SWISSMASIA: Swiss Study of the Impact of siponimod (Mayzent) on SPMS Patients in a Long-term Non-interventional Study

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Introduction: Siponimod (Mayzent®), a selective sphingosine-1-phosphate receptor modulator, received Swiss marketing authorization in October 2020 for the treatment of adult Secondary Progressive Multiple Sclerosis (SPMS) patients with active disease. Here, we present the design of the SWISSMASIA trial (NCT04895202), a prospective non-interventional real-world phase 4 study that aims to describe the long-term effectiveness and safety of siponimod in clinical routine using clinical and patient-reported outcomes.

Methods: A total of 60 patients with active SPMS treated with siponimod as per Swiss label and local clinical practice will be enrolled in the study. The observation period will run over three years and visits will be recorded every 6 months (+/- 3 months) according to clinical routine. The primary endpoint will measure the change of Expanded Disability Status Scale (EDSS) after 36 months vs baseline. Secondary endpoints will include the evaluation of disability progression, cognitive processing speed, walking speed, quality of life, fatigue, upper limb function, safety and tolerability. SWISSMASIA protocol has been based on German AMASIA study (Ziemssen T et al., JMIR Res Protoc, 2020) which will allow for pooled data analysis.

Results: SWISSMASIA was approved by the competent ethics committee on August 4th, 2021 and the first patient was enrolled November 19th, 2021. First results are expected in 2024.

Conclusion: This study will complement the pivotal phase III results of siponimod in SPMS (EXPAND study NCT01665144) with real-world effectiveness and safety data from Swiss patients.

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