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Title: 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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Short title to be displayed on app: Feasibility of the CLASSIC MS study

Background: Treatment with Cladribine Tablets 3.5mg/kg (given as two short courses of 1.75mg/kg per year over two consecutive years) demonstrated significant benefits in patients with relapsing-remitting multiple sclerosis or first clinical demyelinating event across three phase III trials (CLARITY, CLARITY Extension and ORACLE). CLASSIC MS is 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. The success of the study depends on high participation rates from patients and study centres from the original studies. The feasibility survey for CLASSIC MS is presented here.

Methods: A survey was conducted to determine the numbers of study sites/patients and data availability for inclusion in CLASSIC MS. Surveys were sent July 2017 with responses recorded until November 2017.

Results: Of 302 centres contacted, 277 were eligible to participate in the survey, ineligibility was mainly due to not having enrolled patients in the original studies (n=15). Responses were obtained from 138 centres, of which 18 had not enrolled any patients. The remaining 120 responses in the feasibility analysis represent 1087 patients (56%) of 1943 eligible patients that constituted the intention-to-treat cohorts of the three Phase III studies. Of these, 717 patients continue to be followed at the same centre. A further 100 patients are known to be in follow-up at other, but known, centres. Access to medical records for deceased patients was reported by 37% of respondents. Medical records are available in electronic (55%) and paper (45%) formats. Most centres (85–96%) reported having relapse data, details of the rationale for treatment selection

following investigational medicinal product administration, resources and interest in participating in CLASSIC MS.

Conclusions: This survey demonstrates the feasibility of CLASSIC MS, with a good amount of relevant data availability and a willingness to participate from survey responders.

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Author disclosures

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