Design of the non-interventional, prospective study CLEVER (CLadribine Tablets – EValuation of thERapy satisfaction)

Short Title: Design NIS Cladribine Tablets TSQM evaluation

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Rationale and background

Cladribine Tablets received marketing authorisation in Germany on August 22nd, 2017. To date there are no data on patients' treatment satisfaction with Cladribine Tablets. This important patient-reported outcome might show valuable additional information on secondary benefits of Cladribine Tablets.

Research question and objectives

Primary goal is to prospectively evaluate treatment satisfaction in the initial treatment phase with Cladribine tablets by the means of TSQM (Treatment Satisfactory Questionaire for Medication). The objectives are assessment of overall treatment satisfaction in RMS patients treated with Cladribine Tablets 6 months after treatment initiation with special focus on patient perceived effectiveness, tolerability and convenience. Further aim is to describe patients' characteristics and profile prior to Cladribine treatment (such as demographics, prior MS treatments, disease severity) and to evaluate predictors of treatment satisfaction. Furthermore, the impact of participation in a Patient Support Program (PSP) is evaluated.

Study Design

A Non-Interventional Study (NIS) in patients with relapsing multiple sclerosis (RMS) treated with Cladribine Tablets. Records are produced for patients, who are prescribed Cladribine Tablets for the first time. Recruiting period is 24 months and monitoring period for each patient is 6 months.

Population

Recruited patients (at treatment initiation or within 24 weeks after treatment initiation) are first-time users of Cladribine Tablets and receive treatment as per registered label. A signed informed consent is required. Patients with per label contraindications are excluded.

Study Size

700 patients prescribed Cladribine Tablets according to the German SPC. 100 study centers (office based neurologists and neurology departments of hospitals) in Germany.The first patient was included on January 16th, 2018

Abstract acepted for presentation at 91. DGN Congress; Berlin,Germany