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Updated Safety Analysis of Cladribine Tablets in the Treatment of Patients with Multiple Sclerosis

S. Cook[1], G. Giovannoni[2], T. Leist[3], S. Syed[4], A. Nolting[5], R. Schick[5]

[1]Rutgers, The State University of New Jersey, New Jersey Medical School, Newark, New Jersey, United States of America
[2]Queen Mary University of London, Blizard Institute, Barts and The London School of Medicine and Dentistry, London, United Kingdom
[3]Jefferson University, Comprehensive MS Center, Philadelphia, Pennsylvania, United States of America
[4]Emd Serono Research & Development Institute Inc., Billerica, Massachusetts, United States of America
[5]Merck Kgaa, DarMStadt, Germany

Background: Integrated analysis of pooled, long-term safety data allowed comprehensive characterisation of the cladribine tablets (CT) safety profile in patients with relapsing multiple sclerosis. Previous characterisation of a monotherapy oral cohort treated with CT 3.5 mg/kg (CT3.5) included cumulative safety data up to feb 2015, >3 years beyond last clinical study completion. This study aimed to provide a two-year update of the serious treatment emergent adverse event (TEAE) profile from the CT3.5 integrated safety analysis.

Methods: The monotherapy oral cohort was derived from the clarity, clarity extension, and oracle-MS trials, and the premiere registry. 923 patients received CT3.5, and 641 received placebo. Data cut-offs were cumulative to feb 2015 (previously presented, "period [p]1") and cumulative to may 2017 (updated, "p2").

Results: Respective rates of adjusted adverse events incidence per 100 patient-years were (presented as CT3.5, placebo): ≥1 serious TEAE: 3.88, 3.24 (p2), 4.00, 3.57 (p1); serious lymphopenia (preferred term [PT]): 0.11, 0 (p2), 0.12, 0 (p1); serious infection and infestations (system organ class [SOC]): 0.63, 0.44 (p2), 0.69, 0.50 (p1); serious herpes zoster (PT): 0.05, 0 (p2), 0.06, 0 (p1); serious neoplasMS, benign, malignant and unspecified (SOC): 0.65, 0.35 (p2), 0.74, 0.50 (p1).

Conclusions: This integrated analysis confiRMS the serious TEAE profile associated with CT3.5 treatment of patients with early and active RMS. The updated profile (p2) was generally consistent with that from 2 years prior (p1). No new major safety findings were identified in the updated dataset, where patients were followed for up to 10 years.