R106

In Patients With Chronic Inducible Urticaria (CIndU) Treated With Barzolvolimab, Negative Provocation Tests Correlate With Improved Clinical Outcomes

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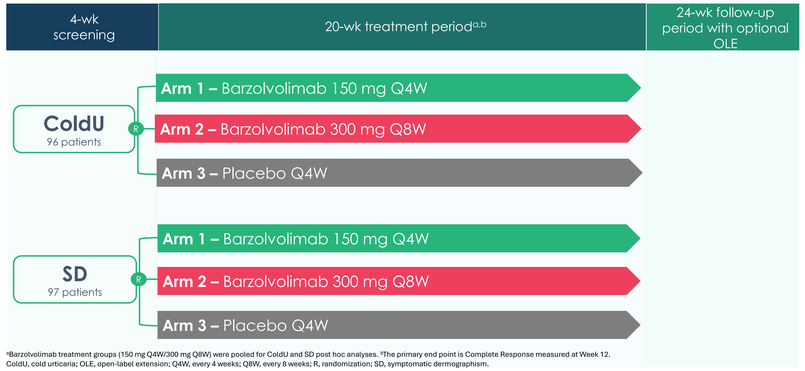
INTRODUCTION

- Chronic inducible urticaria (CIndU), including cold urticaria (ColdU) and symptomatic dermographism (SD), is a group of mast cell (MC)-driven diseases characterized by itch and wheals triggered by specific physical stimuli[1]
- Treatment with barzolvolimab, a highly potent, first-in-class anti-KIT monoclonal antibody that depletes MCs, demonstrated clinically meaningful and statistically significant improvements with up to 53% of patients with ColdU and 58% of patients with SD achieving the primary endpoint (a negative provocation test) at Week 12[2]
- **Objective:** Evaluate whether achieving a negative provocation test ("Complete Response") at Week 12 was associated with clinically meaningful outcomes in disease control (7-day Urticaria Control Test [UCT7]) and quality of life (QoL) (Dermatology Life Quality Index [DLQI])

STUDY DESIGN



[a]Barzolvolimab treatment groups (150 mg Q4W/300 mg Q8W) were pooled for ColdU and SD post hoc analyses. [b]The primary end point is Complete Response measured at Week 12.
ColdU, cold urticaria; OLE, open-label extension; Q4W, every 4 weeks; Q8W, every 8 weeks; R, randomization; SD, symptomatic dermographism.

METHODS

- Post hoc analyses of data collected from a Phase 2, double-blind, placebo-controlled study (NCT05405660) were used to evaluate whether Complete Response across pooled barzolvolimab treatment groups (150 mg every 4 weeks [Q4W]/300 mg every 8 weeks [Q8W]) was associated with improved disease control and QoL at Week 12 and Week 20
- 130 participants enrolled in this study had available UCT7 and DLQI data at Week 12 and Week 20 and were included in this post hoc analyses
- Complete Response was defined as the absence of wheals within 10 minutes after provocation (ColdU: TempTest®; SD: FricTest®)
- Disease control was assessed using the UCT7, where UCT7 = 16 was defined as complete disease control and UCT7 ≥12 was defined as well-controlled disease
- QoL was assessed using the DLQI, where DLQI = 0/1 was defined as no impact of disease on QoL
- Here, we report the percentage of patients with ColdU and SD who concurrently achieved Complete Response by provocation and the following clinically meaningful outcomes at Week 12 and Week 20:
  - Complete disease control (UCT7 = 16)
  - Well-controlled disease (UCT7 ≥12)
  - No impact of disease on QoL (DLQI = 0/1)

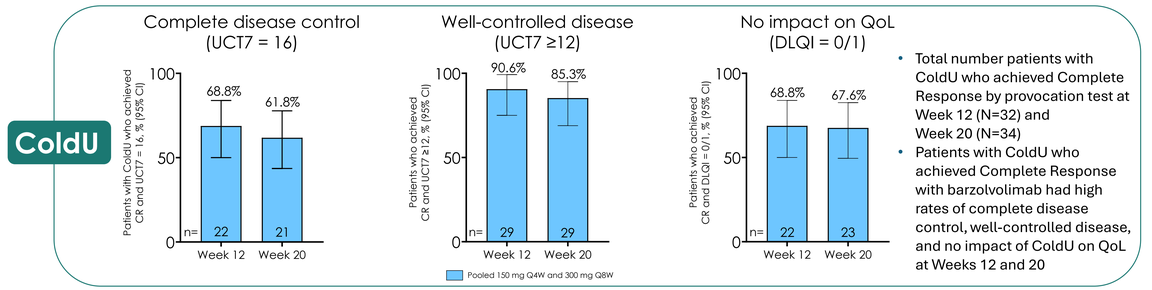
Baseline demographics and disease characteristics

Baseline demographics and disease characteristics were generally well balanced across treatment arms

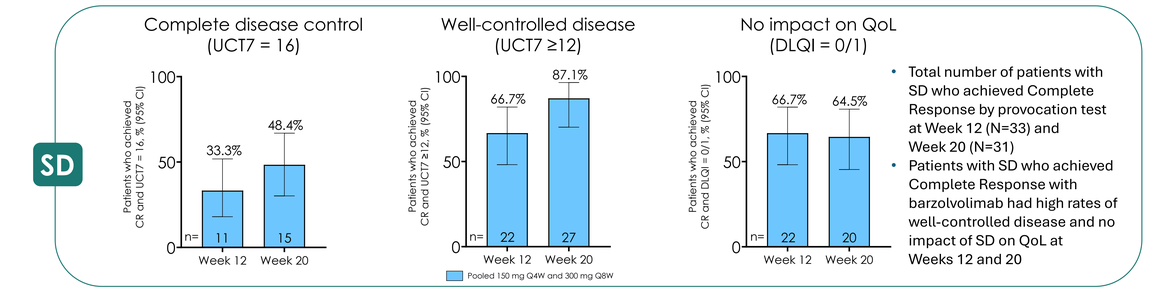
	ColdU			SD		
	Barzolvolimab 150 mg Q4W (n=32)	Barzolvolimab 300 mg Q8W (n=32)	Pooled (n=64)	Barzolvolimab 150 mg Q4W (n=33)	Barzolvolimab 300 mg Q8W (n=33)	Pooled (n=66)
Age, y, mean (range)	40 (18-72)	40 (18-64)	40 (18-72)	41 (19-70)	42 (21-70)	41 (19-70)
Sex, female, n (%)	27 (84)	23 (72)	50 (78)	18 (55)	26 (79)	44 (67)
Weight, kg, mean (range)	83 (55-124)	82 (49-140)	82 (49-140)	84 (58-121)	85 (55-139)	85 (55-139)
CIndU duration, y, mean (range)	7 (0.3-31)	11 (0.3-49)	9 (0.3-49)	7 (0.3-53)	6 (0.3-41)	6 (0.3-53)
Prior antihistamine therapy, n (%)	32 (100)	32 (100)	64 (100)	33 (100)	33 (100)	66 (100)
Baseline UCT7 score,[a] mean (range)	7 (0-16)	7 (1-15)	7 (0-16)	6 (0-12)	7 (0-13)	6 (0-13)
Baseline DLQI score,[b] mean (range)	14 (1-30)	13 (2-26)	14 (1-30)	14 (3-30)	13 (1-28)	14 (1-30)

[a]Number of patients with SD with a UCT7 score measured at baseline: barzolvolimab 150 mg = 32; barzolvolimab 300 mg = 33; pooled = 65. Number for ColdU is same as shown. [b]Number of patients with ColdU with a DLQI score measured at baseline: barzolvolimab 150 mg = 30; barzolvolimab 300 mg = 30; pooled = 60. Number of patients with SD with a DLQI score measured at baseline: barzolvolimab 150 mg = 33; barzolvolimab 300 mg = 31; pooled = 64.
Data shown are mean (range) unless otherwise specified.
CIndU, chronic inducible urticaria; ColdU, cold urticaria; DLQI, Dermatology Life Quality Index; Q4W, every 4 weeks; Q8W, every 8 weeks; SD, symptomatic dermographism; UCT7, 7-day Urticaria Control Test.

Patients with ColdU and SD who achieved Complete Response by provocation also experienced improved disease control and QoL



- Total number patients with ColdU who achieved Complete Response by provocation test at Week 12 (N=32) and Week 20 (N=34)
- Patients with ColdU who achieved Complete Response with barzolvolimab had high rates of complete disease control, well-controlled disease, and no impact of ColdU on QoL at Weeks 12 and 20



- Total number of patients with SD who achieved Complete Response by provocation test at Week 12 (N=33) and Week 20 (N=31)
- Patients with SD who achieved Complete Response with barzolvolimab had high rates of well-controlled disease and no impact of SD on QoL at Weeks 12 and 20

Data shown are percentage (95% CI).
CR, Complete Response; DLQI, Dermatology Life Quality Index; Q4W, every 4 weeks; Q8W, every 8 weeks; QoL, quality of life; SD, symptomatic dermographism; UCT7, 7-day Urticaria Control Test.

CONCLUSIONS

- **In a Phase 2 clinical trial of barzolvolimab-treated patients with ColdU and SD, Complete Response (negative provocation test) was associated with improvements in disease control and QoL at Week 12 and Week 20**
- **The efficacy and safety of barzolvolimab are currently being evaluated in the EMBARQ Phase 3 clinical trial in patients with ColdU and SD (NCT07266402)**

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References

1. Zuberbier T, et al. *Allergy*. 2022;77(3):734-766.
2. Metz M, et al. Presented at: the American Academy of Allergy, Asthma & Immunology (AAAAI) Annual Scientific Meeting; San Diego CA; February 28-March 3, 2025.

Conflicts of interest: MM: advisory board (honoraria): Novartis, Regeneron Pharmaceuticals Inc., Sanofi, Galderma, Amgen, AstraZeneca, Celldex, argenx, GlaxoSmithKline Immunology, Incyte Corporation, Jasper Therapeutics, Escient Pharmaceuticals, Inc., Arcutis Biotherapeutics, Astria Therapeutics, Blueprint Medicines, Deep Apple Therapeutics, Evommune, Inc., Granular Therapeutics, Johnson & Johnson Pharmaceutical Research & Development, Eli Lilly, RAPT Therapeutics, Santa Ana Bio, Septerna, Allegria Therapeutics; speaker (honoraria): Pfizer Inc., Sanofi, Almirall, Celltrion, Galderma, Novartis, AbbVie, Berlin Chemie; speaker/faculty education (honoraria): Aimisil; consultant (1099 relationship – honoraria): argenx, Attovia Therapeutics, Lycia Therapeutics, Enanta Pharmaceuticals, Bayer, Candid, Excellergy, FatiAbGen, Generate Biomedicines, InflaRx, Japan Tobacco Inc., Ono, Tupos; and investigator (no compensation Received): Bayer. **MS:** none. **JA:** served as speakers bureau member for Astra Zeneca, Sanofi/Blueprint, CSL Behring, Ionis, GSK, Kalvista Pharming, Takeda; received consulting fees from Astria, BioCryst, Sanofi/Blueprint, CSL Behring, Ionis, GSK, Kalvista, Novartis, Pharming, Santa Ana Bio, and Takeda; and is a clinical trial investigator for Astria, Sanofi/Blueprint, Biocryst, Celldex, CSL Behring, Kalvista, Novartis, and Pharming. **NT:** received grant research funding for clinical trials with AbbVie, Aclaris, Allakos, Amgen, AnaptyBio Inc, Arcutis, Arteiex, Arena, ARS, AstraZeneca, BioHaven, Blueprint, Braintree, Castle, Celldex, CinDome Pharma, Dr. Falk Pharma GmbH, Eli Lilly, Escient, Evommune, Gossamer, GSK, Incyte, Janssen, Jasper, Knopp, Nerre, Novartis, Optinose, Pearl Therapeutics, Pfizer, Phathom, Q32, Regeneron, Sanofi, Seres, Teva, Uniquity, Upstream Bio, and 9 Meters. **JL** and **AS:** none. **JP:** received educational/research grants from Astria, Biocyrst, Celldex, Intellia, Kalvista, Novartis, Pharvaris, Sanofi, and Takeda/Shire. Received honoraria and speaker fees from Astra Zeneca, Astria, Biocyrst, Celldex, Intellia, Johnson and Johnson, Kalvista, Novartis, Pharvaris, Sanofi, and Takeda/Shire. **DM** and **BB:** employees of Celldex with stock, stock options, salary. **JB:** investigator (paid to institution) and consultant (honoraria): ADARx, Ajou University, Allergy Therapeutics, Amgen, Apogee, Arteiea, ARS, Astra Zeneca, Astria, Biocryst, Blueprint Medicines, Celldex, Cogent, CSL Behring, Eli Lilly, Escient, Evommune, Fresenius Kabi, Genentech, GSK, Incyte, Intellia, Ionis, Japan Tobacco Company, Jasper, Johnson & Johnson, Kalvista, Kernvue, Kymera, Kyowa, Kirin, Lycia, Medscape, Merck, Nasus, Neffy, Nektar, Neopharma, Novartis, Opella, Pharming, Pharvaris, Procter & Gamble, Regeneron, Sanofi, Takeda/Shire, Telios, Teledoc, TEVA, Yuhan, WebMD, Peer Review; consultant (honoraria): Enanta, Pfizer, RAPT); speaker (honoraria): Pharming, Kalvista, CSL Behring – honoraria; chairman (salaried): AAAAI Foundation; and organizational (no compensation): President Interasma, WE CU Board of Directors, US Hereditary Angioedema Association Medical Advisory Board, Cincinnati Urticaria Center of Reference and Excellence/Angioedema Center of Reference and Excellence, World Allergy Organization Centers of Excellence, Cincinnati American Initiative in Mast Cell Diseases Center of Excellence.

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