**INTRODUCTION**

Chronic spontaneous urticaria (CSU) is characterised by the spontaneous occurrence of wheals (hives) and/or angioedema for 6 weeks and has a major impact on patients’ well-being. Remibrutinib (LOU064), a novel, highly selective and potent covalent Bruton’s Tyrosine Kinase inhibitor (BTKi), is currently in Phase 3 development for the treatment of CSU (NCT05030311, NCT05032157, NCT05048342).

In the Phase 2b study, remibrutinib demonstrated clinical efficacy and a favourable safety profile in patients with CSU. The objective of this analysis is to report the safety and tolerability of remibrutinib for up to 52 weeks in patients with CSU from a final analysis of the dose-finding Phase 2b trial (NCT03286111) and an interim analysis of its extension study (NCT04109513).

**METHODS**

The analysis included data from an international, multicentre, randomised, double-blind, placebo-controlled Phase 2b study and its long-term open-label extension study (Figure 1).

Safety assessments comprised of adverse events (AEs), including serious and events of special interest, vital signs, electrocardiogram (ECG) and laboratory parameters.

**RESULTS**

Approximately, 90% of patients completed 12-week treatment in core study (Figure 2). In extension, at the time of interim analysis, 36% had completed the full 52-week treatment (Figure 2).

Demographics in core and extension studies were comparable (Table 1). Safety and tolerability of 52-week treatment with remibrutinib 100 mg b.i.d. dose was comparable to any remibrutinib dose in the core study (Table 2).

Incidence of most frequent events by body system and reported term remained stable with long-term treatment with remibrutinib (Table 3).

**CONCLUSIONS**

Final analysis of the dose finding Phase 2b trial and an interim analysis of its extension study, including long-term exposure with 100 mg b.i.d. dose for up to 52 weeks, showed a favourable safety profile and good tolerability of remibrutinib in patients with CSU.

Remibrutinib is a potential new oral treatment option for patients with CSU.

Findings from the present analysis will be further confirmed from ongoing Phase 3 clinical trials in CSU (NCT05030311 and NCT06302157).

**REFERENCES**

1. Zuberbier T, et al. European Academy of Dermatology and Venereology. 2021 (Oral Presentation # D3T01.3)

**Conflict of Interest**

Ana Gimenez-Arnau reports research support from Amgen, Novartis and Genentech, FaSZ, GSK, AMINO Therapeutics, Menarini and Actelion, all outside the submitted work. Abraham Ballouz reports personal fees from Amgen, Novartis and Genentech, and speaking fees from Menarini, all outside the submitted work. Artem Zharkov is a part of the Multicenter Phase 3 Study Group for patients with CSU and reports personal fees from Amgen, Aralez, Argenx, AstraZeneca, Celldex, Menarini, Novartis, Roche, and Sanofi, all outside the submitted work. Artem Zharkov is also a part of the Multicenter Phase 3 Study Group for patients with COVID-19 and reports personal fees from Amgen, Aralez, Argenx, AstraZeneca, Celldex, Menarini, Novartis, Roche, and Sanofi, all outside the submitted work.

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