvolimab Was Well Tolerated with Favorable Safety Profile in CSU

- Barzolvolimab was generally well tolerated with a favorable safety profile across multiple dose regimens
- Most adverse events (AEs) were mild to moderate in severity; through 12 weeks, the most common treatment emergent adverse events were hair color changes (9%), urticaria (9%) and neutropenia (8%)
- The rate of infections was similar between barzolvolimab-treated patients and placebo with no apparent association between neutropenia and infections

Data cutoff Oct 18, 2023

Positive CSU Data Supports Advancing to Registrational Studies

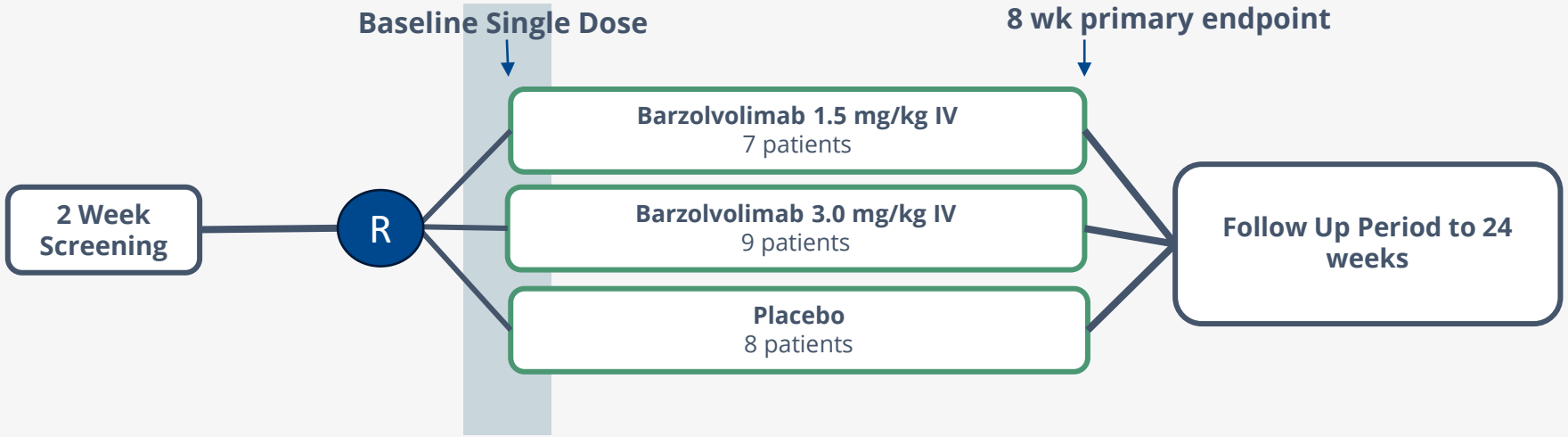
- Barzolvolimab Phase 2 CSU study met the primary efficacy endpoint across all three doses, with a statistically significant mean change from baseline to week 12 of UAS7 (urticaria activity score) compared to placebo
- Demonstrated rapid, durable and clinically meaningful responses in patients with moderate to severe CSU refractory to antihistamines, including patients with prior omalizumab treatment
- Approximately 20% of enrolled patients were omalizumab experienced—these patients experienced a similar clinical benefit as the overall treated population within their individual dosing groups
- Barzolvolimab was generally well tolerated with a favorable safety profile

Data cutoff Oct 18, 2023

Barzolvolimab Phase 1b Prurigo Nodularis Results

World Congress on Itch (WCI) 2023

Prurigo Nodularis Phase 1b Study Design



- Randomized, double-blind, placebo-controlled, single dose study in adults with moderate to severe PN
  - WI-NRS ≥7 at baseline
  - IGA≥3 at baseline
- Primary endpoint is safety profile; secondary endpoints include changes from baseline in Worst Itch-Numerical Rating Scale (WI-NRS) & Investigator Global Assessment (IGA), PK, and serum tryptase
  - Patients followed for safety and efficacy endpoints to 24 weeks
  - ***Primary timepoint for evaluation of clinical activity was 8 weeks***
- 24 patients randomized (evaluable: n=23 safety; n=22 efficacy)

Demographics and Baseline Characteristics

Baseline Characteristic	1.5 mg/kg N=7	3.0 mg/kg N=8	Placebo N=8	Total N= 23
Age years	65 (56-69)	60 (29-63)	55.5 (18-75)	60 (18-75)
Sex Female, n (%)	4 (57)	6 (75)	2 (25)	12 (57)
Race White, n (%)	3 (43)	5 (63)	6 (75)	14 (61)
Black n (%)	4 (57)	3 (37)	2 (25)	9 (39)
Ethnicity Hispanic n (%)	1 (14)	0 (0)	1 (13)	2 (9)
Weight (kg)	89.4 (68.5-103.4)	84.6 (48-117)	84.6 (57.5-137)	85.9 (48-137)
PN duration years	9.7 (1-21.9)	7.3 (0.3-21.1)	9.7 (0.4-32.1)	8.5 (0.3-32.1)
WI-NRS weekly average	8.6 (7.4-10)	8.4 (7.5-10)	8.7 (7.3-10)	8.6 (7.3-10)
IGA	3.1(3-4)	3.3 (3-4)	3.4 (3-4)	3.3 (3-4)
Tryptase (ng/ml)	6.2 (4.4-7.9)	5.3 (3.2-11.2)	5.4 (2.8-7.6)	6.0 (2.8-11.2)

Mean (range) are presented unless otherwise indicated

Barzolvolimab was Well Tolerated

- AEs were generally mild to moderate in intensity and considered unrelated to treatment
- During the initial 8 week observation period in the 3.0 mg/kg dosing arm, as previously disclosed, an anaphylactic reaction occurred in a complicated patient with multiple comorbidities; the event fully resolved without sequelae
- Generally, AEs seen during the 24-week follow-up period were consistent with comorbidities commonly observed in the PN population

Clinically Meaningful Reduction in WI-NRS Following a Single Dose

- Effect was noted as early as the first clinic visit at week 2 and was generally maintained out to week 16
- In the 3.0 mg/kg arm, the decrease in itch was seen as early as the first week and reached a high of 71% of patients at week 6

Proportion % of Subjects with ≥4-point decrease in WI-NRS

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 Treated with Barzolvolimab 3.0 mg/kg Achieved Clear or Almost Clear Skin by Week 8

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

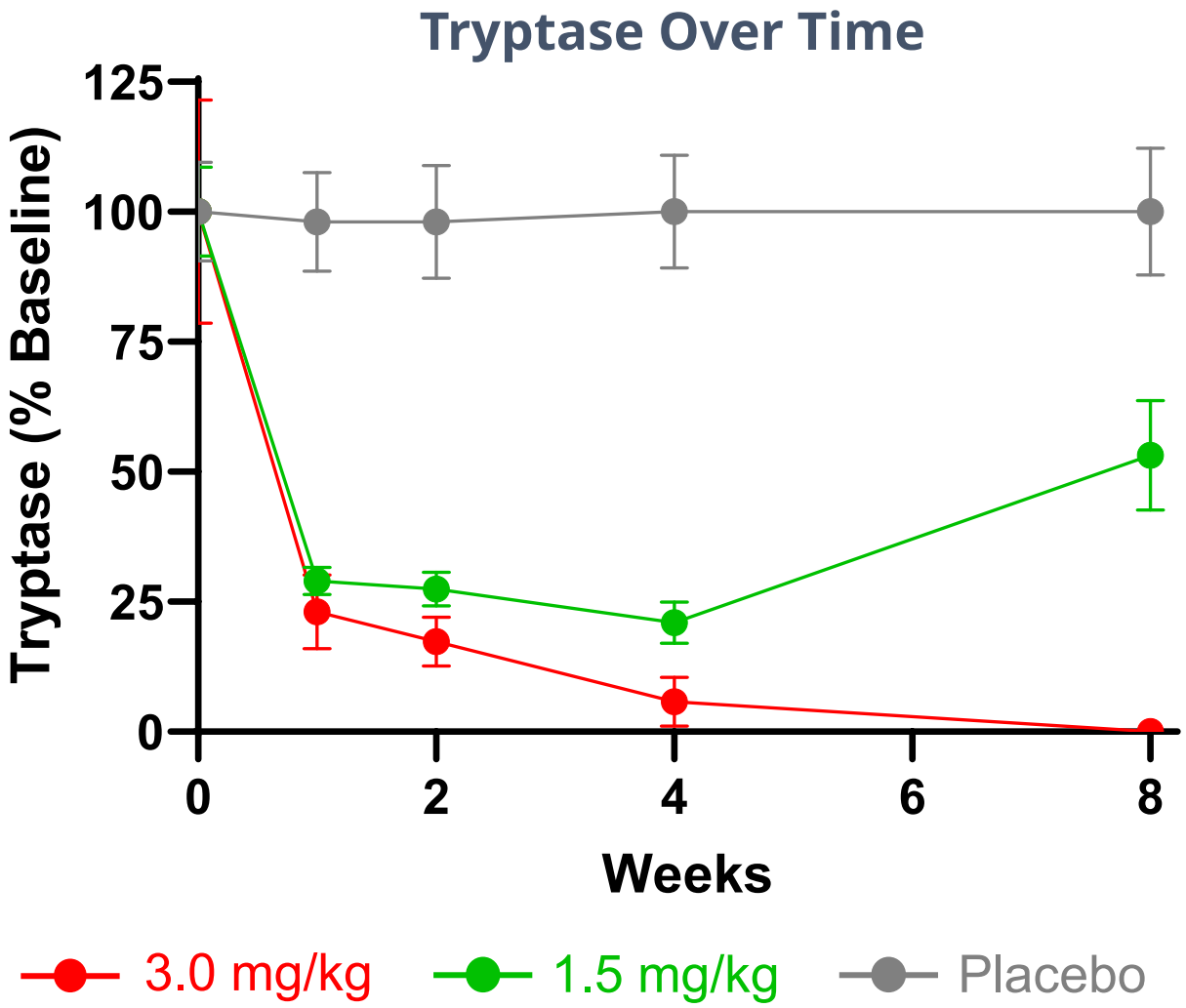
Proportion % of Subjects with Clear/Almost Clear Skin (IGA 0/1)

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

2 additional patients in the 1.5 mg/kg arm, 2 additional patients in the 3.0 mg/kg arm and 1 patient on placebo had IGA 0/1 at timepoints between weeks 8 and 24

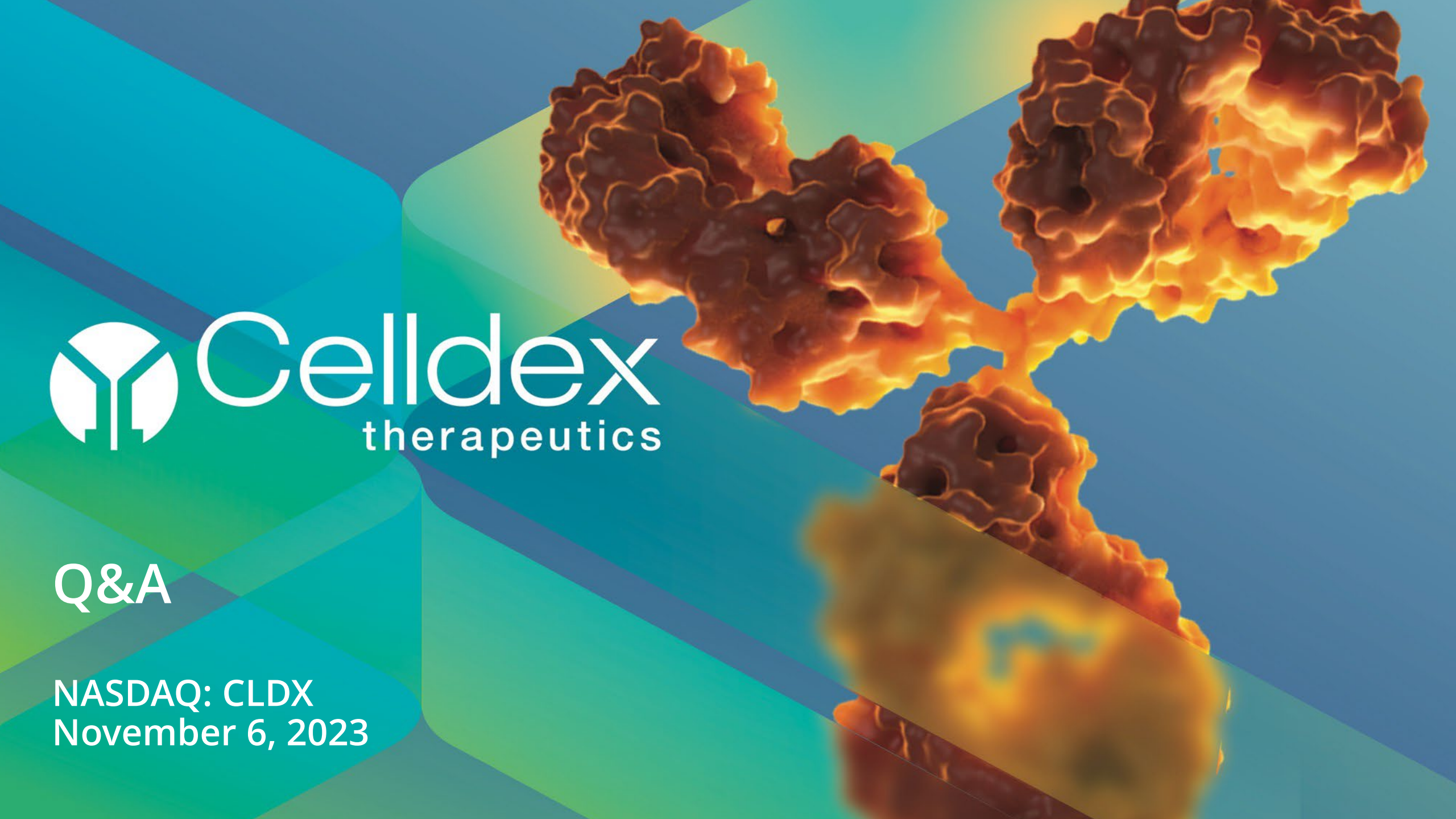
Tryptase is Profoundly and Durably Suppressed by Barzolvolimab 3.0 mg/kg

- Data suggests that in PN, profound and sustained mast cell depletion is required for maximal clinical activity



New Data Support Pipeline in a Product and Expanded Opportunities

- Data support broad development in mast cell driven diseases
- Expect to advance CSU into Registrational Studies in 2024
- PN advancing into Phase 2 in early 2024
- Phase 2 CIndU data expected in 2H 2024
- Phase 2 EoE study actively enrolling



Q&A

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