

Treatment with Barzolvolimab Improves Urticaria Control and Quality of Life in Patients with Chronic Inducible Urticaria

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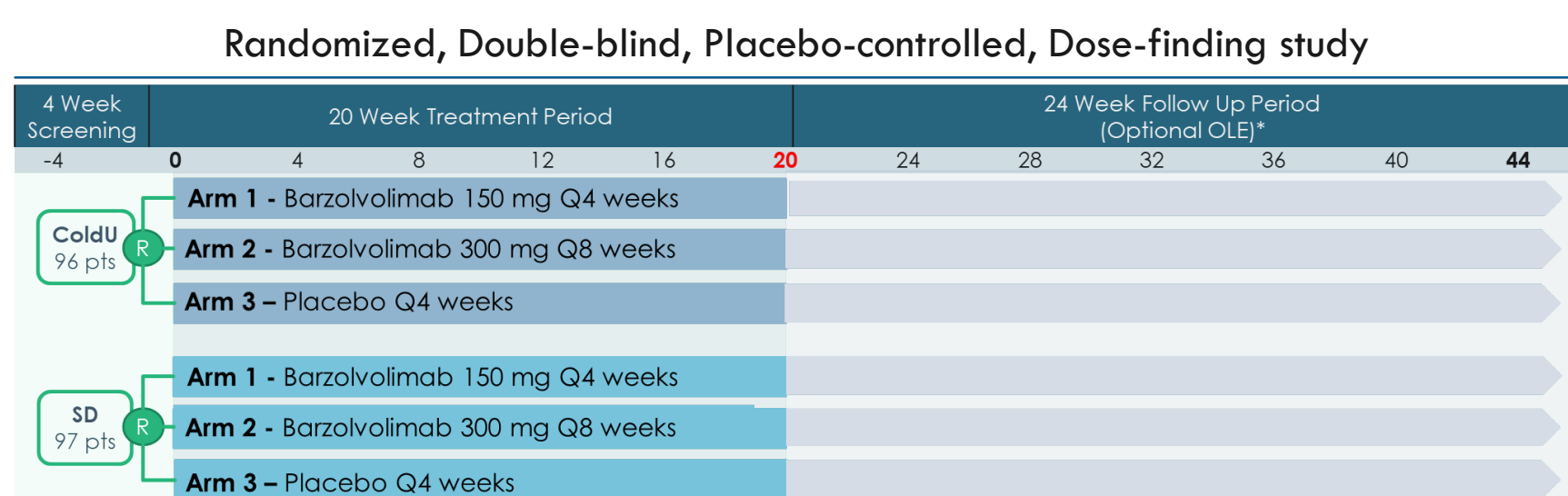
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INTRODUCTION

- Chronic inducible urticaria (CIndU) is a mast cell-driven disease characterized by itch and wheals, triggered by cold in cold urticaria (ColdU), or friction on the skin in symptomatic dermographism (SD)
- In a Phase 2 study (NCT05405660), barzolvolimab significantly improved complete response rates (negative provocation tests) with a favorable safety profile through 20 weeks of treatment in patients with CIndU inadequately controlled by antihistamines²
- Here we report the impact of barzolvolimab treatment versus placebo on urticaria control and quality of life in patients with antihistamine-refractory ColdU or SD through 20 weeks. Urticaria control was measured using the Urticaria Control Test (UCT), and quality of life was assessed using the Dermatology Life Quality Index (DLQI)

STUDY DESIGN & KEY ELIGIBILITY



- Key Eligibility Criteria:**
- Diagnosis of ColdU or SD for more than 3 months
 - Recurrent wheals despite stable antihistamine regimen. Prior biologics permitted
 - Positive provocation test at screening and randomization

STUDY OUTCOMES

- Primary Efficacy Endpoint:**
- % of patients with a negative provocation test
- Exploratory Endpoint:**
- Mean change in UCT and DLQI scores
 - % of patients with UCT ≥ 12 or UCT = 16
 - % of patients with DLQI score of 0 or 1

DEMOGRAPHICS AND BASELINE CHARACTERISTICS

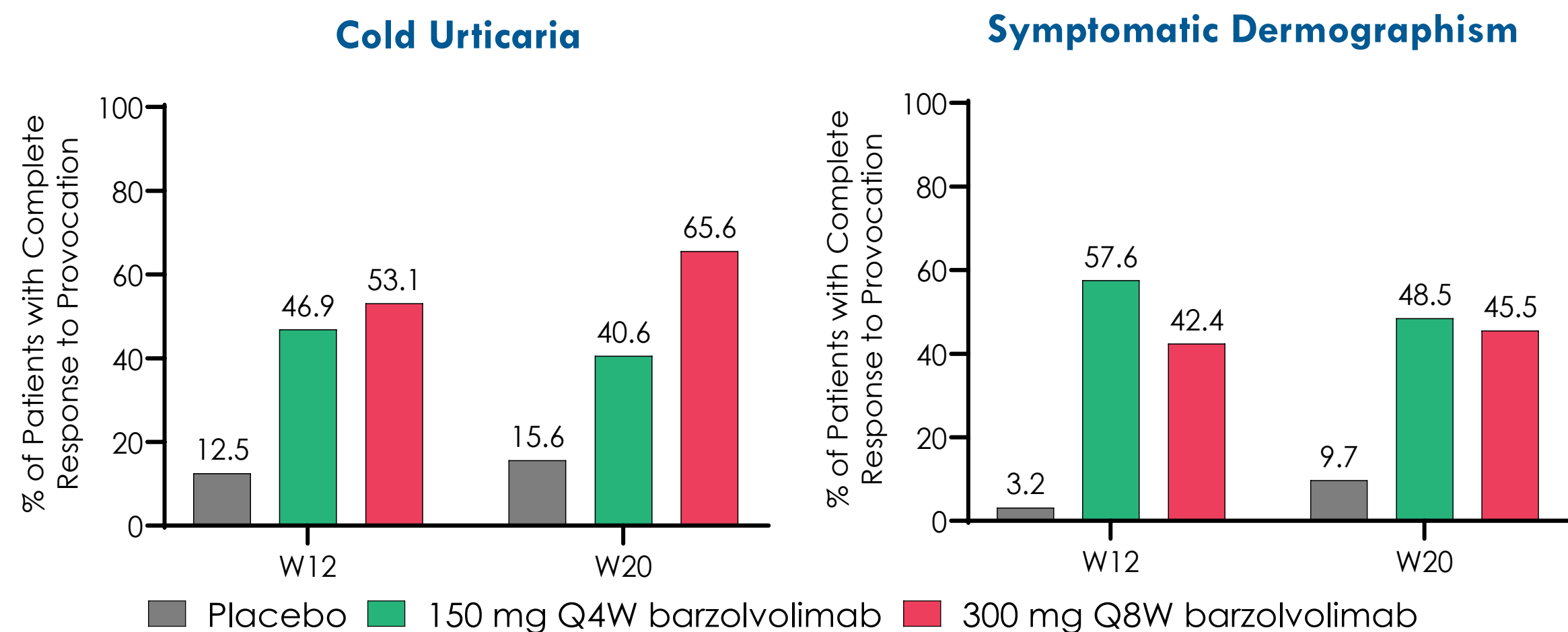
- Well-balanced patient population across treatment groups
- Participants had poorly controlled urticaria and a very large impact on quality of life at baseline

	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%)	30 (91%)	27 (87%)
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%)
UCT score	5.56 (0-12)	4.94 (0-11)	5.78 (0-12)	5.3 (0-11)	5.52 (0-13)	5.26 (0-13)
DLQI score	14.1 (1-30)	12.8 (2-26)	12.6 (1-30)	14.1 (3-30)	13.0 (1-28)	13.5 (1-26)

UCT, Urticaria Control Test; DLQI, Dermatology Life Quality Index
Data shown are mean (range) unless otherwise specified

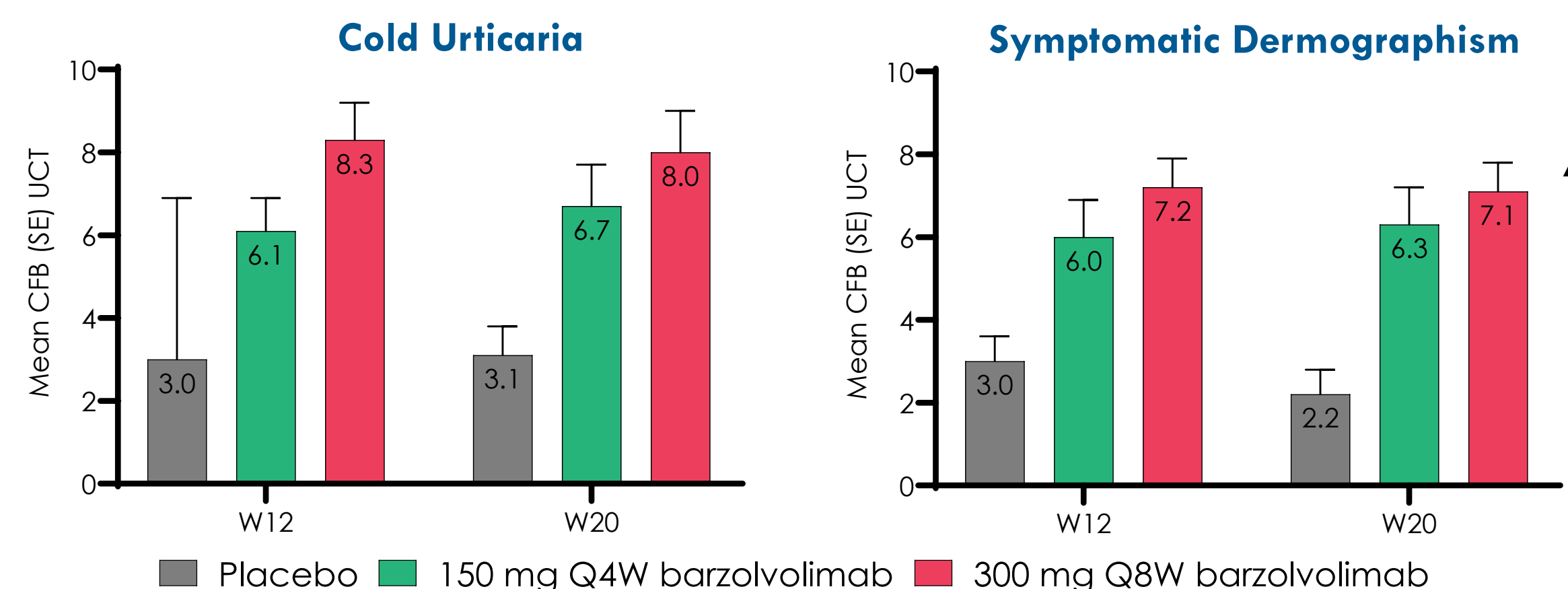
Barzolvolimab Maintains Durable Improvements in Urticaria Control and Quality of Life Through 20 Weeks in Patients with Antihistamine-Refractory ColdU or SD

Clinically Meaningful Improvement in Rates of Complete Responses Through Treatment Period

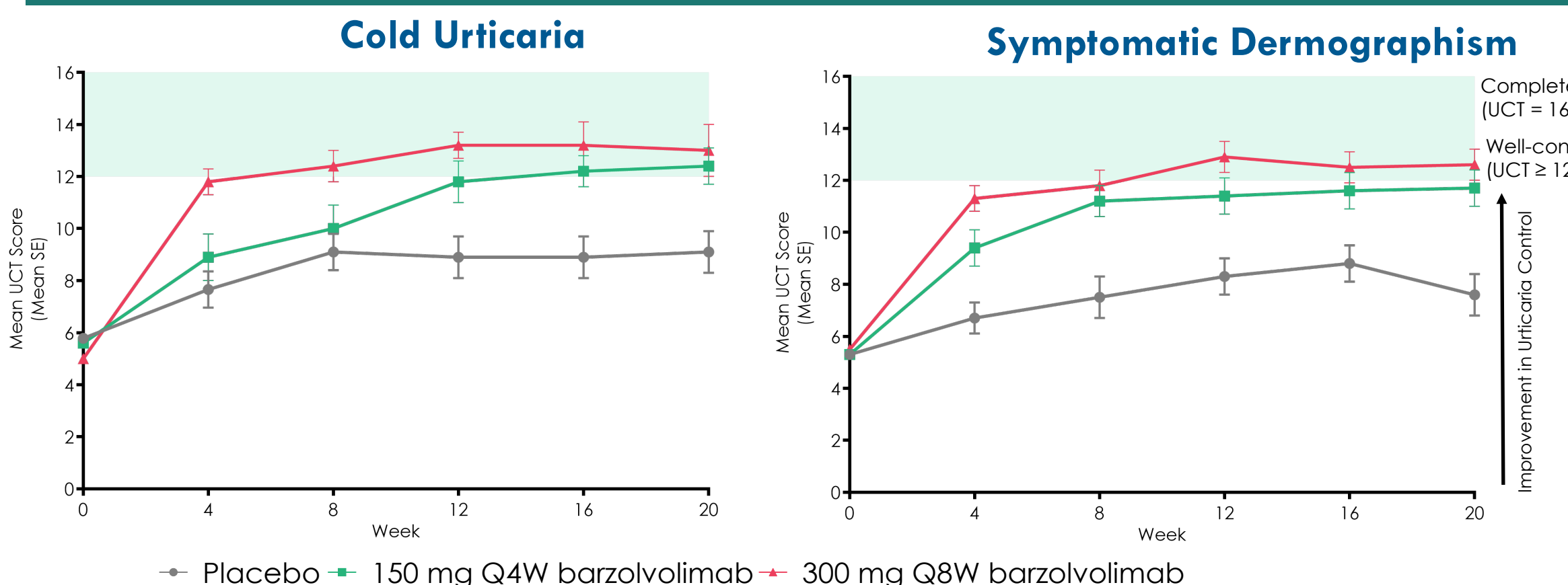


- Up to 65% of patients with ColdU and 58% of patients with SD treated with barzolvolimab achieved a CR with negative provocation tests²
- ColdU: Complete Response (CR) = negative provocation test at ≤ 4°C
SD: Complete Response (CR) = 0 pins

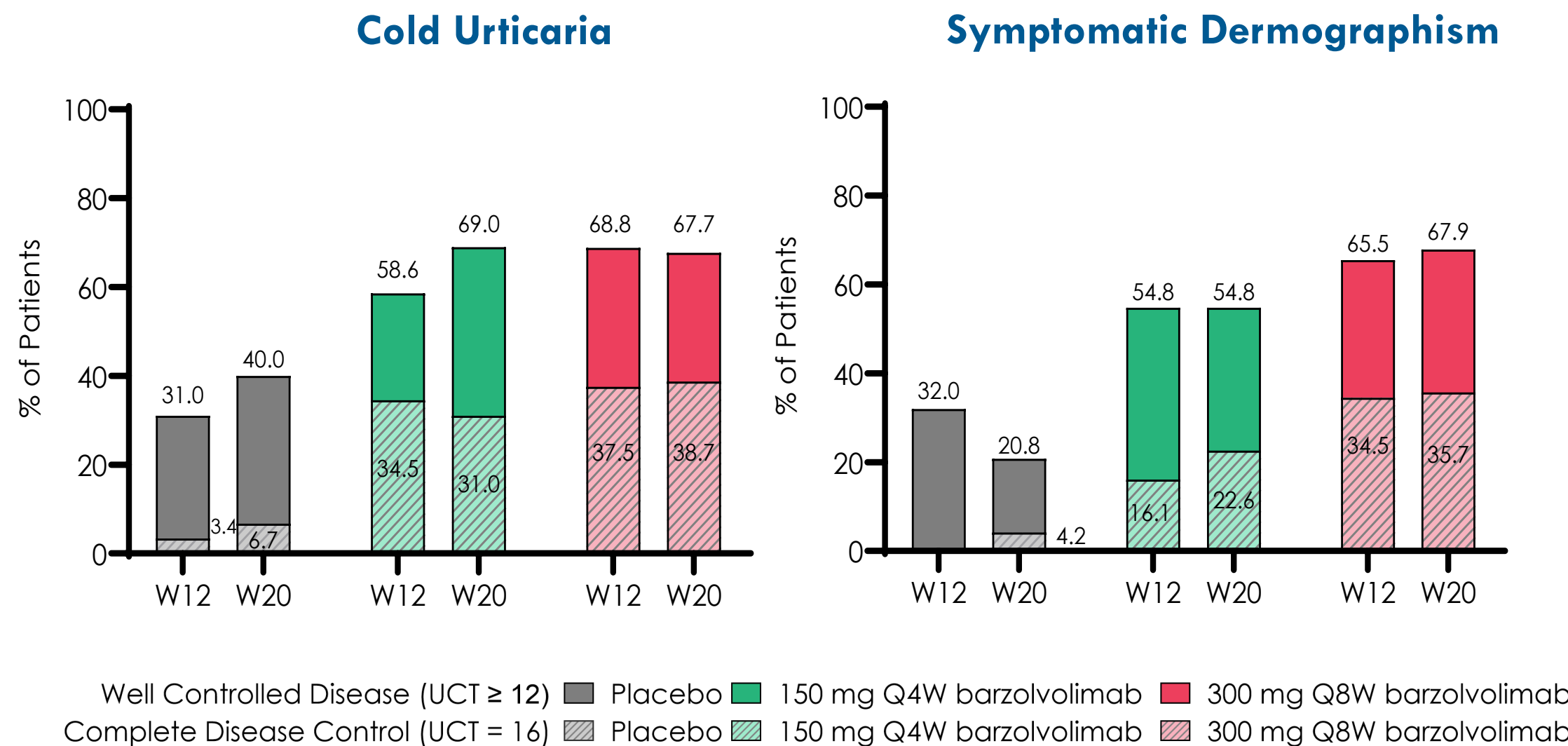
Clinically Meaningful Improvement in Urticaria Control Maintained at Week 20



Continued Improvement in UCT Through Week 20

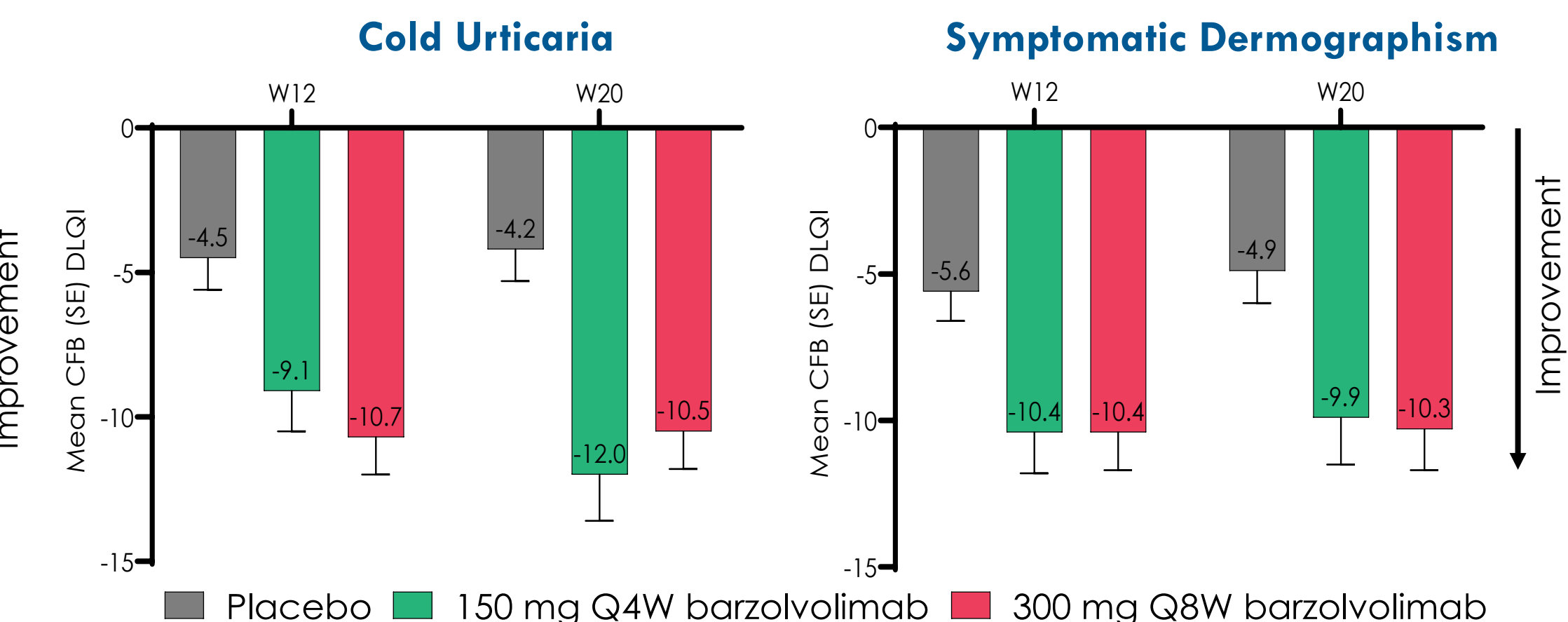


Up to 69% of Participants Achieved Well Controlled Disease by UCT

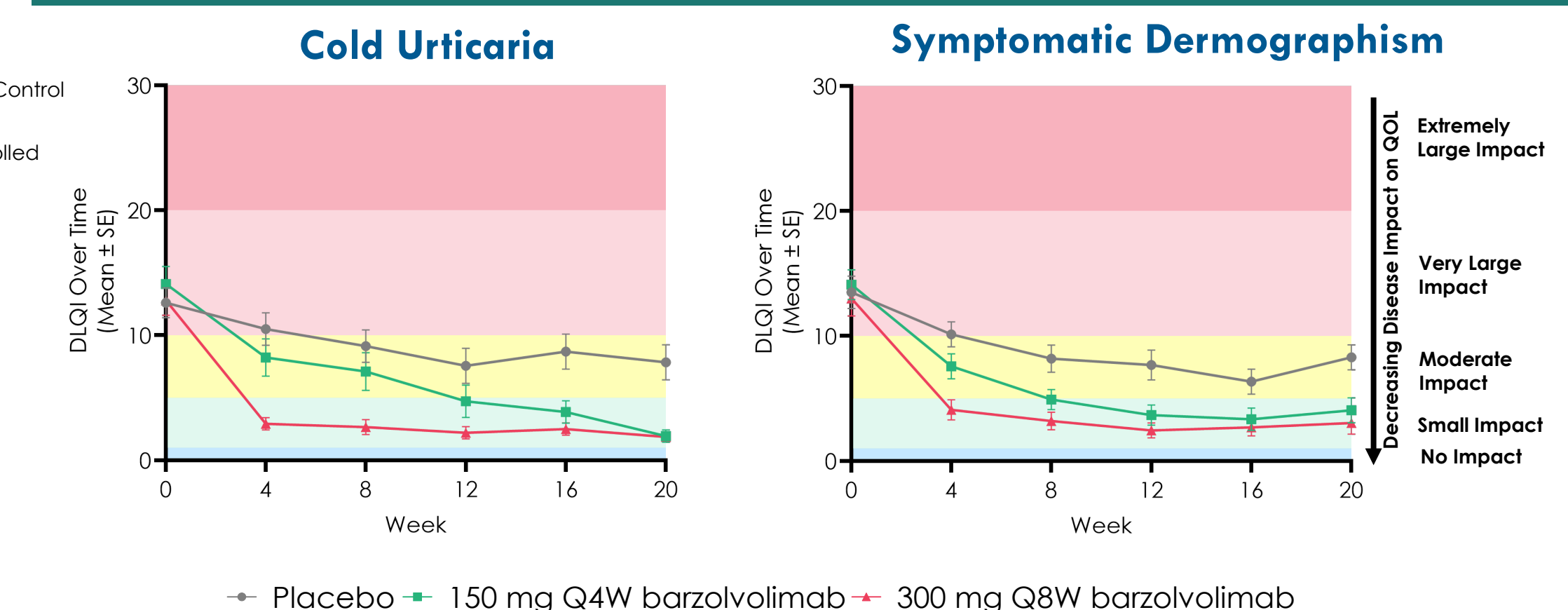


Well Controlled Disease (UCT ≥ 12) █ Placebo █ 150 mg Q4W barzolvolimab █ 300 mg Q8W barzolvolimab
Complete Disease Control (UCT = 16) █ Placebo █ 150 mg Q4W barzolvolimab █ 300 mg Q8W barzolvolimab

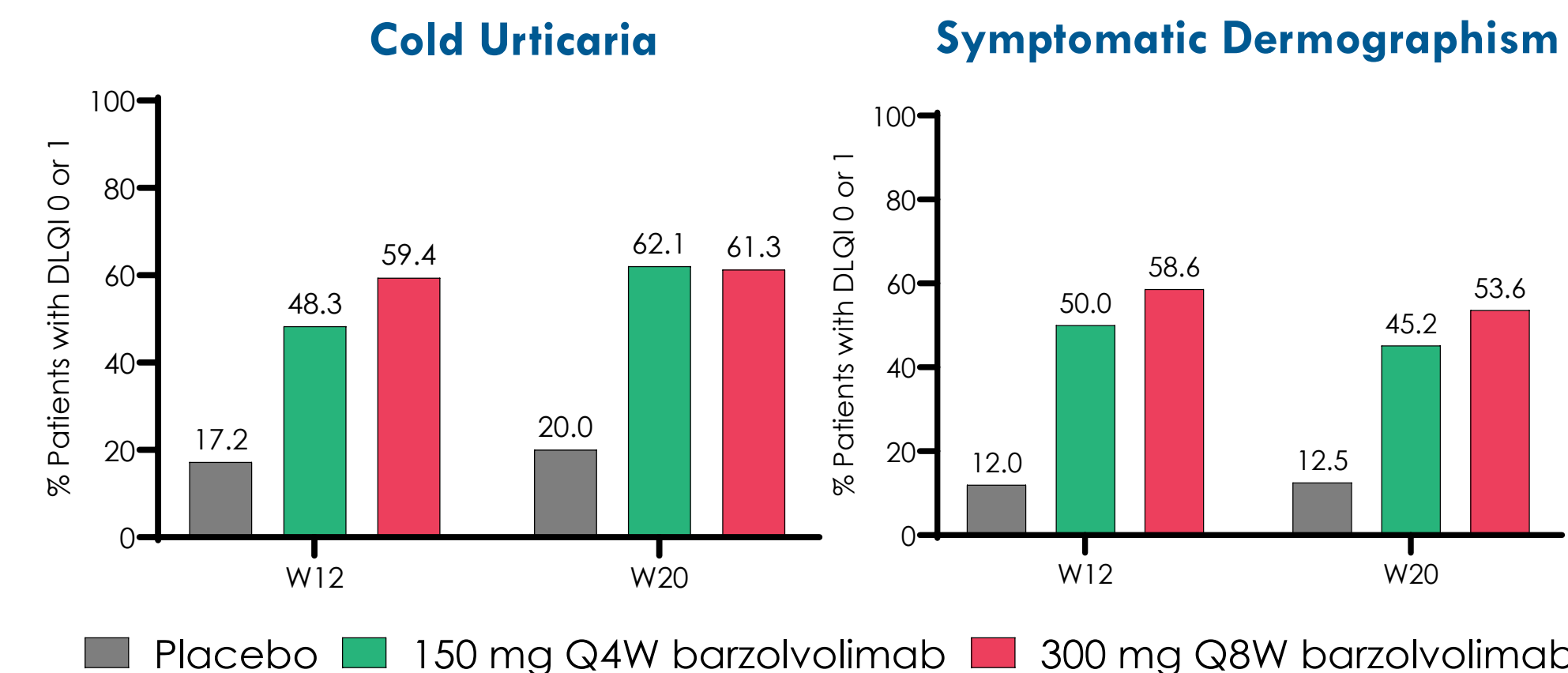
Improvement in Quality of Life Maintained at Week 20



Rapid and Sustained Improvement in Quality of Life Over 20 Weeks



Up to 60% of Patients Reported "No Impact" of Urticaria on Quality of Life (DLQI = 0 or 1) at Week 20



SAFETY

- Barzolvolimab was well tolerated¹
- No difference between active treatment (2%) and placebo (3%) groups in rate of discontinuations due to adverse events
- Most adverse events were mild. Adverse events reported by >10% of patients in any treatment group through week 20 were hair color changes (18%) and neutropenia (12%); No association between infections and neutropenia; neutropenia was transient
- Resolution of hair color changes and skin hypopigmentation observed following discontinuation of treatment

CONCLUSIONS

- First large, randomized, placebo-controlled study to demonstrate clinical benefit in patients with CIndU
- Up to 66% of patients with ColdU and 49% of patients with SD achieved complete response (negative provocation tests) at Week 20
- Barzolvolimab treatment resulted in up to 69% of participants achieving well-controlled disease (UCT) and 60% of participants reporting 'No Impact' of urticaria on QoL (DLQI) in both ColdU and SD patients at Week 20
- Barzolvolimab potentially provides patients with a fast-acting and durable treatment option that offers a meaningful opportunity for complete disease control
- Barzolvolimab was well tolerated with a safety profile consistent with previous studies
- A Phase 3 clinical study in ColdU and SD is ongoing (NCT07266402)

References

1. Metz et al. Sustained Efficacy and Safety of Barzolvolimab in CIndU. Presented at the American College of Allergy Asthma and Immunology Annual Scientific Meeting, Orlando, FL, Nov 6-10, 2025