

## 26<sup>th</sup> Annual Meeting of the European Charcot Foundation

Baveno, Italy 15–17 November 2018

Presentation preference: Oral or Poster

**Title:** Durability of No Evidence of Disease Activity-3 (NEDA-3) status in patients with relapsing multiple sclerosis (RMS) receiving Cladribine Tablets 3.5 mg/kg (CT3.5): CLARITY Extension

**Short Title** (max. 45 characters): Durability of NEDA-3 status in CLARITY Ext

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**Introduction:** In CLARITY, CT3.5 showed efficacy vs placebo over 2-years in patients with RMS. NEDA-3 status was achieved in significantly more patients receiving CT3.5 than placebo. Efficacy with CT3.5 (CLARITY) was maintained in Years-3/4 (CLARITY Ext) when patients were randomised to placebo after a variable bridging interval (Bri; ≤116 weeks), during which CT3.5 was not administered.

**Objective:** Determine NEDA-3 status in patients who received CT3.5 in CLARITY followed by placebo (CP3.5) or CT3.5 (CC7) in CLARITY Ext.

**Methods:** Patients (CP3.5 N=98; CC7 N=186) were retrospectively analysed for NEDA-3 status (no relapse, no 6-month Expanded Disability Status Scale [EDSS] progression, no T1 gadolinium-enhancing or active T2 lesions). Bri between CLARITY and CLARITY Ext was used as a proxy for when patients reached Week 48 of CLARITY Ext. Year 3–4 group: patients with Bri ≤43 weeks (known NEDA status: CP3.5 N=54; CC7 N=98); Year 4–5 group: patients with Bri >43 weeks (known NEDA status: CP3.5 N=40; CC7 N=77). NEDA-3 differences in CP3.5 and CC7 groups were analysed by logistic regression with treatment and Bri as fixed effects.

**Results:** Year 3–4 group: annual NEDA-3 achieved in 46% (25/54) and 48% (47/98) of the CP3.5 and placebo groups. Year 4–5 group: annual NEDA-3 was observed in 35% (14/40) and 48% (37/77) of the CP3.5 and CC7 groups. Adjusting for Bri length, there was no significant difference between annual NEDA-3 in the CP3.5 (41.5%, 95%CI=32.4–60.0%) and CC7 (48.0%, 95%CI=40.2–64.4%) groups (p=0.31). Bri duration was not a significant variable (p=0.38). Similar patterns were observed when

proportions of patients who were annual relapse-free and annual 6-month EDSS progression-free were examined.

**Conclusions:** Following CT3.5 treatment in CLARITY, NEDA-3 status (analysed *post-hoc*) was sustained in patients up to Week 48 of CLARITY Ext, and Brl was not a significant variable.

The CLARITY study: NCT00213135; The CLARITY Extension study: NCT00641537

**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**

**GG** has received speaker honoraria and consulting fees from Abbvie, Actelion, Atara Bio, Almirall, Bayer Schering Pharma, Biogen Idec FivePrime, GlaxoSmithKline, GW Pharma, Merck, Pfizer Inc, Protein Discovery Laboratories, Teva Pharmaceutical Industries Ltd, Sanofi-Genzyme, UCB, Vertex Pharmaceuticals, Ironwood, and Novartis; and has received research support unrelated to this study from Biogen Idec, Merck, Novartis, and Ironwood.

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