therapeutics

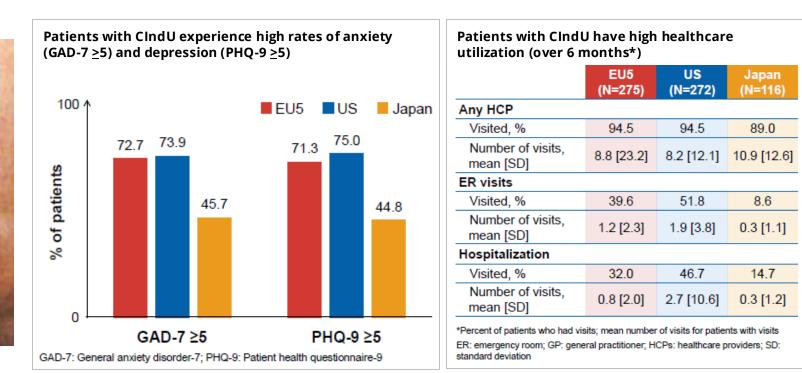
Barzolvolimab Phase 2 Study Chronic Inducible Urticaria (CIndU) 12 Week Results

NASDAQ: CLDX October 28, 2024 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 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 the occurrence of unanticipated events. of unanticipated events.

Chronic Inducible Urticaria is a Disease of Misery Hard to treat condition, impairs patient's QoL, and with no approved treatment to date

- Patients with CIndU have poorly controlled disease and a history of mental comorbidities, along with high medical resource use¹
- CIndU responds poorly to commonly prescribed doses of antihistamines (AH); low rates of spontaneous remission²
- No approved therapies after AH; dupilumab not effective in Phase 3





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://derm.eta.acticle/d7ae42f3-b3ae-47ae-9464-eb8c328fe3dc

Phase 2 CIndU Study Design and Key Eligibility

4 Week Screening			20 Week Trea	tment Period								
-4	0	4	8	12	16	20	24	28	32	36	40	44
		l - Barzolvolim	nab 150 mg Q₄	1 weeks								
ColdU 96 pts	R - Arm 2	Arm 2 - Barzolvolimab 300 mg Q8 weeks						24 Week Follow Up Period				
	Arm 3	– Placebo Q4	weeks			-						
	Arm 1	Arm 1 - Barzolvolimab 150 mg Q4 weeks					Optional 20 Week Open Label Extension (followed by 24 weeks of follow up)					
SD 97 pts	R Arm 2	- Arm 2 - Barzolvolimab 300 mg Q8 weeks										
	Arm 3	Arm 3 – Placebo Q4 weeks										

Key Eligibility Criteria

- Diagnosis of ColdU or SD for more than 3 months
- UCT < 12 and positive provocation test between Week 20 and Week 44 of main study
- Recurrent wheals despite stable antihistamine regimen. Prior biologics permitted
- Positive provocation test at screening and randomization
- UCT< 12

Open Label Extension

Patients can enter Open Label Extension study at any time during the Follow Up Period (between Week 20 and Week 44) of the Main Study, provided that they meet key eligibility criteria:

- Complete 20 week treatment period
- UCT < 12 and positive provocation test between Week 20 and Week 44 of main study

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

Primary Endpoint:

% of patients with a negative provocation test at Week 12 ColdU (TempTest[®]) & SD (FricTest[®])

Secondary Endpoints:

CTT (Critical Temperature Threshold) CFT (Critical Friction Threshold) WI-NRSprovo (Worst Intensity of Itch at Testing) Safety

Exploratory Endpoints:

UCT (Urticaria Control Test)

Demographics and Baseline Characteristics

• Well balanced across the treatment groups

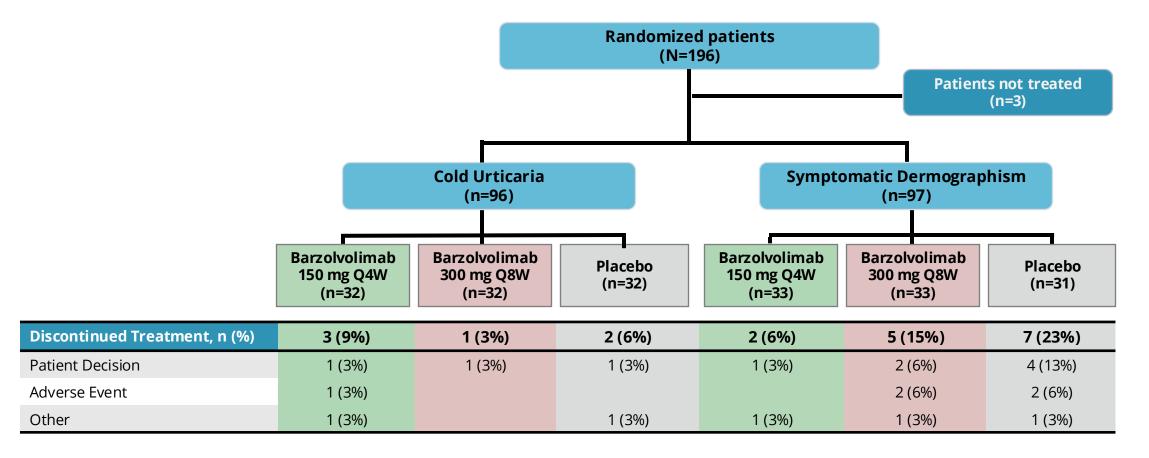
		Cold Urticaria		Symptomatic Dermographism			
	Barzolvolimab 150 mg Q4W (n=32)	Barzolvolimab 300 mg Q8W (n=32)	Placebo (n=32)	Barzolvolimab 150 mg Q4W (n=33)	Barzolvolimab 300 mg Q8W (n=33)	Placebo (n=31)	
Age (years)	40 (18-72)	40 (18-64)	41 (20-69)	41 (19-70)	42 (21-70)	42 (18-71)	
Gender, Female, n (%)	27 (84%)	23 (72%)	19 (60%)	18 (55%)	26 (79%)	19 (61%)	
Race							
White, n (%)	26 (81%)	31 (97%)	28 (88%)	29 (88%)	29 (88%)	27 (87%)	
Black, n (%)	4 (13%)	1 (3%)	2 (6.3%)	3 (9%)	2 (6%)	1 (3%)	
Weight (kg)	83 (55-124)	82 (49-140)	83 (47-129)	84 (58-121)	85 (55-139)	83 (53-115)	
CINDU Duration, yr	7 (0.3-31)	11 (0.3-49)	10 (0.3-34)	7 (0.3-53)	6 (0.3-41)	5 (0.4-23)	
Prior angioedema, n (%)	9 (28%)	11 (34%)	11 (34%)	9 (27%)	7 (21%)	7 (23%)	
Prior anti-histamine therapy, n (%)	32 (100%)	32 (100%)	32 (100%)	33 (100%)	33 (100%)	31 (100%)	
Prior omalizumab therapy, n (%)	2 (6.3%)	1 (3.1%)	1 (3.1%)	1 (3%)	2 (6%)	2 (7%)	
СТТ (°С)	18.7 (4-38)	20.7 (8-40.5)	18.6 (4-44)	NA	NA	NA	
CFT (pins)	NA	NA	NA	3.64 (2-4)	3.58 (2-4)	3.55 (3-4)	
WI-NRSprovo	6.28 (0-10)	5.47 (0-10)	5.41 (0-9)	5.73 (1-9)	5.70 (2-9)	5.23 (1-9)	
ИСТ	5.56 (0-12)	4.94 (0-11)	5.78 (0-12)	5.3 (0-11)	5.39 (0-13)	5.26 (0-13)	

CTT, Critical Temperature Threshold; CFT, Critical Friction Threshold; WI-NRSprovo, Numerical Rating Scale of Worst Itch at the time of provocation testing; UCT, Urticaria Control Test

Data shown are Mean (range) unless otherwise specified

Patient Disposition

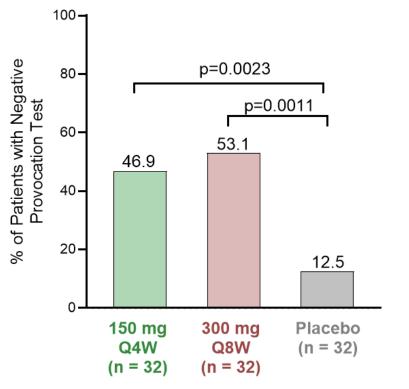
- In total, 196 patients randomized, 193 included in the full analysis (mITT) and safety set
- Overall, 173 (90%) completed through 12-weeks (primary endpoint)
 - 8% of patients treated with barzolvolimab discontinued treatment compared with 14% of patients treated with placebo



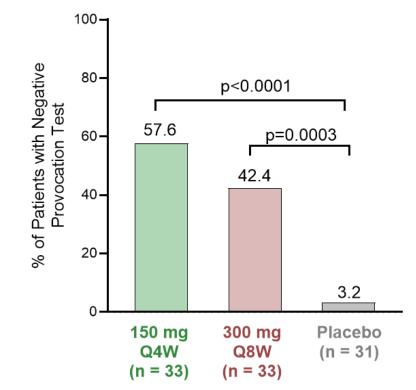
Statistically Significant Improvement in Rate of Complete Response at Week 12

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

Cold Urticaria % of patients with negative provocation test



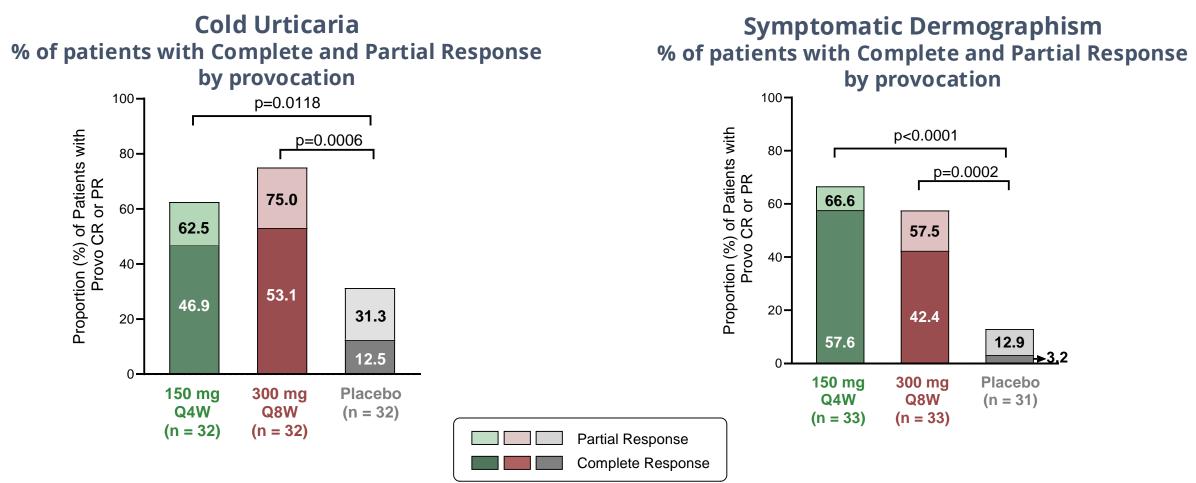
Symptomatic Dermographism % of patients with negative provocation test



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

Statistically Significant Improvement in Rates of Complete and Partial Response at Week 12

• Up to 75% of ColdU and 67% of Symptomatic Dermographism patients treated with barzolvolimab achieve a Complete or Partial Response

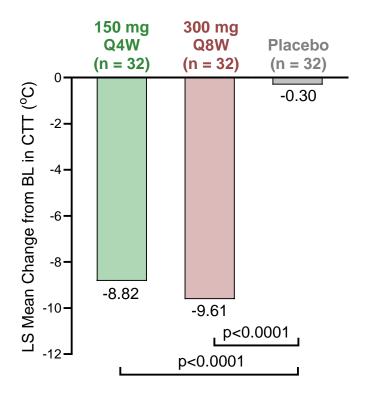


ColdU: Complete Response (CR) = negative provocation test at ≤ 4 °C; Partial Response (PR) ≥ 4 °C improvement in provocation test Symptomatic Dermographism: CR=0 pins; PR ≥ 2 pin improvement in provocation test

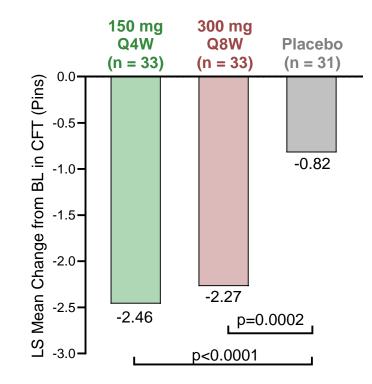
Non-responder imputation approach; mITT population

Marked Improvement in Critical Temperature (CTT) and Friction Thresholds (CFT) at Week 12

Cold Urticaria LS Mean Change in CTT (°C) at Week 12



Symptomatic Dermographism LS Mean Change in CFT (pins) at Week 12

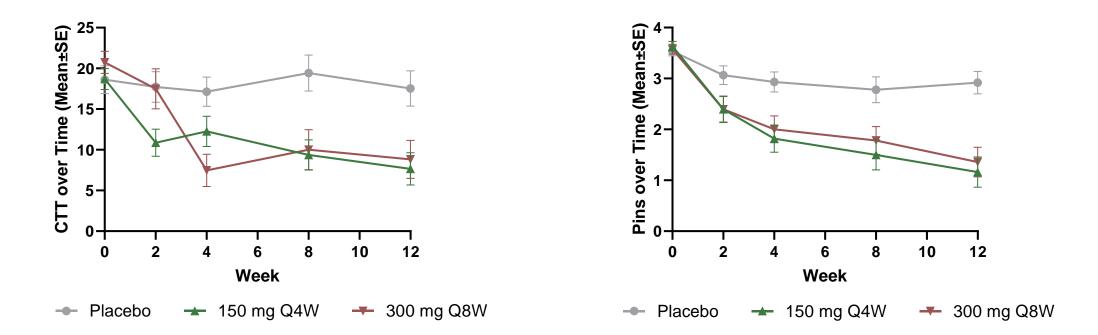


Rapid Reduction in Critical Temperature and Friction Thresholds

• Improvements seen as early as 2 weeks after first dose (first assessment)

Cold Urticaria TempTest[®] Results Over Time

Symptomatic Dermographism FricTest[®] Results Over Time



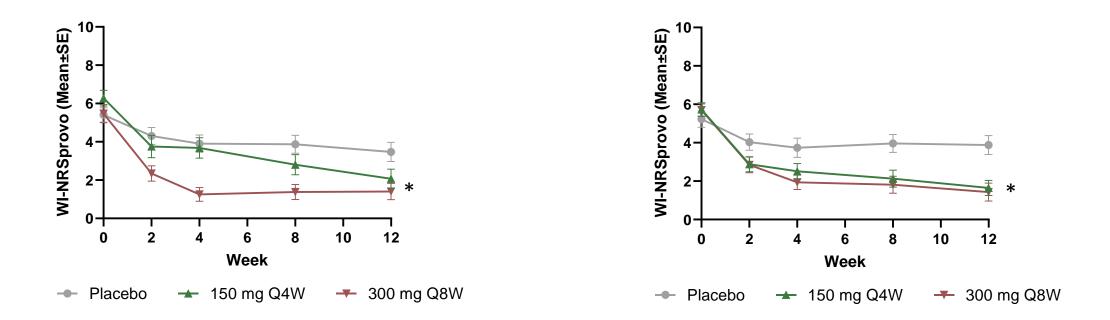
Critical temperature threshold values below 4°C (negative test) assigned a value of 3°C CTT, Critical Temperature Threshold; CFT, Critical Friction Threshold Observed Data; mITT population

Rapid Reduction in Itch at the Time of Provocation Testing (WI-NRSprovo)

• Improvements seen as early as 2 weeks after first dose (first assessment)

Cold Urticaria WI-NRSprovo Results Over Time

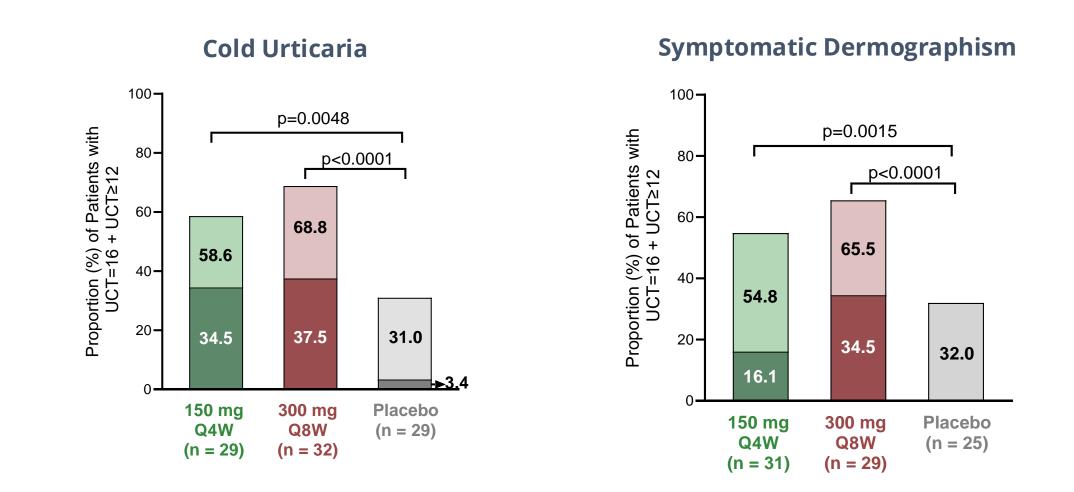
Symptomatic Dermographism WI-NRSprovo Results Over Time



* At Week 12, p=0.0291 and p=0.0016 for barzolvolimab 150mg Q4W and 300mg Q8W compared to placebo for Cold Urticaria and p<0.0001 and p=0.0002 for Symptomatic Dermographism

11 WI-NRSprovo is worst itch at the time of provocation testing Observed data; mITT population

Clinically Meaningful Improvement in UCT at Week 12





Favorable safety profile, consistent with prior studies

- 98% of treatment emergent adverse events were Grade 1 or 2 (mild (66.7%), moderate (31.7%))
- No difference in rate of discontinuations due to AEs between active and placebo
- The most common events are mechanism-related (KIT) and expected to be reversible
- No association between infections and neutropenia; events were mild and transient

Patients, n (%)	Barzolvolimab 150 mg Q4W (n=65)	Barzolvolimab 300 mg Q8W (n=65)	All Barzolvolimab Treated Patients (n=130)	Placebo (n=63)				
Patients with any AE	40 (62%)	39 (60%)	79 (61%)	33 (52%)				
Patients with treatment related SAE(s) ¹	0	1 (2%)	1 (1%)	0				
Discontinued study treatment due to AE(s) ²	1 (2%)	2 (3%)	3 (2%)	2 (3%)				
Most frequent AEs by Preferred Term (≥10% of patients in any treatment group)								
Hair color changes	9 (14%)	8 (12%)	17 (13%)	0				
- Grade 1 / Grade 2, n	8 / 1	7 / 1	15 / 2	0				
Neutropenia	4 (6%)	9 (14%)	13 (10%)	0				
- Grade 1 / Grade 2, n	3 / 1	4 / 5	7/6	0				

¹ Single treatment related SAE (anaphylaxis) reviewed by independent expert adjudication panel who concluded there was no evidence of anaphylaxis ² Other discontinuations due to AEs: urticaria/lip edema (150mg), neutropenia (300mg), cystic acne/aphthous ulcer (placebo) and paraesthesia oral/swollen tongue (placebo)

Hair Color Changes on Study

• Areas of hair lightening on the head, face and/or body; reversible upon treatment cessation





Patient B 54 year old female Grade 2



Patient C 34 year old male Grade 1

Patient A 42 year old female Grade 1

Barzolvolimab Achieves Treatment Goal for CIndU Patients

- First large, randomized, placebo-controlled study to demonstrate clinical benefit in patients with chronic inducible urticaria
- Study met all primary and secondary endpoints at Week 12 with statistically significant and clinically meaningful improvements observed with barzolvolimab 300mg Q8W and 150mg Q4W compared to placebo
- Improvement was **marked and rapid across multiple endpoints and was sustained** through the 12 week treatment period
- Barzolvolimab was well tolerated with safety profile consistent with previous studies
- We believe these study results **achieve the goal of treatment** for patients with CIndU by improving trigger thresholds and **enabling them to regain control of their lives**
- Barzolvolimab potentially provides patients a **fast acting**, **durable treatment option** that offers a meaningful opportunity for **complete disease control**
- Plan to advance CIndU into Phase 3 development