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

Short Title: Design NIS Cladribine Tablets QoL evaluation

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Rationale and background

Cladribine Tablets received marketing authorisation in Germany on August 22nd, 2017. Patients' health-related quality of life (HRQoL) is an important patient reported outcome for overall benefit assessment. To date there are no data in a real-world setting (clinical practice) on QoL of RMS patients treated with Cladribine Tablets. There are also no real-world longitudinal data on cognitive status as well as data of advantages and disadvantages of Cladribine Tablets from a patient's perspective.

Research question and objectives

This study will provide a prospective assessment and annual follow-up (primary endpoint 24 months) of health-related quality of life of RMS patients under therapy with Cladribine Tablets. The objectives are to investigate quality of life (by MSQoL-54), cognitive status, treatment satisfaction, relapse rate, fatigue and disability progression. Furthermore, employment status and maintenance of treatment effect between 2 and 4 years, post-treatment start will be investigated. Other objectives (Exploratory) are Cladribine Tablets administration related aspects, participation in Patient Support Program (PSP) and correlation with treatment satisfaction and quality of life.

Study Design

A Non-Interventional Study (NIS) in patients with relapsing multiple sclerosis (RMS) treated with Cladribine Tablets. Recruitment period is 2 years and monitoring period for each patient is 4 years. In addition to a baseline visit, records should be produced on an annual basis.

Population

Recruited patients are first-time users of Cladribine Tablets and received treatment as per registered label. A signed informed consent is required. Patient with per label contraindications are excluded.

Study Size

Study Size: 385 patients with RMS who are prescribed Cladribine Tablets according to the German SPC. 75 study centres (office based neurologists and neurology departments of hospitals) in Germany. The first patient was included on March 08th, 2018.