EP1377

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

Todd Hardy[1], Patrick Aouad[2], Michael Barnett[1,3], Stefan Blum[4,5], Simon Broadley[6], William Carroll[7], Denis Crimmins[8], Dayna Griffiths[9], Suzanne Hodgkinson[10], Jeannette Lechner-Scott[11,12], Andrew Lee[13], Ram Malhotra[14], Pamela McCombe[15], John Parratt[2,16], Chris Plummer[17], Anneke van der Walt[18], Kate Martel[19] and Rob Walker[19]

1. Brain and Mind Centre, University of Sydney, Camperdown, Australia, 2. University of Sydney, Northern Clinical School, Sharp Neurology and North Shore Private Hospital, St Leonards, Australia, 3. Royal Prince Alfred Hospital, Camperdown, Australia, 4. Faculty of Medicine, The University of Queensland, Brisbane, Australia, 5. Department of Neurology, Princess Alexandra Hospital, Brisbane, Australia, 6. School of Medicine, Gold Coast Campus, Griffith University, Southport, Australia, 7. Department of Neurology Sir Charles Gairdner Hospital and Perron Institute, Nedlands, Australia, 8. Central Coast Neurosciences Research, Erina, Australia, 9. Central Coast MS Clinic, Gosford Hospital, Gosford, Australia, 10. Liverpool Hospital, Liverpool, Australia, 11. Hunter Medical Research Institute, University of Newcastle, New Lambton Heights, Australia, 12. John Hunter Hospital, Hunter New England Local Health District Australia, New Lambton, Australia, 13. Flinders University College of Medicine and Public Health, Flinders Medical Centre, Bedford Park, Australia, 14. Canberra Specialist Centre, Deakin, Australia, 15. University of Queensland, St Lucia, Australia, 16. Department of Neurology and Clinical Neurophysiology, Royal North Shore Hospital, St Leonards, Australia, 17. St Vincent's Hospital Melbourne, Centre for Neurosciences and Neurological Research, Fitzroy, Australia, 18. Department of Neuroscience, Central Clinical School, Monash University, Melbourne, Australia, 19. Novartis Pharmaceuticals Australia, Macquarie Park, Australia**

Introduction

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

An integrated digital platform, 'MSGo', was developed by Novartis and RxMx® to support healthcare professionals and their multiple sclerosis patients to complete the onboarding process that includes CYP2C9 genotype test to determine a siponimod maintenance dose, and the 6-days of dose titration. The data available through the patient support program were utilised in a secondary use of data study to capture the Australian experience of siponimod patient onboarding.

Objective

Primary objective

To characterise the siponimod onboarding experience of SPMS patients in Australia in relation to pre-initiation duration.

Secondary objectives

To characterise adherence to treatment during titration and up to the first 3 months of maintenance and explore how patient demographics and HCP/laboratory assessments, influence SPMS patient onboarding and adherence to siponimod.

Methods

The final analysis included 368 patients enrolled in the study prior to 20th April 2022.

Analyses was carried out from data exclusively extracted from the MSGo platform.

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

Aligned with the results presented for the interim analysis[2], the baseline patient characteristics (Table 1) show more females than males (71% vs 29%), a median age range of 51-60 years and 11% of patients nominating a care partner.

Table 1 Baseline characteristics and confirmed siponimod initiation

	Registered	Initiated Tx
All patients	368 (100)	237 (100)
Sex		
Male	107 (29)	63 (27)
Female	261 (71)	174 (73)
Age (years)		
18-30	1 (0)	0 (0)
31-40	17 (5)	13 (5)
41-50	62 (17)	43 (18)
51-60	132 (36)	85 (36)
61-70	118 (32)	74 (31)
>70	38 (10)	22 (9)
Care partner		
Yes	42 (11)	36 (15)
No	326 (89)	201 (85)

n (percentage of subgroup)

Onboarding

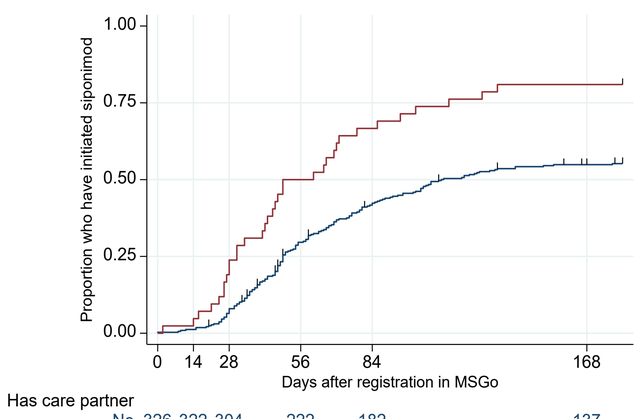
Analysis of time to first dose identified 211 patients that commenced titration, with an estimated median time to initiation of 56 days (95% CI 47-59) in the predicted population of patients who will ever initiate siponimod.

Patients with a nominated care partner had faster onboarding (HR: 2.1 95% CI 1.5-3.0, p=0.0003) (Fig 1).

Among those who initiated siponimod and reported a delay in initiation, the most common reason for delay was 'waiting for vaccination' (11/21 patients) followed by 'HCP choice' (5/21 patients).

Figure 1. Siponimod initiation time by care partner sub-group

Days from registration to siponimod initiation (Kaplan-Meier survival curve) by care partner sub-group



CYP2C9 genotype testing

In total, 294 genotype assessments were performed through MSGo and the median time from registration to receiving results was 19 days (95% CI 17-21). Dose selection was completed for 195 patients with all but two patients having the recommended[1] maintenance dose. A maintenance dose of 1 mg was selected for two patients with rare *1*5 and *1*11 genotypes which have no dose recommendation[1] (Table 2).

Table 2. Maintenance dose selection by CYP2C9 genotype

	1 mg	2 mg
CYP2C9 genotype		
*1*1	0	122
*1*2	0	43
*2*2	0	1
*1*3	21	0
*2*3	6	0
Other	2	0

Adherence analysis

Of the patients enrolled in MSGo, 206 had ≥1 maintenance dose of siponimod with 193 accepting the app terms of service that enabled database maintenance dose entry.

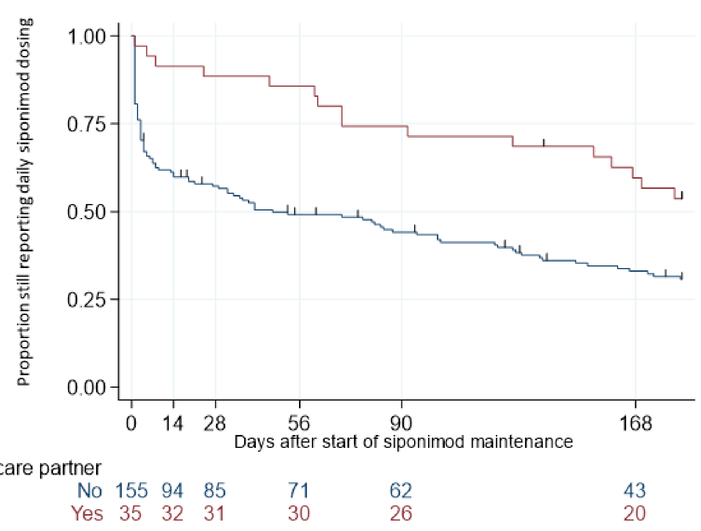
The treatment reminder function in MSGo, used to capture the reporting of daily treatment, identified an ~25% fall in reporting at commencement of maintenance which continued to decline over time.

Patients with a nominated care partner were twice as likely to continue to self-report siponimod dosing (HR: 2.2, 95% CI 1.3-3.7, p=0.0002) (Fig 2).

Analysis of the age sub-group revealed a non-significant trend for reduced reporting with increased age with only 28% of those >70y continuing to self-report at day 90 compared to 47-69% among the younger age groups.

Figure 2 Reporting of maintenance dose

Days from start of siponimod maintenance to discontinuation of reporting (Kaplan-Meier survival curve) by care partner sub-group



Conclusions

- Median time to initiate siponimod was 56 days.
- Median time to complete CYP2C9 genotyping was 19 days and dose selection was aligned to local recommendations1.
- Patients with care partners onboarded more quickly and continued to report their siponimod dose during maintenance for a longer period, highlighting the importance of the role of the support person for people living with SPMS.
- A small proportion of HCPs who provided reasons for delayed initiation revealed the impact of COVID-19 vaccination on siponimod onboarding time
- Utilising dose self-reporting data in the real world provides an estimate of true adherence but in this case was hampered by a high proportion of opt-outs for reminders during maintenance.
- This study provides insights into siponimod onboarding for adults living with SPMS in Australia and demonstrates the impact of MSGo and care partner support during a period challenged by the COVID-19 pandemic

References

1. MAYZENT® TGA-approved Product Information. Novartis Pharmaceuticals Australia Pty Ltd.
2. Hardy, T. 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 [P864] ECTRIMS 2021. Vienna

Acknowledgments

The authors wish to thank patients participating in the MSGo RWE study. MSGo was developed with RxMx®.

The study was funded by Novartis Pharma AG, Basel, Switzerland. The final responsibility for the content lies with the authors.

Disclosures

TH has received honoraria for Biogen, Merck, Teva, Novartis, Roche, Bristol-Myers Squibb and Sanofi-Genzyme and is Co-Editor of Advances in Clinical Neurosciences and Rehabilitation. PA has received honoraria and academic travel from Biogen, Sanofi Genzyme, Novartis, Merck, Roche and Teva. MB reports research grants from Genzyme-Sanofi, Novartis, Biogen, and Merck outside the submitted work and is a co-founder of RxMx and Research Director for the Sydney Neuroimaging Analysis Centre. SB has received honoraria and travel sponsorship for Merck, Biogen, Novartis, Bayer, Sanofi Genzyme, CSL, Roche. SB has received honoraria and travel sponsorship from Novartis, Biogen-Idec, Sanofi-Genzyme, Roche, Bayer-Schering, Teva, CSL and Merck Serono and has been a principal investigator for clinical trials sponsored by Biogen-Idec, Novartis, Sanofi-Genzyme and ATARA. WC has honoraria and travel sponsorship from Bayer Schering Pharma, Biogen-Idec, Novartis, Genzyme, Sanofi-Aventis, CSL, Teva, Merck and Celgene. DC has nothing to disclose. DG has received honoraria for Merck, Novartis and Roche. SH has received honoraria and travel sponsorship from Merck, Biogen, Novartis, Atara, Roche and Sanofi. JL-S has received travel compensation from Biogen, Merck, Novartis; has been involved in clinical trials with Biogen, Novartis, Roche; her institution has received honoraria for talks and advisory board service from Biogen, Merck, Novartis, Roche. AL has nothing to disclose. RM has nothing to disclose. PM has received sponsorship from Novartis, Teva, Sanofi and Biogen. JP has received personal compensation for speaking engagements and conference travel from Biogen, Sanofi/Genzyme, Merck Serono and Roche and served on advisory boards for Sanofi/Genzyme, Novartis, Biogen and Roche and is also a recipient of the Multiple sclerosis research Australia Neil and Norma Hill inaugural junior practitioner fellowship. CP and his Neurology Department have each been paid $AUD1000 for setting up ethics and enrolment in the study for patients in the private and public clinic, respectively. AvdW served on advisory boards, receives unrestricted research grants from Novartis, Biogen, Merck and Roche and has received speaker's honoraria and travel support from Novartis, Roche, and Merck and receives grant support from the National Health and Medical Research Council of Australia and MS Research Australia. RW and KM are employees of Novartis Pharmaceuticals Australia.

Poster presented at the 38th congress of the European Committee for Treatment and Research in Multiple Sclerosis RAI Amsterdam, Amsterdam, Netherlands, 26th - 28th October, 2022.

Presenter email address: thar6109@sydney.edu.au

Scan this QR code to download a copy Poster