Remibrutinib treatment improves sleep and activity in chronic spontaneous urticaria patients: Phase 2b study results

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OBJECTIVE
• This analysis of the remibrutinib Phase 2b study explores the effect of remibrutinib on sleep and activity in patients with CSU

METHODS
• The Phase 2b trial, a randomized, double-blind, placebo-controlled, multicenter that included patients aged ≥18 years, with moderate/severe CSU for >12 months that was inadequately controlled by conventional H1-antihistamines and/or angioedema for ≥12 months, measured the percentage of patients achieving no interference in sleep and activity (AIS7=0) for up to 12 weeks of treatment and dependent on HAs/EC approval from participating countries. Background therapy was a second generation H1-antihistamine at a locally approved licensed posology that differed from the background H1-antihistamine, was eliminated primarily via renal excretion, and could only be given to treat unbearable symptoms (itch) of CSU on a day-to-day basis.

RESULTS
• Approximately 90% (20/33) of patients in all arms completed the 12-week treatment period
• Patient demographics and baseline disease characteristics were generally balanced between the remibrutinib and placebo arms (Table 1).

Conflict of interest
• The present analysis from the Phase 2b dose-finding trial demonstrated:
• Remibrutinib improved sleep and activity versus placebo at Weeks 4 and 12
• More patients on remibrutinib versus placebo achieved no interference in sleep and activity
• These findings will be further evaluated in the ongoing Phase 3 clinical trial in IUIS (RESEARCH-1: NCT03615301; REMBR-2: NCT03615302) (Figure 3a)

Figure 2. a) Change from baseline in SIS7 by treatment group at Week 4, and b) Proportion of patients with AIS7=0 by treatment group at Week 4 and Week 12

Figure 3. a) Change from baseline in AIS7 by treatment group at Week 4 (38.2% to 77.7% vs 21.3%) and Week 12 (65.7 to 76.7% vs 33.1%) (Figure 3a)

Figure 4. a) Change from baseline in AIS7 by treatment group at Week 4 and Week 12; b) Proportion of patients with AIS7=0 by treatment group at Week 4 and Week 12

Legend: AIS7, weekly Activity Interference Score; CSU, chronic spontaneous urticaria; n, number of patients evaluable; n, number of patients with evaluable data; SIS7, weekly Sleep Interference Score; % change from baseline, % change from baseline in AIS7 (mean±SD)