**Severity and frequency of relapses in patients with relapsing-remitting MS treated with cladribine tablets in CLARITY and placebo in CLARITY extension**

**Background and aims:** Patients with relapsing-remitting multiple sclerosis (MS) who received 2 years’ treatment with Cladribine Tablets (CT) 10 mg, (cumulative dose 3.5 mg/kg [CT3.5]) in CLARITY followed by 2 years’ placebo (PBO) in CLARITY Extension (CP3.5) experienced durable clinical benefits. The rate and severity of relapse (proxy indicators; hospitalisation and steroid use) were evaluated.

**Methods:** Qualifying relapse was defined by Kurtzke Functional Score status and specified clinical parameters. Unadjusted annualised relapse rates (ARRs; Week 96) were calculated for CP3.5 patients (N=98). ARRs were also calculated for qualifying and all relapses requiring hospitalisation or steroid treatment. All analyses were posthoc and descriptive.

**Results:** ARRs (CLARITY; CT3.5 and PBO, CLARITY Extension; CP3.5) for qualifying and all relapses (qualifying and non-qualifying) at Week 96 and those leading to hospitalisation or requiring steroid treatment are presented in Table 1. In CLARITY (CT3.5; N=433), ARR for qualifying relapses was 0.15; and for PBO (N=437) was 0.35. CLARITY Extension: ARR for qualifying relapse in CP3.5 (N=98) at Week 96 was 0.14. In CLARITY CT3.5 and in CLARITY Extension CP3.5, ARR for all relapses, as well as those leading to hospitalisation or requiring steroid treatment were low, relative to CLARITY PBO.

**Conclusion:** In CLARITY, CT3.5 was efficacious against relapse versus PBO regardless of relapse type. Relapse frequencies at Week 96 in CLARITY Extension were similar to those in CLARITY CT3.5 (no formal comparison).

Relapse in CLARITY Extension CP3.5 were notably lower than for CLARITY PBO. Therefore, the efficacy demonstrated in CLARITY was sustained for each relapse type in CLARITY Extension without further treatment.