Evaluation of patient-reported outcomes: CLAWIR study 6-month interim analysis

Short Title: NIS Cladribine Tablets PRO evaluation

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Background

This non-interventional study (NIS) aims to gain insight into patient´s perspective evaluating the benefits or burden associated with cladribine tablet therapy using patient reported outcomes (PRO). Set up as a local ancillary study to the post-authorization safety study CLARION. At data cut-off, 81 patients completed the 6-months PROs assessment.

Objectives

To report on the results of an interim analysis focusing on patient reported outcomes to evaluate allevation of burden of treatment and work productivity 6 months after treatement start.

Study design

Records are produced for patients who received cladribine tablets for the first time. The recruitment period is 19,5 months and the monitoring period for each patient is 24 months.

The presented analysis is focused on the descriptive summary of PROs (PROMIS Fatigue MS & PROMIS Physical Function MS, TSQM1.4, WPAI) 6 months after treatement start.

Results

PROMIS Fatigue MS and PROMIS Physical Function MS scores remain stable over time (PROMIS Fatigue MS mean (±SD) score at baseline 56 (±9.37) and after 6 months 54 (±9.90); PROMIS Physical Function MS mean score (±SD) score at baseline 47.9 (±9.93) and after 6 months 47.6 (±11.07)).

At month 6, mean (±SD) global TSQM satisfaction score was 74.5 (±20.75). Mean (±SD) change from baseline to month 6 was 23.2 (±34.16). From baseline to 6 month satisfaction increased in all TSQM domains.

For the WPAI scores a numerical improvement from baseline to 6 month can be observed.

Conclusion

This evaluation of the study data (April 2022) provides additional evidence of the validated PRO in a real-world setting.

The first interim analysis suggests that, based on the PROs, cladribine tablets may have a positive impact on treatment burden and work productivity.