# Novel Generation of Real World Evidence through MSGo, a Digital Support Program Supporting the Use of Siponimod in Secondary Progressive Multiple Sclerosis Patients in Australia

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## Introduction

Siponimod (Mayzent) is approved in Australia for adults with secondary progressive multiple sclerosis (SPMS)[1]

Initiating siponimod involves pre-screen tests, including a CYP2C9 genotype test to determine siponimod maintenance dosing, and patients undergo a 6-day titration prior to maintenance

To support onboarding, an integrated digital platform, 'MSGo', has been developed by Novartis and RxMx® for Healthcare Professionals and their multiple sclerosis patients

## Objective

**Primary objective:** To evaluate the time to onboarding siponimod in Australian SPMS patients

**Secondary objective:** To evaluate adherence during titration and the first 3 months of maintenance treatment and to explore how patient demographics and HCP/laboratory assessments, influence onboarding and adherence to Mayzent

## Methods

Up to 500 adults with SPMS will be enrolled over a period of approximately 12 months

Analyses will be carried out from data exclusively extracted from the MSGo platform (Figure 1)

**Primary endpoint:** Average time for siponimod onboarding, (days between patient MSGo registration to taking the first dose of siponimod)

**Secondary endpoint:** Rate of adherence to siponimod and sub-group analyses determining the absolute and relative differences for onboarding time and adherence

## Results

### Baseline patient characteristics

An interim analysis, triggered on April 19th, 2021, included a total 211 patients

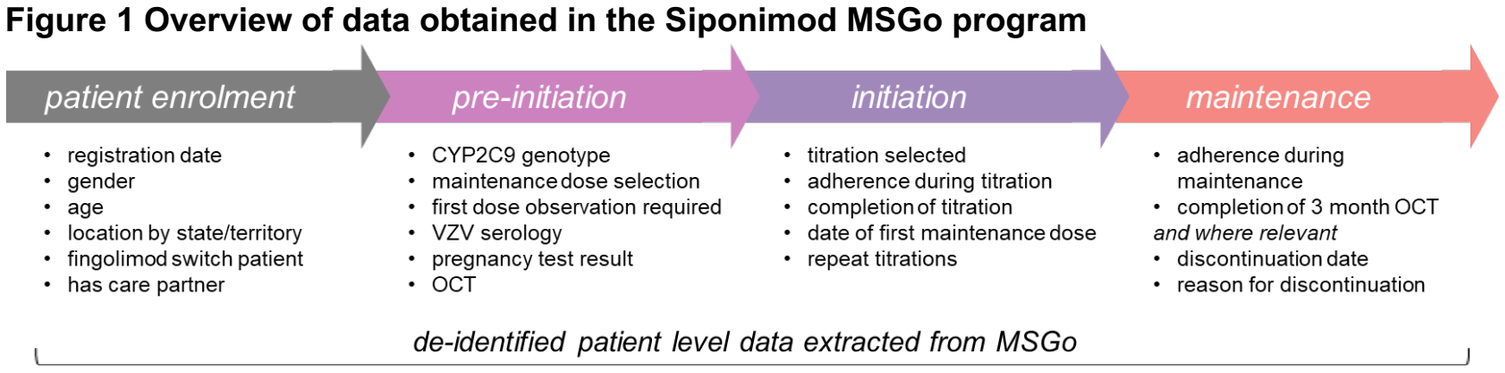
Baseline patient characteristics (Table 1) revealed more females than males (70% vs 30%), a median age range of 51-60 years and 13% of patients nominating a care partner

**Table 1 Baseline characteristics and confirmed siponimod initiation**

| | Registered | Initiated Tx |
|---|---|---|
| All patients | 211 (100) | 93 (100) |
| Gender | | |
| male | 64 (30) | 26 (28) |
| female | 147 (70) | 67 (72) |
| Age (years) | | |
| 18-30 | 0 (0) | 0 (0) |
| 31-40 | 10 (5) | 7 (8) |
| 41-50 | 32 (15) | 13 (14) |
| 51-60 | 69 (33) | 30 (32) |
| 61-70 | 78 (37) | 35 (38) |
| >70 | 22 (10) | 8 (9) |
| Care partner | | |
| yes | 27 (13) | 17 (18) |
| no | 184 (87) | 76 (82) |

n (percentage of subgroup)

**Figure 1 Overview of data obtained in the Siponimod MSGo program**




Data was obtained during and after onboarding, including at enrolment, pre-initiation, initiation and maintenance

### Onboarding time

Ninety-three patients (44%) proceeded to siponimod initiation; eighty-eight (42%) via titration. Seventy-five patients (36%) recorded ≥ 1 day of maintenance

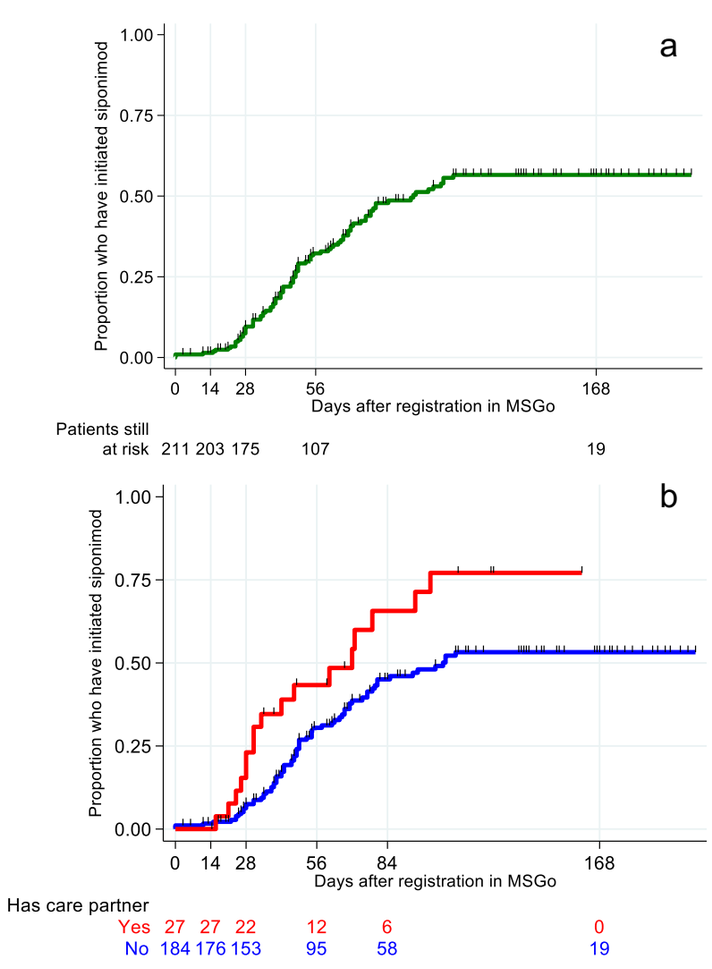
A median time to initiation of 53 days was estimated in the predicted population of patients who will ever initiate on siponimod (Figure 2a)

Patients with a nominated care partner had faster onboarding (HR: 2.0, p=0.011) (Figure 2b)

Neither age nor gender significantly correlated with differences in onboarding

Seven patients unenrolled prior to siponimod initiation whilst 10 patients ceased after initiation

**Figure 2 Siponimod onboarding time**




Days from registration to siponimod initiation (Kaplan-Meier survival curve and fitting mixture model) in the entire cohort (a) and for patients with/without a nominated care partner (b)

### CYP2C9 genotype testing

In total, 163 genotype assessments were performed through MSGo and the median time to receiving results from registration was 21 days

Dose selection was completed for 87 patients (Table 2) with all but one patient having the recommended[1] maintenance dose

A maintenance dose of 1 mg was selected for a patient with a rare *1*5 genotype which currently has no dose recommendation[1]

**Table 2 Maintenance dose selection by CYP2C9 genotype**

| | 1 mg | 2 mg |
|---|---|---|
| CY2C9 genotype | | |
| *1*1 | 0 | 58 |
| *1*2 | 0 | 13 |
| *2*2 | 0 | 1 |
| *1*3 | 10 | 0 |
| *2*3 | 4 | 0 |
| Other | 1† | 0 |

† *1*5 (no recommended dosing)

### Conclusions

- Median time to initiate siponimod was 53 days
- Patients with care partners onboarded more quickly, underscoring the importance of personalised support for SPMS patients
- Median time to complete CYP2C9 genotyping was 21 days and dose selection was aligned to local recommendations[1]
- These interim results provide early insights into siponimod onboarding for SPMS patients in Australia and explore the utility of MSGo during a period challenged by COVID-19 and related vaccination considerations

**References**

1. MAYZENT® TGA-approved Product Information. Novartis Pharmaceuticals Australia Pty Ltd.

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