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Presentation preference: Oral or Poster

**Title**: An exploratory analysis of the efficacy of Cladribine Tablets 3.5mg/kg (CT3.5) in patients with relapsing multiple sclerosis (RMS) stratified according to age above and below 45 years in the CLARITY study

**Short title to be displayed on app**: Age-stratified efficacy of Cladribine Tablets

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**Introduction**: In CLARITY, Cladribine Tablets 3.5 mg/kg (CT3.5) demonstrated efficacy vs placebo (PBO) for patients with RMS. Age-related variability in response to disease-modifying treatments has been observed in patients with MS.

**Objectives**: *Post hoc* evaluation of response to CT3.5 in patients with RMS aged ≤45 years or >45 years.

**Methods**: The CLARITY CT3.5 and PBO intention-to-treat populations were stratified by age (≤45 and >45 years). Efficacy endpoints included qualifying relapse, all relapses and mean/cumulative numbers of new T1 gadolinium-enhancing (Gd+), active T2 and combined unique (CU) lesions.

**Results**: There were 649 patients aged ≤45 years (CT3.5 N=330; median age: 34.5 years) and 221 aged >45 years (CT3.5 N=103; median age: 51 years). The >45 group had a higher proportion of females (CT3.5 77.7%) than the ≤45 group (CT3.5 66.1%). CT3.5 was associated with significant relative risk reductions for annualised qualifying relapse rate vs PBO in both age groups (≤45 years: relative risk [RR] 0.39 [95% confidence interval (CI) 0.31, 0.51], p<0.0001; >45 years: RR 0.5 [95%CI 0.31, 0.80] p=0.004). Similar RRs were obtained in the two age groups for 'all relapses' (p<0.0001 for

CT3.5 vs PBO in both age groups). Compared to PBO in both age groups, CT3.5 reduced the number of cumulative new T1 Gd+ lesions, mean number of active T2 lesions per patient per scan (≤45 years: -0.667 [95%CI -0.67, -0.50], p<0.0001; >45 years: -0.167 [95%CI -0.33, 0.00], p<0.0001) and mean number of CU lesions per patient per scan (≤45 years: -0.667 [95%CI -1.00, -0.67] p<0.0001; >45 years; -0.333 [95%CI -0.33, 0.00] p<0.0001).

**Conclusions**: CT3.5 treatment was efficacious in patients above and below 45 years of age with respect to reduction of relapse frequency and number of MRI lesions, consistent with previous analyses.

The CLARITY study: NCT00213135

**Disclosures:** This study was sponsored by EMD Serono Inc, a business of Merck KGaA, Darmstadt, Germany (in the USA), and Merck Serono SA, Geneva, an affiliate of Merck KGaA Darmstadt, Germany (ROW).

**Author disclosures**

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