Design of the non-interventional, prospective study CLADQoL (CLADribine Tablets – evaluation of Quality of Life)

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INTRODUCTION

- Receiving marketing authorization in Germany on August 22nd, 2017, Cladribine tablets represent the first oral short-course treatment indicated for adult patients with relapsing multiple sclerosis (RMS).¹
- Patients' health-related quality of life (HRQoL) has been shown to be an important patient reported outcome for overall benefit assessment.
- To date, no real-world data are available on QoL of RMS patients treated with Cladribine tablets.
- Furthermore, real-world longitudinal data on cognitive status as well as data on advantages and disadvantages of Cladribine tablets from a patient's perspective are lacking.

OBJECTIVES

- This study aims to investigate the quality of life of RMS patients initially treated with Cladribine tablets.
- The primary endpoint was defined as improvement of HRQoL after 24 months (MSQoL-54 assessed).
- Secondary endpoints include cognitive status, treatment satisfaction, relapse rate, fatigue, disability progression, employment status and maintenance of treatment effect between 2 and 4 years.
- Other objectives (exploratory) are Cladribine tablets according to the German SPC.
- 75 study centers in Germany and Austria
- Inclusion of 1st patient: March 8th, 2018

METHODS

Study Design

- Non-interventional (NIS) in patients with relapsing multiple sclerosis (RMS) treated with Cladribine tablets (3,5 mg/kg body weight) (Figure 1 and 2).
- Participants of this NIS have the possibility to take part in PASS as a continuation for long term observation of safety aspects of Cladribine tablets

Population

- Recruited patients are first-time users of Cladribine tablets and received treatment according to the German SPC. A signed informed consent is required.
- Patient with per label contraindications are excluded.

Variables

- Demographic data, MS and medication history, disease course (relapse rate, disability, MRI) laboratory values and safety data
- Questionnaires: MSQoL (generic and total score), TSQM (total and subscores), SDMT and FSMC (total and subscores)
- Usage and service related experience, PSP participation and employment status

Data Sources

- Data will be collected by means of an eCRF; paper questionnaires will be filled out by the patient and then transferred into an eCRF by the study nurse.

Table 1: Visit plan

<table>
<thead>
<tr>
<th>Assessment</th>
<th>Screening Baseline</th>
<th>Documentation of visit (months)</th>
<th>Study termination (loss to FU, exclusion, IC withdrawal)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Demography</td>
<td>- y - y - y - y</td>
<td>6* 12* 18* 24* 36* 48*</td>
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<tr>
<td>Medical History</td>
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<tr>
<td>Quality of life (MSQoL-54)</td>
<td>- y - y - y - y</td>
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<tr>
<td>Cognition (SDMT)</td>
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<tr>
<td>Treatment Satisfaction (TSQM)</td>
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<tr>
<td>Fatigue (FSMC)</td>
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<tr>
<td>Employment status</td>
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<tr>
<td>PSP participation</td>
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<tr>
<td>Usage related questionnaire</td>
<td>y y y y y y</td>
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<tr>
<td>Service related questionnaire</td>
<td>y y y y y y</td>
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<tr>
<td>Reason for study termination</td>
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</tbody>
</table>

Documentation if recorded EDSS score, S-HPFT score, T25-FW score, MRT (number of new lesions), relapse rate, laboratory values
FU: follow-up; IC: Informed Consent; PSP: Patient Support Program; *: time slot; +/- 1 month; : time slot: 6 months, according to specifications for the second treatment phase.

CONCLUSION

This study investigates a prospective assessment and annual follow-up of health-related quality of life of RMS patients receiving Cladribine tablets. It will thereby provide essential real-world data for overall benefit assessment of cladribine treatment.

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¹ An affiliate of Merck KGaA, Darmstadt, Germany

REFERENCES

1. SmPC MAVENCLAD 10 mg tablets (May 2018)

DISCLOSURES

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