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Abstract Title: Characterizing up to 2 years of ofatumumab onboarding and utilization among real-world relapsing multiple sclerosis patients in Australia - the EAFToS Secondary Use of Data Study

Abstract Category: Therapy - 38 - Real world evidence (RWE) and MS registries

Preferred Presentation Type: Oral or poster presentation

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Introduction:
Ofatumumab is approved in Australia for the treatment of adults with relapsing forms of multiple sclerosis (RMS). This Real-World Evidence study will analyze the onboarding data, determine the impact of baseline factors on compliance to treatment and identify the ofatumumab patient profile, through secondary use of data (SUD) from the integrated digital patient support program MSGo.

Objectives/Aims:
The primary objective is to characterize the onboarding experience and utilization of ofatumumab in RMS patients in Australia. Secondary objectives are to describe the profile of patients initiating ofatumumab, evaluate patient demographics and prior therapy.

Methods:
Retrospective and longitudinal SUD analyses were conducted on data in the MSGo patient digital support program. The primary endpoint was proportion of doses not completed within 3 days of the expected date during initiation and +/-14 days during the first 3 months of maintenance. Key secondary endpoints will assess the patient demographics, prior therapy and whether the treatment administrator influences compliance to treatment.

Results:
Data from 213 de-identified patients were extracted from MSGo under the SUD study protocol in the 1st interim analysis. 22% were treatment naive, 93% self-administered ofatumumab and 6% discontinued therapy. Adherence during initiation was analysed by initiation dose 2 and 3 administered within 7 days ±3 days from the previous dose. Most patients were adherent within the expected timeframe (proportion 0.985, 95% CI 0.96-0.997). The proportion of adherent doses during maintenance doses 2 and 3 administered within 28 ±14 days from the previous dose, was 0.977 (CI 0.94-0.994) and 0.981 (CI 0.95-0.996) respectively. In addition, a more stringent cut-off of 30±3 days was conducted and the proportion of adherent doses during the two maintenance doses were 0.948 (CI 0.90-0.97) and 0.968 (CI 0.92-0.99). Compliance remained high with 98.5% (198/201) and 95.5% (192/201) remaining at least 80% or 90% compliant to ofatumumab, respectively. A 2nd interim analysis was triggered on 30th Mar 2023 and updated results including an additional 156 patients will be presented.

Conclusion:
These data show high rates of adherence during initiation and first 3 months of maintenance and the high proportion of patient compliance in EAFToS was comparable to a clinical trial setting. This study uses data derived exclusively from a digital support platform and represents a novel approach for understanding quality use of medicines for RMS in the real world.

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Simon Broadley has accepted honoraria for attendance at advisory boards, speaker fees and sponsorship to attend scientific meetings 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.
Jason Burton has received speaker honoraria, scientific advisory board fees from Bayer, Biogen-Idec, Novartis, Sanofi-Aventis, Merck, Merck, Sanofi-Genzyme and Roche.
Todd Hardy has received speaking fees or received honoraria for serving on advisory boards for Bayer, Biogen, Merck, Teva, Novartis, Roche, Bristol Myers Squibb and Sanofi-Genzyme.
Clare Kemp, Rob Walker, Patricia Berry, Kate Martel, Lien Lam and Morag Nelson are employees of Novartis Pharmaceuticals Australia.

Travel / Abstract Grant Application and Young Scientific Investigators' Session: I will not apply for Travel Grant or Young Scientific Investigators' Session

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