Rationale and Feasibility of a Phase IV Study (CLASSIC MS) Assessing Long-Term Efficacy Outcomes for Patients with Multiple Sclerosis Treated with Cladribine Tablets in the Phase III Trials

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ABSTRACT

Introduction

The CLASSIC MS study will be a phase IV ambispective study evaluating long-term efficacy outcomes, durability of effect and real-world treatment patterns in patients who participated in these trials.

Objectives

• To evaluate the success of the study will depend on data availability, data quality and willingness of the patients and study centers from the original Phase III studies to participate.

Methods

A survey was conducted to determine the numbers of study sites, patients and data available for inclusion in the CLASSIC MS study.

Results

• Of 302 centres contacted, 277 were eligible to participate in the survey (Figure 1).
• 180 sites had not enrolled any patients in the original studies (n=180).
• 80 sites had enrolled patients in the original studies but were not included in the analysis (Figure 2).
• 617 patients were enrolled into ORACLE-MS.

• A retrospective review of medical records was performed by ~45% of sites between the end of the phase III study and the time of the survey providing information on 50% of the CLARITY patient population.

• A survey was sent electronically to the centres, comprising 26 English language questions.

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• The success of the study will depend on data availability, data quality and willingness of the patients and study centres from the original Phase III studies to participate.

• The majority of sites (74%) need ≥3 weeks to retrieve the retrospective data from patient medical records and to transcribe it into eCRF.

Conclusion

This survey demonstrates the feasibility of CLASSIC MS, with relevant data availability and a willingness to participate from survey respondents.

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DISCLOSURES

All authors have been involved in the study and have contributed to any potential conflicts of interest.

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