CLARITY and CLARITY extension studies

Durable efficacy of cladribine tablets in patients with multiple sclerosis: analysis of relapse rates and relapse-free patients in the CLARITY and CLARITY extension studies

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INTRODUCTION

In the CLARITY study, cladribine tablets, given annually for 2 years in doses of 5.25 mg/kg (3.5 mg/kg of bodyweight) and cumulative dosage 3.5 mg/kg (0.25 mg/kg of bodyweight) significantly improved clinical (relapses and disability progression) and magnetic resonance imaging (MRI) outcomes in patients with relapsing multiple sclerosis.

The CLARITY Extension (EXT) study compared the safety and efficacy of 2-year additional cladribine tablet treatment versus no additional treatment and the effect of switching from two courses of placebo to two courses of cladribine tablets (Figure 1).

Figure 1. CLARITY Extension study design

OBJECTIVE

To assess efficacy outcomes in CLARITY EXT and compare with those obtained in the same patient groups during CLARITY.

METHODS

Patients

Inclusion criteria in CLARITY were assigned to cladribine tablets 3.5 mg/kg in CLARITY EXT and all other patients were re-randomized 2:1 to cladribine tablets 3.5 mg/kg or placebo for 2 years (Table 1).

Table 1. Treatment group allocation in CLARITY Extension

Table 2. Baseline demographics and disease characteristics in CLARITY Extension

RESULTS

Patients

Of patients randomized/assigned to treatment in CLARITY EXT, Table 2).

Figure 2. ARR by treatment group, for CLARITY and CLARITY Extension

Patients who received cladribine tablets 3.5 mg/kg in CLARITY and 3.5 mg/kg in CLARITY EXT (CP 3.5 mg/kg) also showed a low mean number of new T1 Gd+ lesions during CLARITY (0.09) and a significant increase during CLARITY EXT (CP 3.5 mg/kg=p=0.01).

- This despite the increase, the value was >2 fold lower than in patients treated with placebo in CLARITY (CP 3.5 mg/kg=0.6).
- Analyses of the distribution of mean T1 Gd+ counts in the CP 3.5 mg/kg group associated with a subgroup of patients (11.6%) in which the mean number of new T1 Gd+ lesions was >10 (Table 3).

Figure 3. Proportion of patients who remained relapse free in CLARITY Extension irrespective of their treatment in CLARITY

Figure 4. Mean per-run number of new T1 Gd+ lesions in patients in CLARITY Extension

- Patients who received cladribine tablets 3.5 mg/kg in CLARITY and 3.5 mg/kg in CLARITY EXT (CP 3.5 mg/kg) showed a low mean number of new T1 Gd+ lesions during CLARITY (0.09) and a significant increase during CLARITY EXT (CP 3.5 mg/kg=p=0.01).

Figure 5. ARR by treatment group, for CLARITY and CLARITY Extension

CONCLUSIONS

- Patients who received cladribine tablets 3.5 mg/kg in CLARITY, further treatment in CLARITY EXT did not show any additional efficacy.

- 1 T1 Gd+ MRI activity was low in the majority of patients in each group at the end of CLARITY EXT, with patients who received cladribine in CLARITY and 3.5 mg/kg in CLARITY EXT experiencing a significant reduction in new T1 Gd+ lesions.

- A subgroup of patients who experienced a prolonged treatment showed a slight increase in T1 Gd+ activity but this appeared to have no impact on the persistent clinical benefits of cladribine tablets.

REFERENCES


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DISCLOSURES

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