AMASIA Study - Real World Insights on Siponimod Treated Patients with Secondary Progressive Multiple Sclerosis in Germany

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Introduction

- 85% of Multiple Sclerosis (MS) patients are initially diagnosed with relapsing-remitting MS (RRMS).[1]
- 60% will probably convert to secondary progressive MS (SPMS) within 20 years due to evolvement of the disease over time.[2,3]
- Progressive motor dysfunction and cognitive decline are typical hallmarks of SPMS.[4-7]
- The EMA has approved siponimod (Mayzent®), a selective sphingosine-1-phosphate receptor modulator, specifically for the treatment of active SPMS as evidenced by relapses or imaging features of inflammatory activity.
- First real-world evidence on the long-term effectiveness and safety of siponimod as well as the impact on quality of life and socioeconomic conditions is analyzed in the prospective non-interventional study AMASIA (Imp**A**ct of **M**ayzent® (siponimod) on second**A**ry progressive multiple **S**clerosis patients in a long-term non-**I**nterventional study in Germ**A**ny).

Objective

The non-interventional AMASIA study will provide real-world evidence on the long-term effectiveness and safety of siponimod as well as its impact on quality of life.

Methods

Study design

- Non-interventional (**Figure 1**)
- 1,200 siponimod-treated SPMS patients
- 3 years follow-up in 250 centers across Germany
- Study visits every 6 months

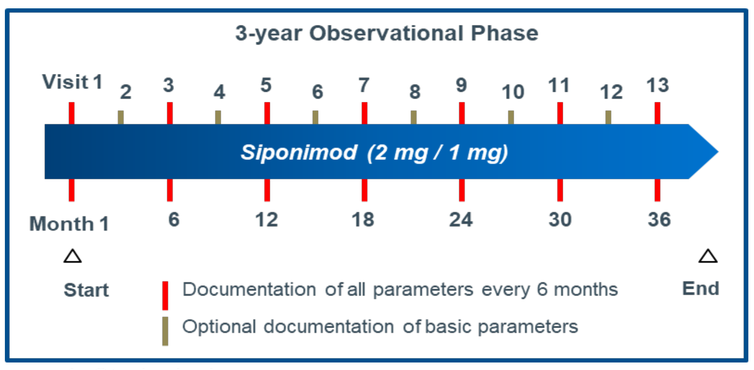

Figure 1: *Study design.*

Assessment

Clinic: Ophthalmic and physical evaluation, laboratory

MS-activity: Magnetic Resonance Imaging (MRI), MS Activity Scale Score (MS-AS), Expanded Disability Status Scale (EDSS)

Functional domains: Symbol Digit Modalities Test (SDMT), EDSS

Patient's perspective: United Kingdom Neurological Disability Scale (UKNDS), Fatigue Scale For Motor And Cognitive Functions (FSMC), EuroQol-5D (EQ-5D)

Physician's perspective: Clinical Global Impression (CGI), progression questionnaire

Socioeconomic factors: Multiple Sclerosis Health Resource Survey (MS-HRS)

Results

Baseline characteristics

Table 1: *Baseline characteristics.*

Variable	AMASIA
Number of patients (n)	584
Age [years] (mean ± SD)	54.5 (8.4)
Time since first MS diagnosis [years] (mean ± SD)	17.4 (9.2)
EDSS (mean ± SD)	5.3 (1.4)
SDMT (mean ± SD)	40.1(13.8)
Patients with relapse during last 24 months (%)	49.0

*Represents population of the EMA label, SD = standard deviation

- As of June 9th, 2022, 584 patients were enrolled in AMASIA and included in this interim analysis.
- Baseline data of AMASIA patients are shown in **Table 1**.
- As last pretreatment prior to siponimod, more than half of the patients received moderately effective therapies or were untreated (**Figure 2**).

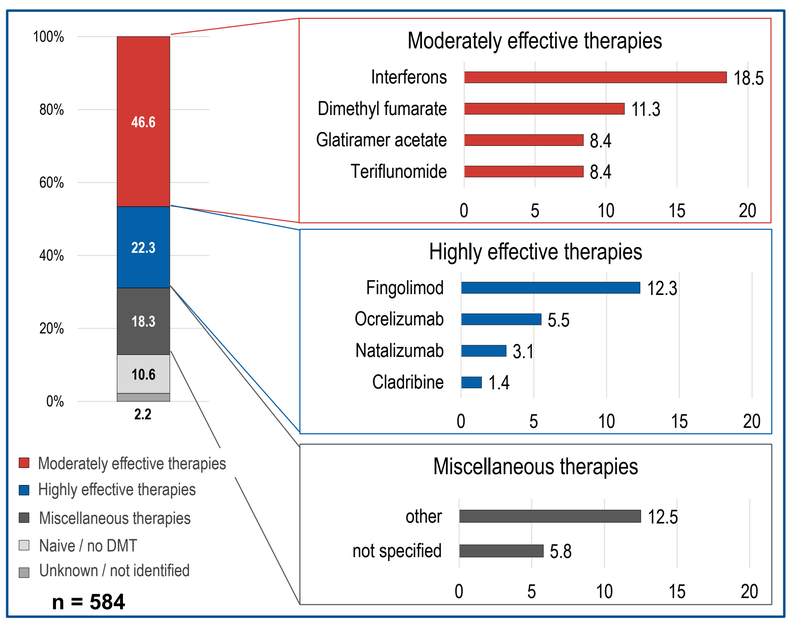

Figure 2: *Last treatment before siponimod (AMASIA).*

As of June 9th, 2022, subgroups were analyzed in further detail. Subgroups included separation by age and by time between diagnosis and inclusion into study (date of informed consent) (**Figure 3**). Additional subgroups were based on prior moderately effective therapy (interferons, glatiramer acetate, DMF/TFN = dimethyl-fumarate and teriflunomide; **Figure 4**).

However, the results have to be seen as preliminary as up to June 9th only small cohorts could be assessed.

EDSS remained stable during the first twelve months on siponimod, regardless of age or time since diagnosis at study start (time of informed consent) (**Figure 3**) and regardless of last pretreatment (moderately effective therapy) before study start (**Figure 4**).

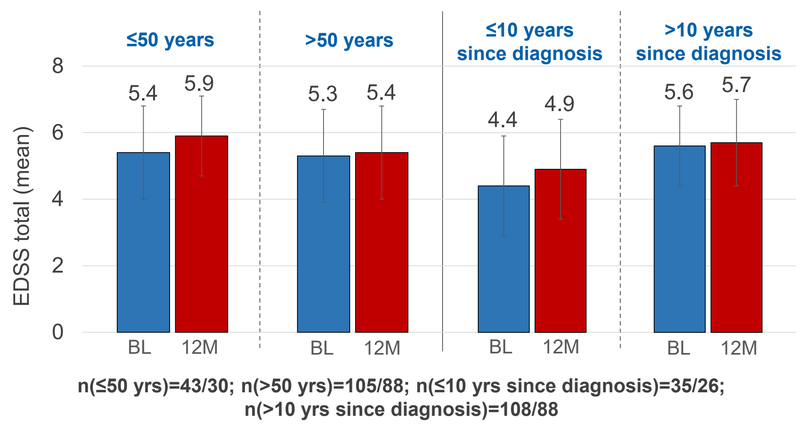

Figure 3: *EDSS score at baseline (BL) and after 12 months (12M) on siponimod by age of patient (≤50 vs. >50 years) and by time since diagnosis (≤10 vs. >10 years).*

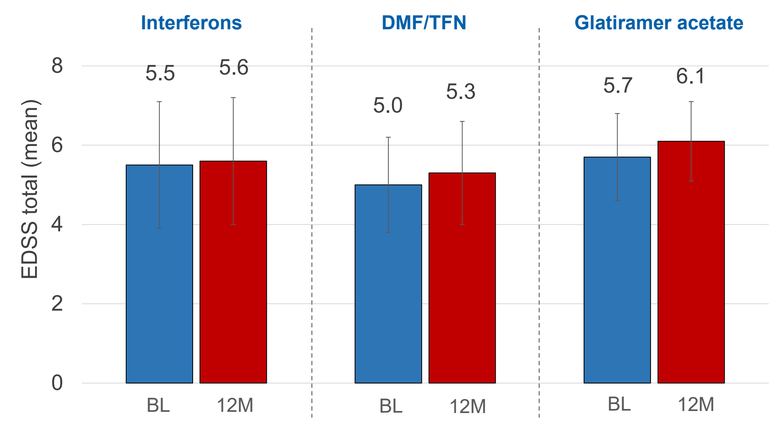

Figure 4: *EDSS score at baseline (BL) and after 12 months (12M) on siponimod by type of last treatment before study.*

TSQM scores show high levels of "Global Satisfaction", "Convenience", and "Effectiveness" after 12 months on siponimod regardless of previous type of moderately effective therapy (**Figure 5**).

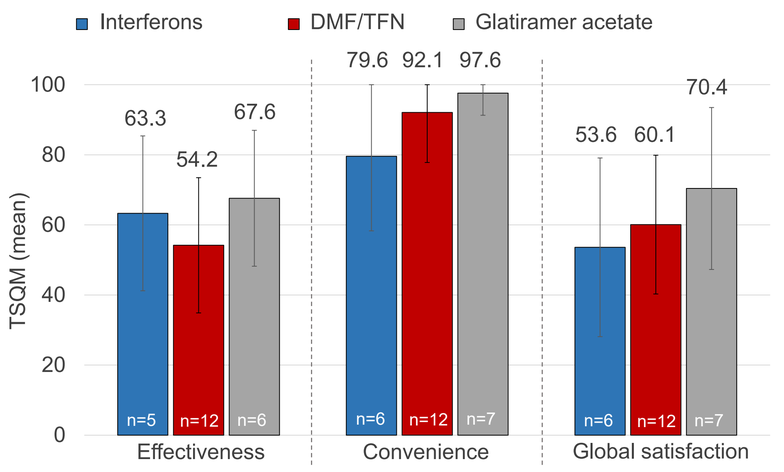

Figure 5: *TSQM scores* "Effectiveness", "Convenience", and "Global Satisfaction" after 12 months on siponimod, grouped by prior therapy (interferons, DMF/TFN, glatiramer acetate).

Conclusions

- The results provide insight into the profile of siponimod patients in routine clinical practice.
- As last pretreatment prior to siponimod, more than half of the patients received moderately effective therapy or were untreated.
- Disease status as reflected by EDSS remained stable during 12 months of siponimod therapy regardless of age or time since diagnosis.
- EDSS remained stable after 12 months on siponimod regardless of last moderately effective therapy before study start.
- Preliminary TSQM scores indicate high levels of "Effectiveness", "Convenience" and "Global Satisfaction" after 12 months on siponimod, regardless type of moderately effective therapy before study start. "Convenience" in particular was rated highly.
- **AMASIA enables a comparison of clinical trial data and outcomes in the actual real-world treatment context. Subgroup analyses give additional insights.**

References

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Disclosures

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