Abstract title (limit to 150 characters): Baseline Characteristics and 6-Month Tolerability, Safety and Persistence in a Real-World Cohort of Multiple Sclerosis Patients Initiating Ofatumumab

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Introduction: Ofatumumab (OMB) is a highly effective disease modifying therapy (DMT) approved for relapsing multiple sclerosis (MS). Real-world data are needed to understand utilization and safety of OMB in a broader population outside of a clinical trial.

Objectives: To describe baseline characteristics and 6-month tolerability, safety and persistence in a real-world cohort of MS patients starting OMB.

Methods: Patients prescribed OMB from October 2020-August 2022 at 2 Cleveland Clinic MS centers were identified, and electronic medical records were retrospectively reviewed. Baseline demographics, disease characteristics, and treatment histories were collected, as well as 6-month tolerability, safety, and DMT persistence data. Categorical variables were reported using frequencies (%) of relevant subgroups, and numerical variables were summarized using means (SD: standard deviation) or medians (IQR: interquartile range). Baseline was defined as up to 12 months pre-OMB, and 6-month follow-up was defined as 6 ± 3 months post-OMB initiation. OMB was defined as a switch therapy when patients started OMB within 3 months of discontinuing a prior DMT.

Results: 175 patients were included in the analyses. At baseline, mean age=44.9 years (SD 10.4, range 21-72) with 73.7% of the cohort being female and 81.1% Caucasian, 12.6% Black, and 4.6% Hispanic. Baseline disease characteristics: 77.7% relapsing-remitting (n=136), 15.4% secondary progressive (n=27); mean disease duration 13.6 years (SD 9.6, range 0-48); prior DMT use in 86.9% with a median of 2 agents (IQR 1-4), 58.9% switching from prior DMT. Most common reasons for prior DMT discontinuation were adverse effects (AE, 36.2%), breakthrough disease (34.9%), and inconvenience (20.4%). Median time between prior DMT and OMB was 5.3 months (IQR 1-12.5). DMTs before OMB change were ocrelizumab/rituximab (36.2%), fumarates (19.7%), S1PRM (15.1%), teriflunomide (7.2%), and natalizumab (6.6%). At 6 months, 33.1% of those starting OMB reported ≥1 tolerability concern, most commonly systemic reactions (96.6%), mostly occurring with the first injection (43.1%). Overall, 7.4% discontinued OMB at a mean of 99.7 days (SD 79.5, range 7-275), usually due to intolerance/AE (61.5%). No unexpected safety events were observed.

Conclusions: This study describes how OMB is commonly used in clinical practice. There were no unexpected tolerability concerns, and 6-month adherence remained high with excellent safety.

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