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A Phase 2, Open-Label Extension Study to Evaluate the Long-Term Safety and Efficacy of Briquilimab in Adults with Chronic Urticaria (Trial in Progress)

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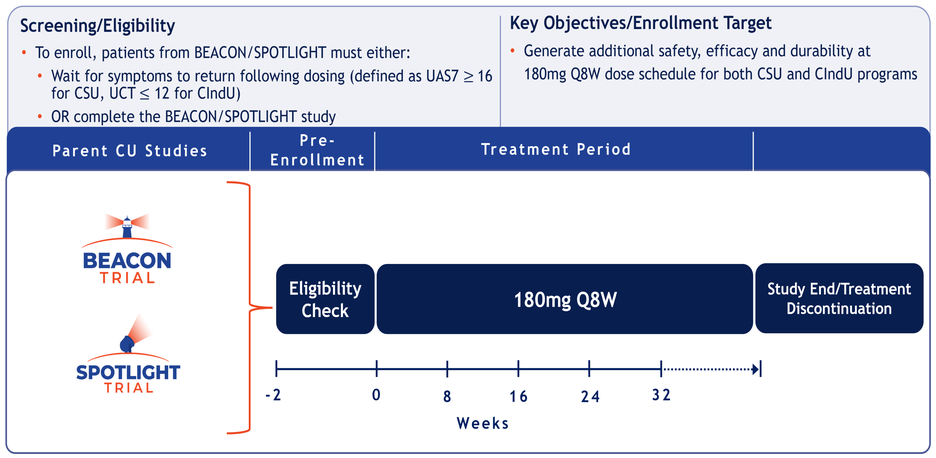
Introduction & Objectives

- Briquilimab, a humanized, aglycosylated, anti-KIT monoclonal antibody, directly blocks the SCF binding site on KIT, leading to inhibition of SCF/KIT signaling and mast cell apoptosis.
- Chronic Spontaneous Urticaria (CSU) is a recurring inflammatory skin condition lasting ≥ 6 weeks, with itchy wheals (hives), angioedema, or both driven by aberrant activation and degranulation of mast cells in cutaneous tissues.
- Briquilimab (subcutaneous) was evaluated for safety, tolerability, and efficacy in a Phase 1b/2a randomized, double blind, placebo-controlled multiple ascending dose clinical study (BEACON, NCT06162728) in participants with moderate to severe CSU who were symptomatic despite H1 antihistamines.
- Chronic inducible urticaria (CIndU) is a debilitating inflammatory condition of the skin with a specific trigger such as heat, cold, sunlight, rubbing or friction.
- Briquilimab (subcutaneous) was evaluated for safety, tolerability, and preliminary efficacy in a Phase 1b/2a open-label, dose escalation trial (NCT06353971, SPOTLIGHT) in adult participants with CIndU who are symptomatic despite treatment with H1 antihistamines.
- To evaluate the briquilimab's long-term safety and efficacy durability in chronic uriticaria, participants previously treated with briquilimab in BEACON and SPOTLIGHT studies were enrolled in an open-label extension (OLE) study (NCT06736262) .

Methods

Briquilimab 180mg was administered subcutaneously every 8 weeks (Q8W) to adult participants from the parent BEACON and SPOTLIGHT studies, regardless of previous dose/regimen



Results

Pharmacokinetics and Pharmacodynamics

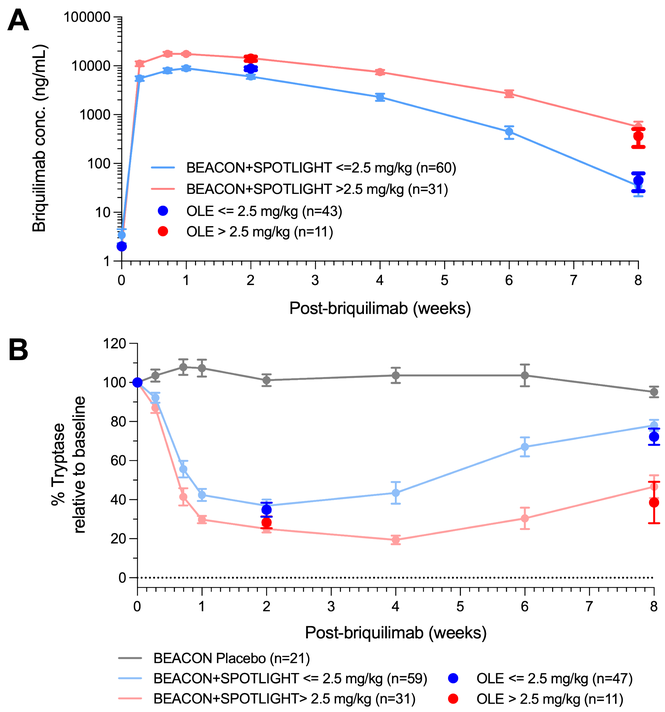
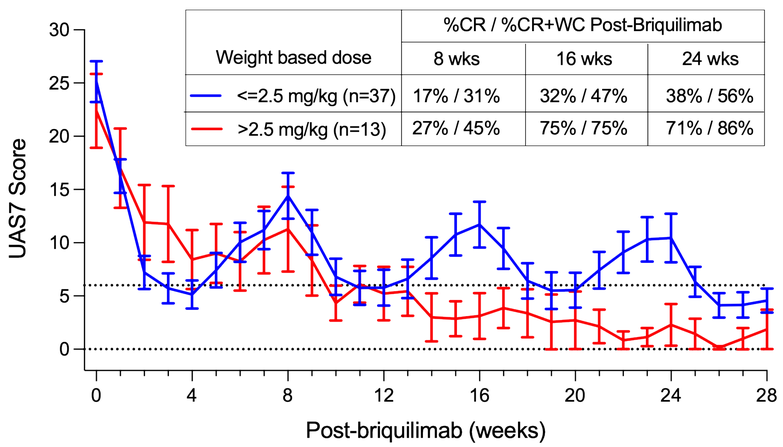


Figure 1. Weight based dose dependent briquilimab's pharmacokinetic and pharmacodynamic profiles. (A) Briquilimab serum concentration-time curves and (B) serum tryptase relative to baseline over 8 weeks following administration from OLE (0, 2, 8 weeks only) and BEACON+SPOTLIGHT studies presented by weight-based doses. All data are presented as mean±SEM. December 2025 data cut.

Total n=17	Wk2	Wk8	Wk16	Wk24	Wk32
% of CR	50%	35%	41%	64%	67%
% of CR+PR	69%	59%	65%	64%	100%

Table 1. Clinical responses in the OLE study from the parent SPOTLIGHT participants were maintained at 32 weeks. CR; Complete Response, PR; Partial Response. December 2025 data cut.

Clinical Responses and Safety



Weight based dose	%CR / %CR+WC Post-Briquilimab		
	8 wks	16 wks	24 wks
<=2.5 mg/kg (n=37)	17% / 31%	32% / 47%	38% / 56%
>2.5 mg/kg (n=13)	27% / 45%	75% / 75%	71% / 86%

Figure 2. Weight based dose dependent clinical efficacy in the OLE study from the parent BEACON participants. All data are presented as mean±SEM. CR; Complete Response (UAS7=0), WC; well controlled disease (UAS7<=6). April 2026 data cut.

	<=2.5 mg/kg (N=51)	>2.5 mg/kg (N=16)
Any Adverse Event	39 (76.5%)	12 (75.0%)
Any Serious Adverse Event	1 (2.0%)	2 (12.5%)
Any adverse event leading to discontinuation	2 (3.9%)	0 (0%)
Adverse event leading to death	0 (0%)	0 (0%)
Any Treatment-Related TEAE ≥Grade 3	0 (0%)	0 (0%)
Hair color change	1 (2.0%)	0 (0%)
Skin discoloration	2 (3.9%)	1 (6.3%)
Taste disorder/hypogeusia	7 (13.7%)	2 (12.5%)
Neutrophil count decreased	7 (13.7%)	4 (25.0%)

Table 2. Adverse events (AE) and key KIT-related AE by weight-based dose in the OLE study. Median duration of follow up is 223 days. The incidences of AE and KIT-related AE do not correlate with briquilimab dose. April 2026 data cut.

Conclusion

- Briquilimab is well-tolerated and results in rapid, clinically meaningful disease control in patients with moderate-to-severe CSU and CIndU refractory to H1-AH.
- The depth and durability of tryptase suppression and clinical responses increase in a dose-dependent manner.
- The higher dose of briquilimab (>2.5 mg/kg) does not compromise safety profile.
- The data to date support advancing briquilimab for CSU and CIndU to late-stage clinical trials.