Remibrutinib, a BTKi, has no Impact on Serum Immunoglobulin levels: Insights from Chronic Spontaneous Urticaria

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INTRODUCTION

Remibrutinib is a highly selective, potent, covalent, oral Bruton's tyrosine kinase inhibitor (BTKi) that downregulates B cell as well as myeloid cell activation without cellular depletion. Here, we report on serum immunoglobulin (Ig) levels over time in a Phase 2b core (NCT03926611) and extension (NCT04109313) study of remibrutinib in patients with chronic spontaneous urticaria (CSU), receiving various doses for up to 52 weeks including 100mg b.i.d., the dosing regimen being evaluated in the Phase 3 REMODEL trials (NCT05147220, NCT05156281) in relapsing multiple sclerosis (MS).

DESIGN/METHODS

Patients were randomized to receive various doses of remibrutinib (10–100 mg q.d./b.i.d.) or placebo for up to 12 weeks (core study). Eligible patients entered a 52-week open-label extension study with remibrutinib 100 mg b.i.d. Total serum levels of different immunoglobulins were assessed at baseline, Week 12 (end of core) and Week 52 (end of extension).

RESULTS

Of the 309 patients included in the analysis,194 rolled-over to the 52-week extension. No relevant changes in the total serum immunoglobulin levels up to Week 12 and Week 52 were observed. In the 194 patients receiving remibrutinib 100mg b.i.d. in the extension study (mean age: 45.5 years; % female: 71.6), mean baseline and Week 52 IgG levels (µg/mL) were 11.0±2.41 and 10.5±2.47, respectively, and the corresponding mean IgM levels were 1.0±0.80 and 0.9±0.73.

CONCLUSIONS

Remibrutinib treatment did not affect total immunoglobulin levels in CSU patients of phase 2 studies, including with long-term treatment up to 52 weeks with 100mg b.i.d., the dose used in MS clinical trials.

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