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Characterizing the use of ofatumumab in a real world setting (EAFToS): Secondary Use of Data Study characterizing ofatumumab onboarding and utilization in relapsing multiple sclerosis patients using MSGo : Part I - 2nd Interim Analysis

P746

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SUMMARY

1 This retrospective study provides insights into the baseline characteristics of patients initiating ofatumumab in Australia between May 2021 and August 2023, of which 26% were treatment naive and 93% of patients self-administered their dose.

2 These data show high rates of adherence during the initiation and first 3 months of maintenance phases. The high proportion of patient compliance in the Real World setting from EAFToS (>95% at 90% compliance or higher) was comparable to a clinical trial setting[1].

INTRODUCTION

- Ofatumumab (OMB) was approved in Australia for the treatment of adults with relapsing forms of multiple sclerosis (RMS) in March 2021[2].
- A patient support program (PSP), including the digital support platform “MSGo” developed by Novartis and RxPx®[3], was made available to Healthcare Professionals (HCPs) and patients to facilitate onboarding and assist with compliance to the dosing schedule.
- EAFToS[4] is a novel two part study that links MSGo data to other real world data sources.
- Part 1 is a longitudinal secondary use of data from de-identified patient-level onboarding and adherence data in MSGo.
- Part 2 is a non-interventional, longitudinal primary use of data sub-study of up to 110 participants to explore the impact of 12 – 18 months OMB dosing on relevant patient reported outcomes with respect to clinical outcomes via data linkage between MSGo, MSBase and centrally reviewed MRI findings.

OBJECTIVE

Primary Objective

- To characterize the onboarding experience and utilization of OMB of RMS patients in Australia.

Secondary Objectives

- **Part I:** To describe the profile of the patients initiating OMB and evaluate patient demographics, prior therapy and whether treatment administrator (the patient themselves, HCP, or care partner) influences compliance to treatment.
- **Part II:** To understand the impact of OMB on patient relevant outcomes relative to clinical outcomes, baseline demographics and administration of injection-location and administrator, relative to relapse rate, EDSS and changes in MRI findings in an Australian population.
- Further, we describe the results from the second Interim Analysis (IA2) from Part I of the study

METHODS

- Up to 1500 adults with RMS will be enrolled into Part I of this trial over a period of approx. 36 months.
- **Key inclusion criteria**: Adult patients diagnosed with RMS with Expanded Disability Status Scale (EDSS) of 5.5 or lower, treatment with OMB and enrolment in the study via MSGo.
- **Primary Endpoint:** The proportion of doses not completed within three days of the expected date during initiation and the first three months of maintenance.
- **Secondary Endpoint:** Rate of adherence to OMB and sub-group analyses determining the differences for onboarding time and adherence.
- **Exploratory endpoint:** Compliance per patient was calculated as the duration of exposure to OMB/duration of the on-treatment period x100%, with ≥80% and ≥90% defined as thresholds to indicate patients as compliant. Patients who had not yet commenced their maintenance dose were excluded from this analysis.

RESULTS

Baseline patient characteristics

- In IA2, 567 patients were enrolled in the study prior to 15th Aug 2023. The median time to initiate treatment from registration in MSGo was 21 days. 23 patients were excluded from the analysis of dosing compliance during initiation and maintenance as they were confirmed to have not completed initiation through the MSGo platform.
- The baseline characteristics for the IA2 cohort show 25% of patients were treatment naive compared to 22% for IA 1[5] (March 2021 to June 2022) (Table 1). In the additional 14 months to Aug 2023, the percentage of treatment naive patients increased to 28% resulting in a cumulative total of 25% of patients in IA2 being treatment naive.

Table 1: Baseline characteristics and confirmed OMB initiation

Characteristic	Registered in MSGo*	Initiated Treatment^
All patients	567 (100)	497(100)
Sex		
Male	137 (24)	120 (24)
Female	430 (76)	377 (76)
Age (years)		
18-30	68 (12)	58 (12)
31-40	143 (25)	132 (27)
41-50	159 (28)	143 (29)
51-60	118 (21)	100 (20)
> 60	79 (14)	64 (13)
Prior therapy		
Yes	426 (75)	373 (75)
No	139 (25)	122 (25)

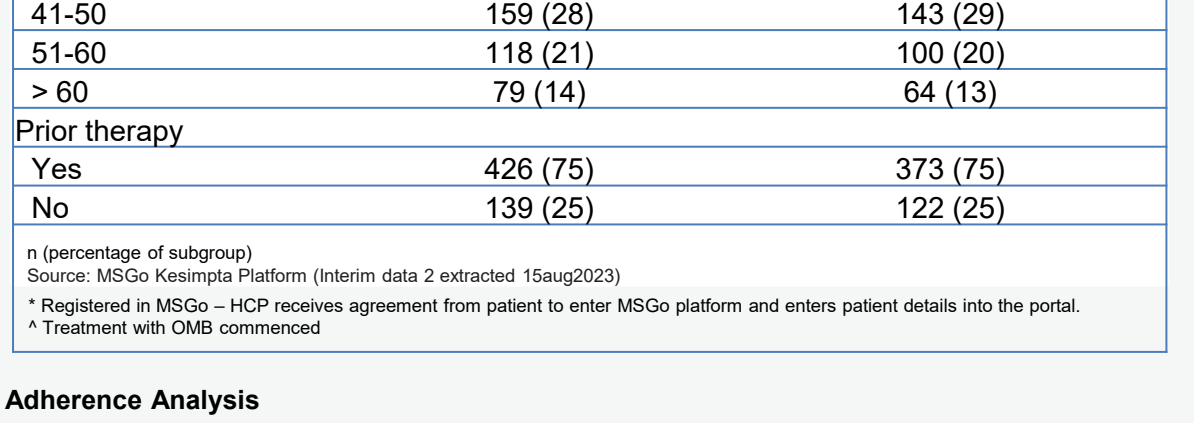
n (percentage of subgroup)
Source: MSGo Kesimpta Platform (Interim data 2 extracted 15aug2023)

* Registered in MSGo – HCP receives agreement from patient to enter MSGo platform and enters patient details into the portal.
^ Treatment with OMB commenced

Adherence Analysis

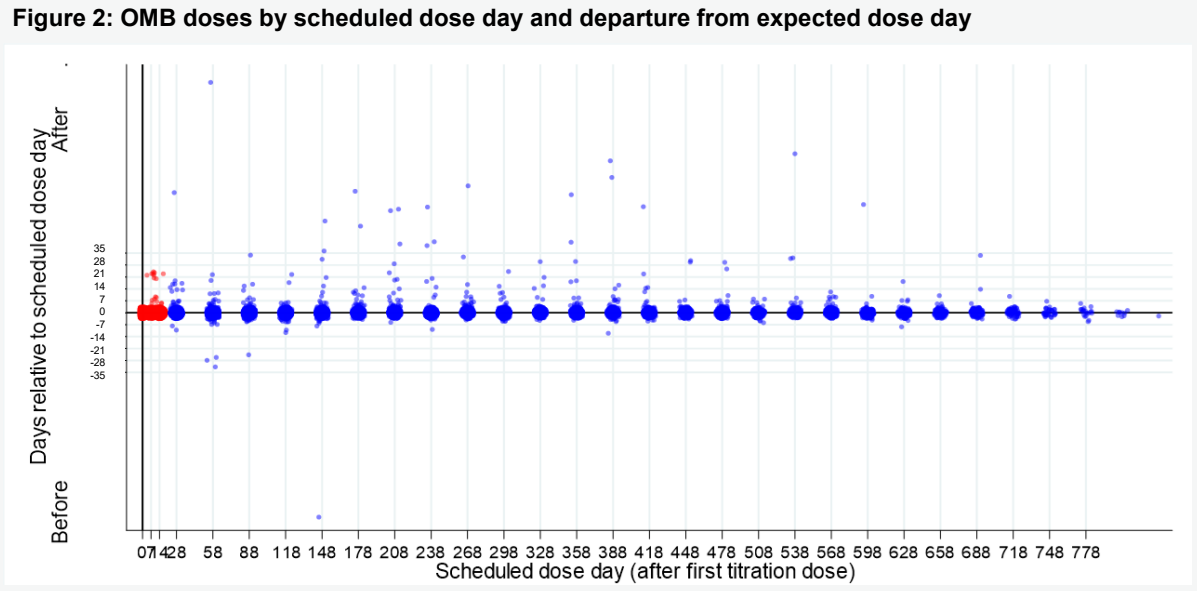
- Of the 567 patients who registered in MSGo, 47 had/have not yet received a dose of OMB. Of the remaining 520 patients, 23 reported they would skip titration.
- 497 patients received at ≥ 1 dose of OMB and 475 received two or more doses. Adherence during initiation was analysed by initiation dose 2 and 3 administered within 7 days ±3 days from the previous dose. 11 patients had non-adherent doses during this time, with 97.6% of patients completing this within the expected timeframe (proportion 0.976, 95% CI 0.96-0.988) (Fig. 1, 2).
- The proportion of adherent doses completed during maintenance doses 2 and 3 administered within 28 days ±3 days from the previous dose, was 95.6% (CI 0.93- 0.974) and 96.9% (CI 0.95-0.983), respectively.
- Out of the 497 patients who initiated treatment for the study in MSGo, 41 patients discontinued therapy. Reasons for discontinuation were adverse event (n=10), patient choice (n=21), lack of efficacy (n=1), unknown (n=1) and other (n=8).

Figure 1: Distribution of initiation and maintenance doses



To allow for patients whose next dose might be received after the end of follow-up (14 August 2023), analysis of the first maintenance dose was restricted to patients who had had their third titration dose ≥ 42 days before the end of follow-up and analysis of the second and third maintenance doses was restricted to patients who had had their previous maintenance dose ≥ 60 days before the end of follow-up.

Figure 2: OMB doses by scheduled dose day and departure from expected dose day



Distribution of OMB dose dates relative to the previous dose, for the patients who initiated within MSGo. Initiation doses shown in red and maintenance doses in blue. This data shows that the trend for high compliance is continued well beyond the first three maintenance doses.

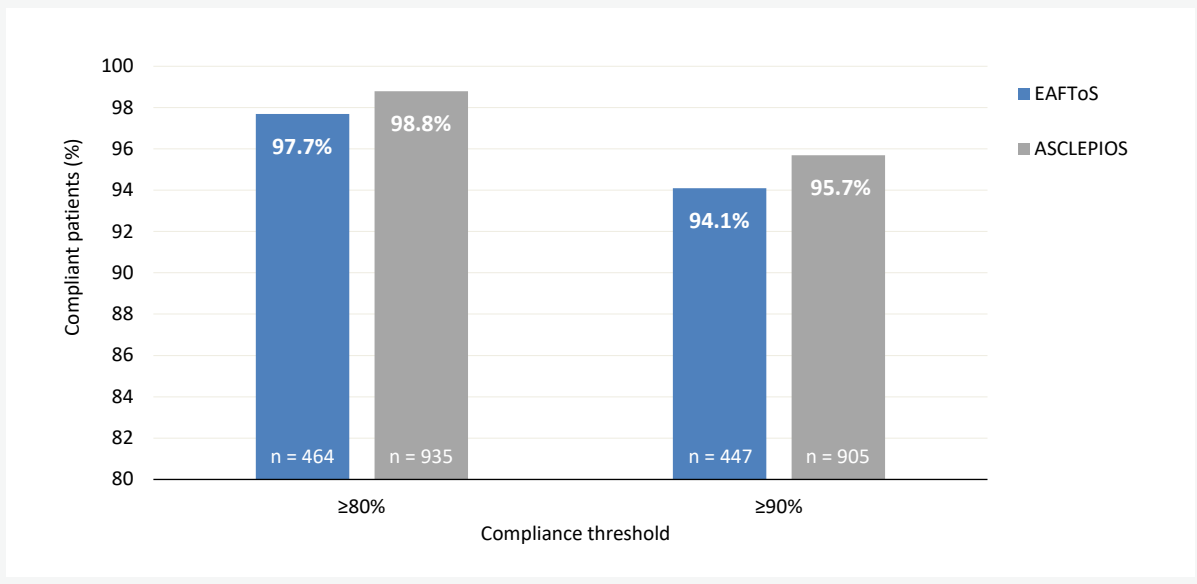
Compliance

- Compliance remained high over duration of treatment with 97.7% (464/475) and 94.1% (447/475) of EAFToS patients remaining at least 80% or 90% compliant to OMB, respectively. These results were comparable to the proportion of compliant patients recorded in the core phase of the ASCLEPIOS I/II clinical trials[1] (Fig. 3).

Dose administration

- The person administering the dose was collected for 2252 doses. From this analysis, 93% of patients self-administered their dose.

Figure 3: Patient compliance in EAFToS and ASCLEPIOS I/II



On treatment period includes days from the 1st injection date until 30 days after the last injection date. N, number of patients included in the analysis; n, number of patients meeting compliance threshold. The measure of compliance includes the data for all reported maintenance doses, not just the first three.

CONCLUSIONS

- OMB patients had high adherence during the first 3 months of treatment and maintained high compliance throughout duration of treatment. The high proportion of patient compliance in the Real World setting from EAFToS (>94% at 90% compliance or higher) was comparable to a clinical trial setting[1].
- Furthermore, the proportion of naive patients initiating treatment with OMB increased from 22% to 28% between the 1st and 2nd IA.
- This interim analysis provides enhanced insight into the Australian OMB patient cohort. Further data collected in the secondary use of data study and primary use of data sub-study will aide in the understanding of the real-world experience in Australia for ofatumumab patients and HCPs.

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