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

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CONCLUSIONS

1. **At study start, mean patient age was 55 years. 87% were 45 years or older. MS had been diagnosed about 17 years prior to study start. More than two thirds of patients are female.**
2. **The mean EDSS at baseline was 5.1. Almost 90% of patients presenting with an EDSS of 3.5 or higher. More than one third had an EDSS of 6 or 6.5.**
3. **Before switching to siponimod, nearly half of all patients had received a moderately effective therapy, mostly interferons. Almost one quarter of patients had received a highly effective therapy as last pretreatment. About 10% were treatment naive.**
4. **The majority of patients (86%) suffered from at least one comorbidity. Nervous system and psychiatric disorders were the most often reported concomitant disorders.**
5. **AMASIA provides insight into the average population treated with siponimod in routine clinical practice. Results underline the importance of timely diagnosis and treatment of SPMS. They may facilitate the development of real-life therapeutic strategies.**

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INTRODUCTION

- 85% of Multiple Sclerosis (MS) patients are initially diagnosed with relapsing-remitting MS (RRMS).[1]
- 60% will convert to secondary progressive MS (SPMS) within 20 years due to evolvement of the disease over time.[2,3]
- In the EU, siponimod, a selective sphingosine-1-phosphate receptor modulator, is approved specifically for the treatment of active SPMS as evidenced by relapses or imaging features of inflammatory activity.
- Randomized controlled trials (RCTs) impose rigid inclusion criteria and assessment schedules for outcome parameters, whereas the general patient population seen in clinical routine is more variable. Thus, data from real world settings are mandatory to complement data obtained from RCTs.

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

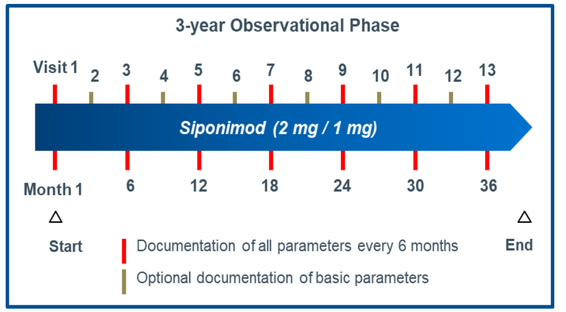
Study Design

- Non-interventional study, observational phase: 2-3 years with study visits every 6 months (Fig. 1)
- 673 siponimod-treated SPMS patients with disease activity at 104 sites in Germany out of which 670 patients were available for the analysis

Assessment

- Clinic: Laboratory, ophthalmic, and physical evaluation
- 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.

Figure 1. Study design.



RESULTS

Demography

- The baseline data of AMASIA patients after completion of recruitment (cut-off February 9th, 2023) are compared to the active SPMS subgroup population of the pivotal EXPAND RCT (Tab. 1) .
- The real-life population of AMASIA seems older with a longer disease history and a higher proportion of relapses within the 24 months before study start in comparison to the active subgroup of EXPAND.

Table 1. Patient characteristics at baseline.

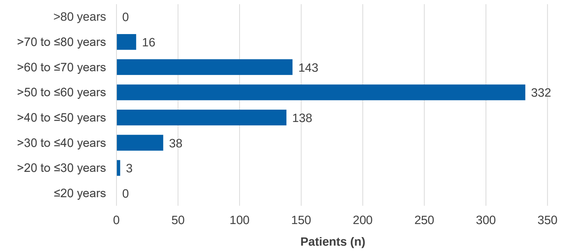
Variable	AMASIA	EXPAND (active SPMS subgroup[a])
Number of patients (n)	670	779
Age, n=670 (years) (± SD)	55±8.4	47
Time since first MS diagnosis, n=633 (years) (± SD)	17.3±9.5	13
EDSS, n=618 (score) (± SD)	5.1±1.5	6
SDMT, n=529 (score) (± SD)	39.7±13.1	38.3
Patients with relapse (past 24 months) (%)	43.1	36

[a] Represents population of EMA label.

- The majority of the study population is female (69%) (Fig. 2).
- At baseline, most patients were between 50 and 60 years old (Fig. 3), the youngest patient was 27 and the oldest 78 years of age. About 87% were aged 45 years or older at baseline.

Figure 2. Gender distribution at baseline; n=670.

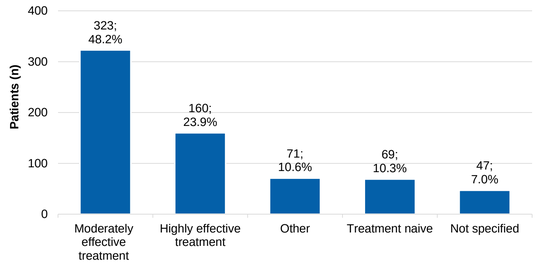
Figure 3. Age distribution at baseline; n=670.



Previous Therapies

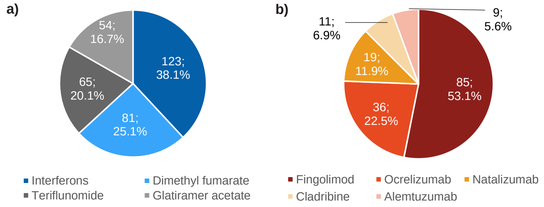
- Before switching to siponimod, most patients (89.7%) had received at least one treatment other than siponimod (Fig. 4)
- The time between the end of the last pretreatment and study start varied between 0 months (min.) and 313.3 months (max.). The median time was 5.0 months.
- Nearly half of all patients (48.2%) were prescribed a moderately effective therapy as last treatment before switching to siponimod (Fig. 4). Out of these, the majority was treated with interferons (38.1% of patients who had received a moderately effective therapy, 18.4% of all patients) (Fig. 5a).
- About one quarter of patients (23.9%) had received a highly effective therapy before study start (Fig. 4). Most reported fingolimod as their last pre-treatment (53.1% of patients who had received a highly effective therapy, 12.7% of all patients) (Fig. 5b).
- 10.3% of patients were treatment naive when enrolling into the study (Fig. 4).

Figure 4. Last therapy before starting siponimod treatment.



[a] Moderately effective treatment: interferons, dimethyl fumarate, teriflunomide, glatiramer acetate. [B] Highly effective treatment: fingolimod, ocrelizumab, natalizumab, cladribine, alemtuzumab. [C] Other: mitoxantrone, azathioprine, daclizumab, rituximab.

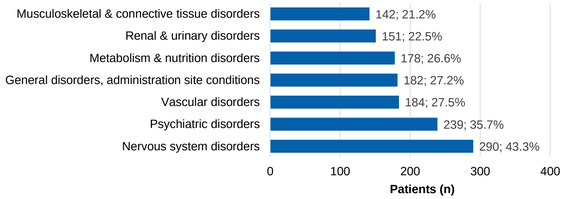
Figure 5. Last therapy before starting siponimod treatment. 5a) Moderately effective therapies. 5b) Highly effective therapies.



Concomitant disorders

- In total, 579 patients (86.4%) reported at least one concomitant disorder, most often a nervous system disorder (43.3%) or a psychiatric disorder (35.7%) (Fig. 6).

Figure 6. Concomitant disorders (cut-off 20%); n=670.



Disability Status

- At baseline, about 87% of patients presented with an EDSS score of 3.5 or higher. Overall, most patients had an EDSS score of 6 or 6.5 at study start (Fig. 7).
- The impact on functional domains at baseline varied considerably within the study population with ambulation and pyramidal functions being most affected (Fig. 8).

Figure 7. EDSS distribution at baseline; n=618.

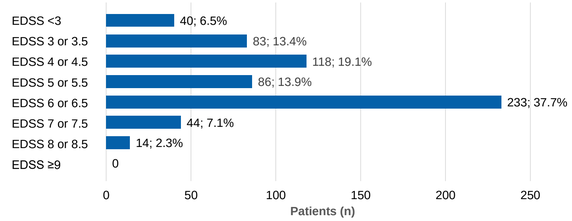
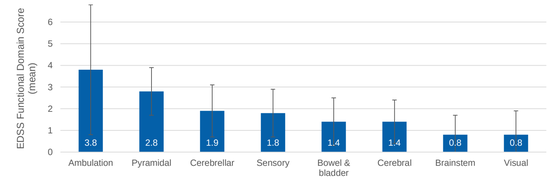


Figure 8. EDSS functional domain scores at baseline; n=256.



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