Longitudinal Observation of SPMS Patients Treated with Siponimod in Germany – Two Years Interims Data from Real World Study AMASIA

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Background

The selective sphingosine-1-phosphate receptor modulator siponimod is approved for the treatment of relapsing forms of MS in the US and for the treatment of active secondary progressive multiple sclerosis (SPMS) in the EU. Real-word data on the long-term effectiveness and safety of siponimod will support treatment decisions.

Objectives

The non-interventional AMASIA study aims to investigate the long-term effectiveness and safety of siponimod for the treatment of patients suffering from active SPMS in a real-world setting and provides insight into the impact on disease progression and quality of life as well as clinical routines in Germany.

Methods

In this ongoing multi-center non-interventional study in Germany, 670 siponimod-treated active SPMS patients are followed over 2-3 years. Every 6 months, disability progression and changes in cognitive performance and fatigue are evaluated by EDSS, FSMC and SDMT. The perspectives of patients, physicians, and relatives on disability progression, cognitive worsening and quality of life are documented using specific questionnaires. Here we present data from patients treated with siponimod for up to 24 months.

Results

24 months follow-up data from approximately 240 active SPMS patients receiving siponimod for the first time expand on previously presented findings and give insight into the real-world clinical practice in Germany. At baseline, AMASIA participants were already significantly impaired in the functional domains of disability, cognition and fatigue, as measured by EDSS, SDMT, and FSMC. Stabilization of these

measures indicates a sustained effectiveness of siponimod over 2 years in preventing further disease progression. Effectiveness was not restricted by patient age, baseline EDSS, or time since diagnosis of MS according to subgroup analyses. However, younger patients and patients who started siponimod treatment earlier after disease onset showed greater benefit. Regardless of age, TSQM subscores for effectiveness, convenience, and global treatment satisfaction remained on a high level throughout the observational period.

Conclusion

AMASIA provides real-world evidence on the use of siponimod in the treatment of active SPMS patients in Germany. While our data confirm a particular benefit from siponimod for younger patients and patients who are treated early after disease onset, advanced deficits in baseline EDSS, SDMT, and FSMC illustrate the challenges in timely diagnosis of SPMS. Multimodal clinical and behavioral phenotyping of MS patients is required since biomarkers are still lacking.

Disclosure

Olaf Hoffmann served on scientific advisory boards, received speaker honoraria from Alexion, Bayer Healthcare, Biogen, Bristol Myers Squibb/Celgene, Janssen, Merck, Novartis, Roche, Sandoz, Sanofi, Teva; received financial support for research activities from Biogen, Novartis, and Sanofi.

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