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### Remibrutinib, a Highly Selective and Potent Btki in Development for MS, Did Not Impact Serum Immunoglobulin Levels: Insights from Chronic Spontaneous Urticaria

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#### Abstract Text:

**Background:** Remibrutinib is a highly selective, potent, covalent, oral Bruton's tyrosine kinase inhibitor (BTKi) that downregulates myeloid and B-cell activation without depleting B-cells. Here, we report immunoglobulin (Ig) levels in participants with chronic spontaneous urticaria (CSU) exposed to remibrutinib up to 100 mg bid for up to 52 weeks.

**Objectives:** To assess serum Ig levels over time in a phase 2b core (NCT03926611) and extension (NCT04109313) study of remibrutinib in CSU, including 100 mg bid, the dosing regimen being evaluated in the phase 3 REMODEL-1 (NCT05147220) and REMODEL-2 (NCT05156281) trials in relapsing multiple sclerosis (MS).

**Methods:** Participants were randomized to receive various doses of remibrutinib (10-100 mg qd/bid) or placebo for up to 12 weeks (core study). Eligible participants entered a 52-week open-label extension study with remibrutinib 100 mg bid. Baseline, Week 12 (core), and Week 52 (extension) total IgA, IgG, and IgM levels were assessed.

**Results:** Of the 309 participants included in the analysis, 194 participants rolled over to the 52-week extension. No relevant numerical changes in the total serum Ig levels up to Weeks 12 and 52 were observed. In the 194 participants receiving remibrutinib 100 mg bid in the extension study (mean age, 45.5 years; female, 71.6%), mean (standard deviation [SD]) baseline and Week 52 IgG levels ( $\mu\text{g/mL}$ ) were 11.0 (2.43) and 10.5 (2.49), respectively, and the corresponding mean (SD) IgM levels were 1.1 (0.83) and 0.9 (0.74).

**Conclusions:** Remibrutinib treatment did not affect total Ig levels in participants with CSU in phase 2 studies, including with long-term treatment up to 52 weeks with 100 mg bid, the dose used in MS clinical trials.

**Title:**

Remibrutinib, a Highly Selective and Potent Btki in Development for MS, Did Not Impact Serum Immunoglobulin Levels: Insights from Chronic Spontaneous Urticaria

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**Preferred Presentation Format:**

Poster

**Category:**

Disease-modifying therapy

**Has this abstract been presented/published elsewhere prior to this meeting?:**

No

**Have you simultaneously submitted this abstract to another organization for consideration?:**

Yes

**Simultaneous submission details:**

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**Would you give CMSC and International Journal of MS Care the first preference to any article that is submitted for publication based on this abstract presentation?:**

No

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