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Body

Title
Remibrutinib: A Novel BTKi in Development for MS With a Favorable Safety Profile in Various Autoimmune Disorders

Introduction
Remibrutinib is a novel, potent, highly selective, covalent, oral Bruton's tyrosine kinase inhibitor (BTKi) currently investigated in Phase 3 trials for treatment of multiple sclerosis (MS; NCT05147220/NCT05156281). This analysis presents an overview of the safety of remibrutinib from Phase 2 clinical trials in various autoimmune disorders.

Methods
Data were collected from final analyses of trials in chronic spontaneous urticaria (CSU), Sjögren syndrome (SjS), and asthma, and interim analysis of open-label extension (OLE) in CSU. Safety assessments comprised of AEs, including serious and AEs of special interest (AESI), vital signs, ECGs, and laboratory parameters.

Results
Overall, 363 patients (267 CSU; 49 SjS; 47 asthma) who received various doses (10–100 mg q.d./b.i.d.) of remibrutinib for 12–52 weeks were included. Among CSU patients, the safety of remibrutinib 100 mg b.i.d. in the 52-week OLE study was comparable to doses in the core study (Table 1). Overall, most frequently reported grouped AEs (≥10%) were infections and infestations, skin, subcutaneous, gastrointestinal, and nervous system disorders. AEs were similar to placebo in core studies except for skin disorders, where post-treatment CSU flares caused an imbalance. There were no increases in infection rates. Other AESI, including bleeding (all minor) and cytopenia were not altered during long-term treatment. No safety concerns were noted in laboratory analyses, ECGs, or vital signs.

Conclusion
Remibrutinib demonstrated a favorable safety profile and was well tolerated at all doses studied in Phase 2 trials and the 52-week OLE (up to 100 mg b.i.d.), supporting its development in Phase 3 clinical trials in MS.

Disclosure
The study was supported by Novartis Pharma AG, Switzerland. The detailed author disclosures will be presented in the subsequent presentation.

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Table 1_Remibrutinib Safety Overview.png	Table 1. Safety and Tolerability...	Results	Preview	Download