INTRODUCTION

- In the CLARITY study, treatment with Cladribine Tablets 10 mg (3.5 mg/kg cumulative dose over 2 years; referred to as Cladribine Tablets 3.5 mg/kg) showed significant efficacy compared with placebo over 2 years in a large cohort of patients with relapsing-remitting multiple sclerosis.1

- The annualised relapse rate at 96 weeks was significantly reduced in the Cladribine Tablets 3.5 mg/kg group compared with placebo (relative reduction of 58%, P < 0.001).1

- The proportion of patients who remained relapse-free at 96 weeks was significantly higher in the Cladribine Tablets 3.5 mg/kg group compared with placebo (80% versus 51%, P < 0.001).1

- Time to first qualifying relapse was significantly longer in the Cladribine Tablets 3.5 mg/kg group compared with the placebo group (hazard ratio: 0.44, P = 0.001).1

OBJECTIVES

- Pilot hoc evaluation of the effect of Cladribine Tablets 3.5 mg/kg on the rate and severity of relapses (qualifying and all relapses) in the CLARITY study (using hospitalisation and steroids as proxy indicators), and the effect of adjusting for covariates.

- The aim of this analysis was to compare the effect of Cladribine Tablets versus placebo on qualifying versus to all relapses.

METHODS

- Qualifying relapse was defined by the Kurtzke Functional Score status and specified clinical parameters.1

- Relative risk of relapse was estimated between patients treated with Cladribine Tablets 3.5 mg/kg (N = 433) and placebo (N = 437) (Figure 1): At Weeks 24, 48 and 96 by Poisson regression.

- Treatment and various alternating covariates were analysed as main effects.

- Covariates included: gender, age, age at time of diagnosis, disease duration (time since diagnosis), and prior use of disease modifying treatments.

- All analyses were post hoc and exploratory.

RESULTS

- Baseline demographics and disease characteristics for the placebo and Cladribine Tablets 3.5 mg/kg groups are shown in Table 1. The number of relapses in the 12 months prior to study were balanced between the treatment groups.

- Compared with placebo, patients in the Cladribine Tablets 3.5 mg/kg group had a significantly reduced risk of experiencing a qualifying relapse at Weeks 24, 48 and 96 (Figure 2).

- Compared with placebo, patients in the Cladribine Tablets 3.5 mg/kg group had a significantly reduced risk of qualifying relapses leading to hospitalisation and qualifying relapses leading to steroid treatment at all time-points (Table 2).

- At Week 96, annualised relapse rate for Cladribine Tablets 3.5 mg/kg for qualifying relapses leading to hospitalisation and qualifying relapses leading to steroid treatment was 0.06 (95% CI: 0.06, 0.10) and 16 (95% CI: 13, 19) for placebo.

- For qualifying relapses requiring steroid treatment it was 0.12 (95% CI: 0.06, 0.14) for Cladribine Tablets 3.5 mg/kg and 0.28 (95% CI: 0.25, 0.32) for placebo.

CONCLUSIONS

- The relative risk for qualifying relapses and all relapses was consistently and significantly lower in the Cladribine Tablets 3.5 mg/kg group, relative to placebo, for all time-points (Weeks 24, 48 and 96), including relapses requiring hospitalisation or steroid treatment.

- Treatment with Cladribine Tablets 3.5 mg/kg reduced annualised relapses requiring hospitalisation and those requiring steroids by > 50% compared with placebo.

- After adjusting for covariates, the treatment benefit of Cladribine Tablets compared with placebo was consistent by any of the model adjustments.

REFERENCES


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DISCLOSURES

1 None of the authors of this manuscript has a financial or personal relationship with other people or organizations that could inappropriately influence or bias the content of the manuscript. The CLARITY study is supported by the European Commission for the treatment of adult patients with highly active relapsing multiple sclerosis (MS) as defined by clinical or MRI markers.