INTRODUCTION

- Efficacy of Cladribine Tablets was demonstrated in the CLARITY1 CLARITY Extension2 and ORACLE-MS3 studies in patients with both early and relapsing multiple sclerosis (RMS).
- Integrated analysis by pooling of safety data is an established methodology for the comprehensive characterisation of the safety profile of a therapy.
  - The safety profile of Cladribine Tablets based on the integrated analysis of safety data has been presented previously.4
- With the recent approvals of Cladribine Tablets 10 mg (3.5 mg/kg cumulative dose over 2 years; referred to as Cladribine Tablets 3.5 mg/kg) for patients with highly active RMS, the integrated safety profile from clinical trials represent the best source of safety data until comprehensive real-world post-approval safety data are accumulated.
- Although post-approval experience is limited, we report the sum total of serious adverse drug reactions (ADR) from post-approval data sources, in addition to clinical data.

OBJECTIVES

- To provide integrated safety data for Cladribine Tablets 3.5 mg/kg, cumulative to May 2017: an update to the previously reported serious treatment emergent adverse event (TEAE) profile.
- To report final (1-year) post-approval safety data from Europe.

METHODS

- The Monotherapy Oral cohort was derived from the CLARITY, CLARITY Extension, and ORACLE-MS trials, and the PREMIERE registry (30 November 2009 start date) (Figure 1).
- 923 patients received Cladribine Tablets 3.5 mg/kg.
- 641 patients received placebo.

RESULTS

Clinical data

- Patient characteristics were generally balanced among groups (Table 1).
- The reported number of serious TEAEs was higher in the Cladribine Tablets 3.5 mg/kg group and placebo group, respectively.
  - There were 130/923 patients with serious TEAEs in the Cladribine Tablets 3.5 mg/kg group and 68/641 patients with serious TEAEs in the placebo group.
  - Adj-AE per 100PY for serious lymphoma (preferred term) was 0.11 in the Cladribine Tablets 3.5 mg/kg group (Table 2).
  - Lymphopenia is expected due to the mechanism of action of Cladribine Tablets.
  - No serious lymphoma events were observed in the placebo group.
  - Adj-AE per 100PY for serious infection and infestations (system organ class) was 0.63 in the Cladribine Tablets 3.5 mg/kg group and 0.44 in the placebo group (Table 2).
  - For serious herpes zoster (preferred term), an expected event after treatment with Cladribine Tablets, Adj-AE per 100PY in the Cladribine Tablets 3.5 mg/kg group and placebo group were 0.35 and 0.44, respectively.
  - Similarly, no new safety findings were identified in the latest integrated safety data.
  - The safety profile was generally consistent with the previously-published integrated safety analysis profile for Cladribine Tablets 3.5 mg/kg.
  - No new major safety findings were identified in this latest integrated safety data.
  - Similarly, no new safety signals were identified in the post-approval data. However, with Cladribine Tablets 3.5 mg/kg having on less than 1 year, it must be noted that this represents a smaller number of PY compared with the clinical trial follow up.
  - The benefit-risk balance of Cladribine Tablets for the treatment of highly active RMS is considered positive.

REFERENCES


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DISCLOSURES

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