Real world insight into the characteristics of siponimod treated SPMS patients in Germany from the AMASIA study

Olaf Hoffmann[1], Herbert Schreiber[2], Luisa Klotz[3], Martin S. Weber[4], Cordula Weiss[5], Tjalf Ziemssen[6]

[1]Department of Neurology, St. Josefs-Krankenhaus, Allee nach Sanssouci 7, 14471 Potsdam, Germany; Medizinische Hochschule Brandenburg Theodor Fontane; 16816 Neuruppin, Germany.

[2]Neurological Practice Center Ulm, Pfauengasse 8, 89073 Ulm, Germany.

[3]University Hospital Münster, Department of Neurology with Institute of Translational Neurology, Albert-Schweitzer-Campus 1, 48149 Münster, Germany.

[4]Institute of Neuropathology, University Medical Center Goettingen, Robert-Koch-Str. 40, 37075 Goettingen, Germany; Fraunhofer Institute for Translational Medicine and Pharmacology ITMP, Goettingen, Germany.

[5]Novartis Pharma GmbH, Roonstr. 25, D-90429 Nuernberg, Germany.

[6]Department of Neurology, Center of Clinical Neuroscience, Carl Gustav Carus University Clinic, University Hospital of Dresden, Fetscherstr. 74, 01307, Dresden, Germany.

Introduction

The non-interventional AMASIA study aims to investigate the long-term effectiveness and safety of siponimod for the treatment of patients with active SPMS in a real-world setting. The study also provides insight into siponimod patient profiles and clinical routines in Germany.

Methods

Siponimod-treated SPMS patients are followed over 3 years. Every 6 months, disability progression and cognitive changes are evaluated by EDSS and SDMT. Questionnaires from the perspective of patients and physicians on disability progression, cognitive worsening and quality of life are documented.

Results

According to previous interim analyses of the AMASIA population, patients on average were 54.5 years old and had been diagnosed with MS for 17.4 years when starting siponimod treatment. The largest group of patients (more than 45%) were switched to siponimod from moderately effective therapies, while about 10% were treatment-naïve. Here, we expand these previous analyses by analyzing the complete patient population, following the end of the recruitment period in January 2023. In addition to patient characteristics, details on MS activity, FSMC, SDMT and UKNDS scores and medical history are reported. Results are compared to data from the pivotal clinical trial EXPAND to obtain further insight.

Conclusion

Data and characteristics of the AMASIA study population enable a comparison of clinical trial data to the average siponimod patient treated in routine clinical practice, thus potentially facilitating translation into real-

life therapeutic strategies by underlining the importance of a timely SPMS diagnosis and treatment intervention.

Disclosure

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

Herbert Schreiber received research grants and honoraria from Almirall, Bayer Healthcare, Biogen, Merck, Novartis, Roche, and Teva.

Luisa Klotz received compensation for serving on scientific advisory boards, speaker honoraria, travel support, research support from Alexion, Janssen, Novartis, Merck Serono, Sanofi Genzyme, Roche, Biogen, TEVA. She receives research funding from the Deutsche Forschungsgemeinschaft (DFG), the German Ministry for Education and Research, the Interdisciplinary Center for Clinical Studies (IZKF) Muenster, and the Innovative Medical research Muenster.

Martin S. Weber received research support from the DFG (DFG; WE 3547/5-1), Novartis, TEVA, Biogen-Idec, Roche, Merck, and the ProFutura Programm of Uni Göttingen; editor for PLoS One; received travel funding and/or speaker honoraria from Biogen, Merck Serono, Novartis, Roche, TEVA, Bayer, and Genzyme.

Cordula Weiss is an employee of Novartis Pharma GmbH, Germany.

Tjalf Ziemssen received speaking honoraria and financial support for research activities from Almirall, Biogen, Celgene, Novartis, Roche, Teva, and Sanofi.

This study is financed by Novartis Pharma GmbH, Nuremberg, Germany.