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Efficacy of Cladribine Tablets as Add-On to IFN-beta Therapy in Patients with Active Relapsing MS: Final Results from the Phase II ONWARD Study (P3.029)

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Abstract

Objective: To assess the efficacy of cladribine tablets (3.5mg/kg) as an add-on to IFN- β in patients with active relapsing MS **Background:** Cladribine tablets given annually for 2 years in short-duration courses to RRMS patients significantly improved clinical and MRI outcomes (CLARITY). In CLARITY Extension, the clinical benefits of 2-years of cladribine treatment (3.5mg/kg bodyweight) were maintained in the study for 4 years or more without further active treatment. ONWARD evaluated the safety/tolerability of cladribine tablets (3.5mg/kg) as an add-on to IFN- β therapy. Efficacy is reported here. **Methods:** ONWARD was a 2-year, randomized, double-blind Phase IIb study in patients aged 18-65 years, with ≥ 1 relapse during the prior 48 weeks while on IFN- β therapy, with EDSS scores 1.0-5.5 and normal blood cell counts within 28 days of baseline. **Results:** 14.5[percent] of patients (N=172) had SPMS at baseline. The mean number of qualifying relapses on study was lower (0.23) in patients treated with cladribine 3.5mg/kg plus IFN- β (N=124) vs. patients who received placebo plus IFN- β (0.56; N=48). The respective ARRs were 0.12 (95[percent] CI 0.08, 0.17) and 0.32 (95[percent] CI 0.20, 0.45). Cladribine-treated patients were 63[percent] less likely to have a qualifying relapse ($P<0.001$). The proportion of patients with confirmed EDSS progression over 2 years was not significantly different for cladribine 3.5mg/kg plus IFN- β vs. placebo plus IFN- β ; however, the study was not powered for this endpoint. The mean numbers of new T1-Gd+, active T2 and CUA lesions/patient/scan were reduced in the combined treatment arm vs. placebo plus IFN- β . **Conclusions:** In patients with active relapsing MS with breakthrough disease while on IFN- β therapy (including SPMS with ongoing relapses), treatment with cladribine tablets added on to IFN- β demonstrated significant efficacy benefits. These results support the demonstrated efficacy of cladribine tablets in RRMS shown in CLARITY. Study supported by: Merck KGaA Darmstadt, Germany.

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