

# Prolonged and Enhanced Quality of Life in Patients with Chronic Spontaneous Urticaria Treated with Barzolvolimab

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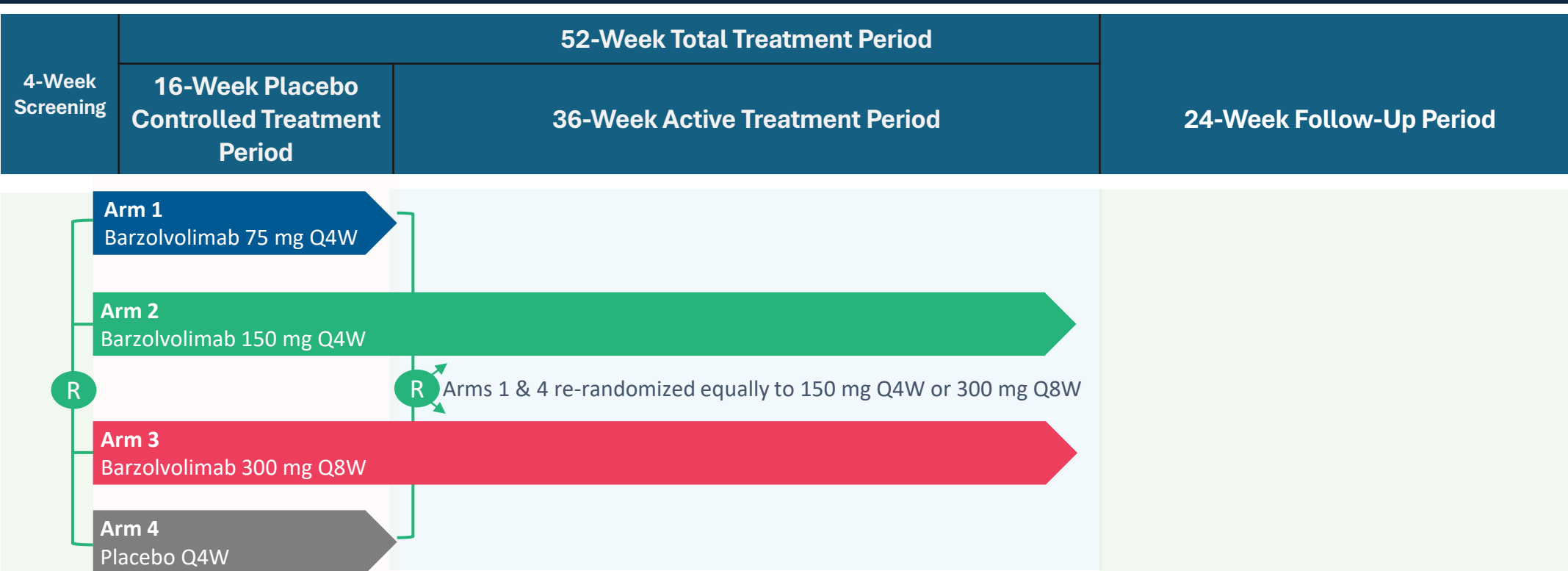
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## INTRODUCTION

- Mast cells (MCs) are key effector cells in chronic spontaneous urticaria (CSU)
- Barzolvolimab, a humanized monoclonal antibody that inhibits KIT activation by SCF, demonstrated rapid and durable depletion of skin MCs<sup>1</sup>
- We previously reported that barzolvolimab treatment resulted in statistically significant and clinically meaningful improvement in weekly Urticaria Activity Score (UAS7) at 12 weeks,<sup>2</sup> with deepening of response over 52 weeks<sup>3</sup> in antihistamine-refractory CSU patients, including patients who received prior omalizumab<sup>2</sup> (NCT05368285)
  - Treatment with barzolvolimab led to prolonged, off-treatment efficacy
  - 7 months after the last dose of barzolvolimab, 69% of patients demonstrated a UAS7 ≤ 6 (well controlled disease) at Week 76<sup>4</sup>
- The objective of this analysis was to characterize off-treatment improvement in quality of life (QoL) among patients who achieved well-controlled disease (UAS7 ≤ 6) at Week 52

## STUDY DESIGN



## METHODS

- We performed a post hoc analysis of QoL in patients who were randomized to barzolvolimab 150 mg Q4W or 300 mg Q8W for 52 weeks (Arms 2 and 3), completed the full treatment period (52 weeks), achieved at least well-controlled disease (UAS7 ≤ 6) at Week 52 (n = 55) and had available DLQI data through Week 76 (n = 50; "study population"). Out of the 50 patients with available DLQI data at Week 76, 26 and 24 patients were treated with barzolvolimab 150 mg Q4W and 300 mg Q8W, respectively
- The DLQI is a 10-item questionnaire (score 0–30) assessing the impact of skin disease on QoL over a 1-week period across six domains: symptoms/feelings, daily activities, leisure, work/school, personal relationships, and treatment
- Analyses of barzolvolimab concentrations versus urticaria activity scores and circulating tryptase, a circulating mast cell marker, were conducted. As a comparison, serum tryptase levels (n = 78) from Phase 1 studies in Healthy Volunteers (NCT05031624, NCT04146129, NCT06650761) were provided

### Baseline Demographics and Disease Characteristics

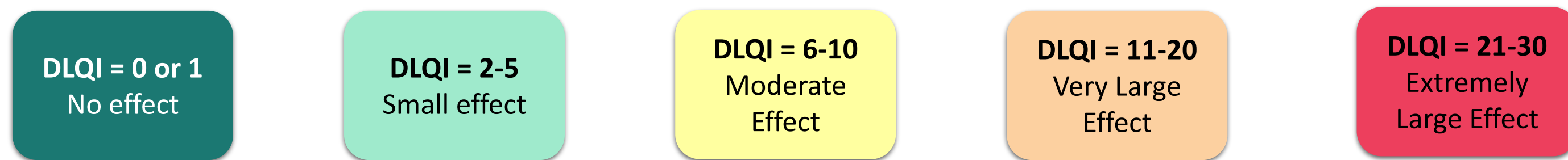
- Baseline demographics/disease characteristics for this subpopulation are similar to overall study population
- 68% of patients had both severe CSU and angioedema at baseline

		Subpopulation with DLQI Data at Week 76 (n = 50) <sup>1</sup>
Age, years (SD)		47.1 (14.0)
Female, n (%)		36 (72.0)
Race, n (%)	African American	2 (4.0)
	Asian	5 (10.0)
	Mixed Race	2 (4.0)
	White	41 (82.0)
Weight, kg (SD)		82.3 (22.0)
UAS7 (SD)		31.1 (7.5)
UAS7, severe disease, <sup>4</sup> n (%)		34 (68.0)
UCT7 score (SD)		4.6 (2.9)
DLQI score (SD)		15.6 (7.6)
Tryptase, ng/mL (SD)		5.8 (3.0)
Angioedema at baseline, n (%)		34 (68.0)
Duration of Disease, months (SD)		65.6 (78.6)
Prior omalizumab stratum	Omalizumab Experienced, n (%) <sup>5</sup>	9 (18.0)
	Omalizumab Naïve, n (%)	41 (82.0)

<sup>1</sup> 55/78 (71%) had UAS7 ≤ 6 (well controlled disease) at Week 52; <sup>2</sup> 47/50 (94%) reported a DLQI score of 0-1 at Week 52; <sup>3</sup> Baseline demographics in the subpopulation used for analysis were similar to the overall population and are consistent with CSU patient populations from other studies; <sup>4</sup> Severe UAS7 range 28-42; <sup>5</sup> Includes patients with inadequate response or intolerance to omalizumab and patients that have received prior omalizumab but are not refractory, or with unknown status. Unless otherwise stated, all values represent means.

## Prolonged off-treatment quality-of-life improvement in barzolvolimab-treated patients

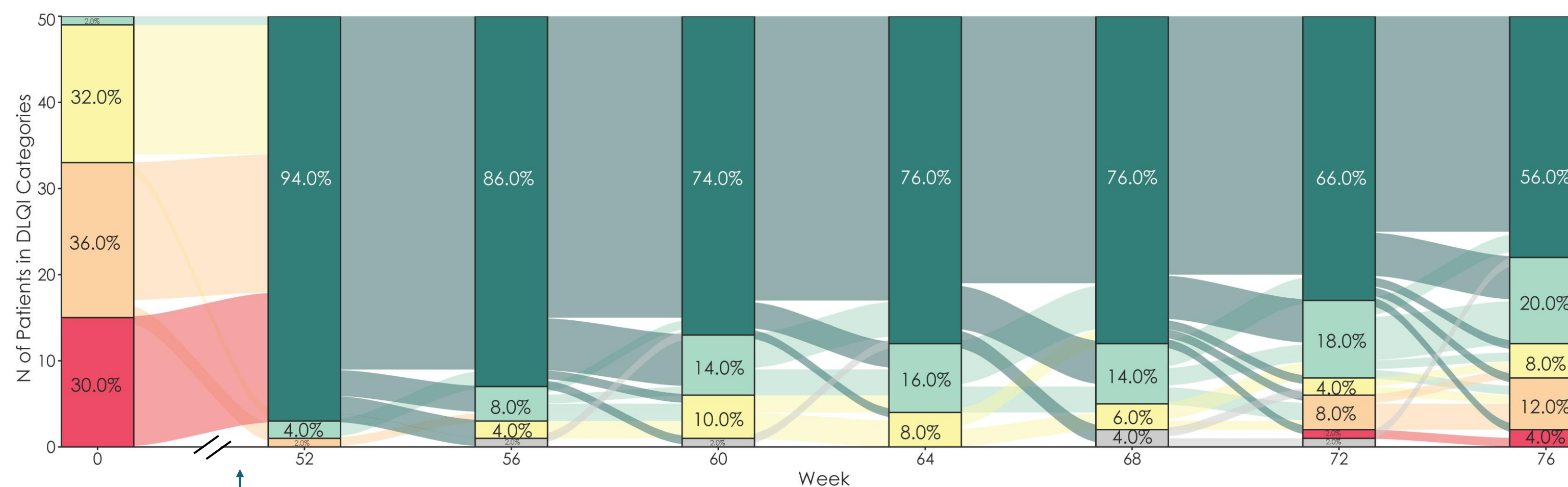
Dermatology Life Quality Index (DLQI) is classified into 5 Distinct Score Bands



DLQI score-based health-related quality-of-life measures were used to characterize the impact of CSU on patients' quality of life over the 24-week follow-up period (Week 52–Week 76).

Based on: Hongbo Y, et al. J Invest Dermatol. 2005; 125(4):659-64.

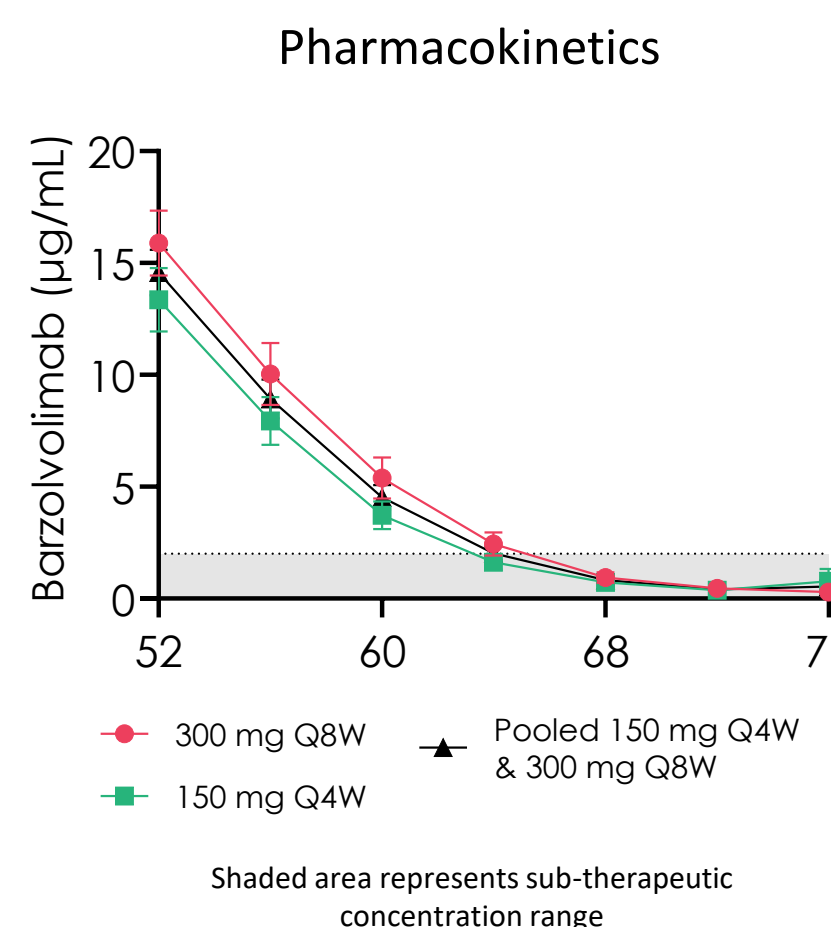
### Sustained DLQI improvement (score ≤ 5) was observed 7 months after the last barzolvolimab dose in 76% of patients



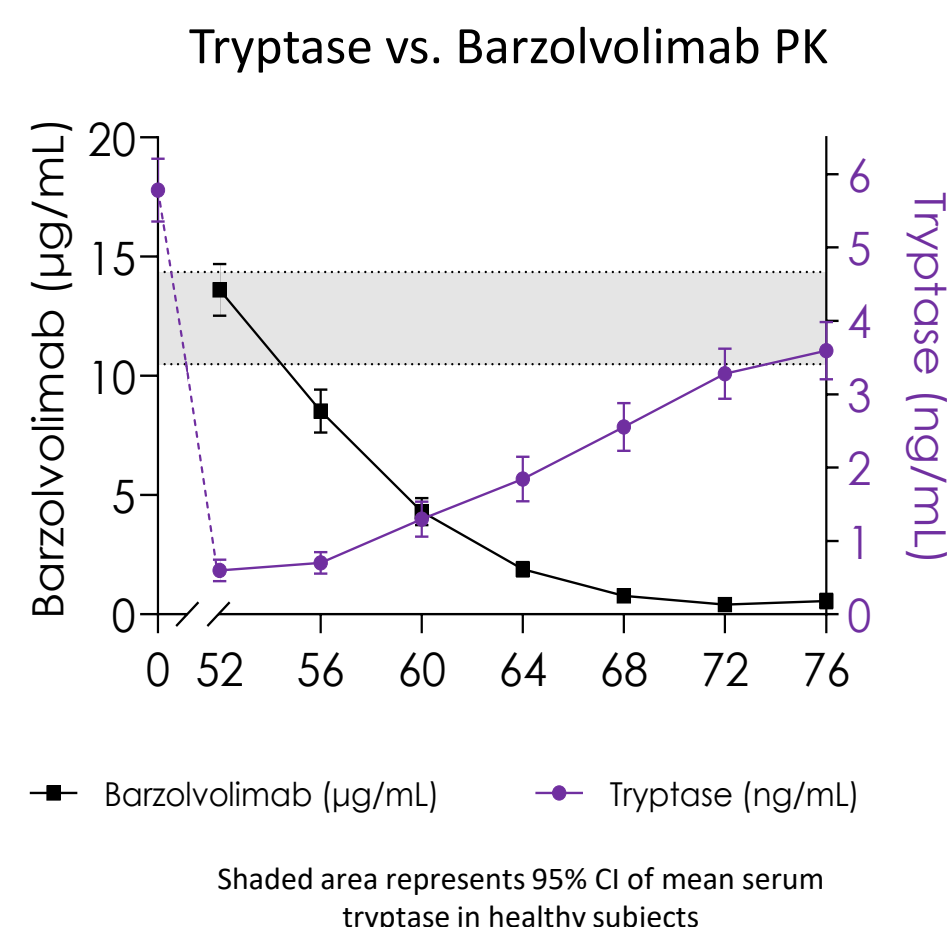
- Last dose of barzolvolimab was at Week 48

Grey colored bars = missing DLQI data at specified timepoint.

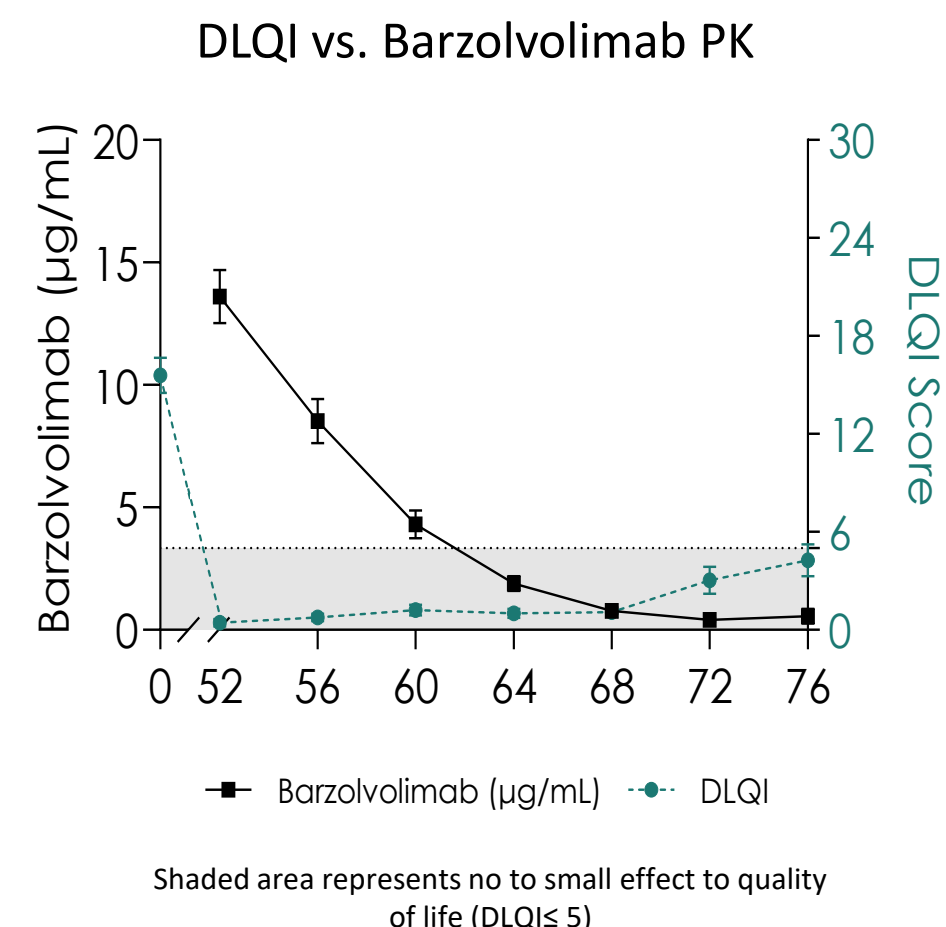
### Concentration of barzolvolimab falls below therapeutic levels by Week 64



### Tryptase levels recover to normal levels in healthy subjects by Week 76



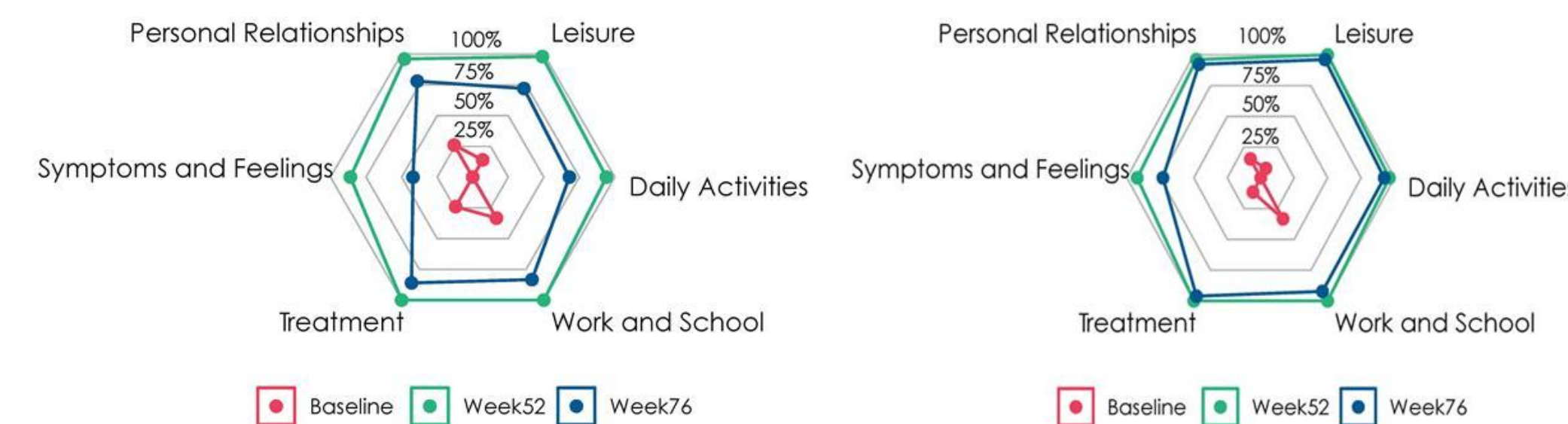
### Maintenance of a favorable QoL despite subtherapeutic concentrations



- DLQI scores remained low through Week 76 despite barzolvolimab clearance and tryptase recovery to normal levels

### Patients with sustained off-treatment efficacy also reported excellent and prolonged off-treatment QoL, as measured by DLQI domains

#### Proportion of Patients with DLQI Domain Score of 0 Over Time



- 32 of 50 (64%) patients had well-controlled disease at Week 76
- 26 of 50 (52%) patients had continuous, well-controlled disease from Week 52
  - 85% of these patients had a total DLQI score of 0/1
- 56% of study population had a total DLQI score of 0/1
- Baseline CSU impacted all domains. Patients who were well-controlled on barzolvolimab had profound improvement in all domains

## CONCLUSIONS

- In a Phase 2 trial of patients with antihistamine-refractory CSU treated with barzolvolimab, 94% of patients with well-controlled disease at Week 52 also reported the disease had no impact on their QoL at that week
- Treatment with barzolvolimab led to prolonged, off-treatment enhanced QoL 7 months after the last dose of barzolvolimab
  - 76% of patients who achieved well-controlled disease at Week 52 also reported that the disease had small to no impact on their QoL at Week 76
  - The majority of patients with well-controlled disease at Week 52 achieved DLQI domain scores of 0 at Week 76
- Sustained off-treatment improvement in QoL was observed despite barzolvolimab clearance and normalization of tryptase, suggesting disease modification<sup>4</sup>
- Barzolvolimab represents a promising treatment for CSU patients and is being evaluated in ongoing Phase 3 studies in patients with CSU (NCT06445023 and NCT06455202)

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## References

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