MSMilan2023
9th Joint ECTRIMS-ACTRIMS Meeting
11–13 October 2023 | Milan, Italy

Abstract Number: [964]

Abstract Title: Real-world effectiveness, tolerability and safety of ofatumumab at 12-month follow-up

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

Preferred Presentation Type: Oral or poster presentation

Moein Amin*[1], Tucker Harvey[2], Brandon Moss[1], Ming-Hui Tai[3], Abhijit Gadkari[3], Brandon Brown[3], Devon Conway[1], Carrie Hersh[4]

[1]Mellen Center for MS Treatment and Research, Cleveland Clinic, Cleveland, United States, [2]Quantitative Health Sciences, Cleveland Clinic, Cleveland, United States, [3]Novartis Pharmaceuticals Corporation, East Hanover, United States, [4]Lou Ruvo Center for Brain Health, Cleveland Clinic, Las Vegas, United States

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

Objectives/Aims:
To describe 12-month effectiveness, tolerability, and safety of ofatumumab in a real-world MS population.

Methods:
Electronic medical records of patients starting OMB from October 2020 to August 2022 at two comprehensive MS centers were reviewed. Baseline demographics, disease characteristics, and clinical and radiographic outcome measures at 6 and 12 month follow-up were reviewed. Wilcoxon signed-rank tests, paired t-tests, and negative binomial mixed-effects models were used to calculate differences between timepoints. A p-value <0.05 was considered statistically significant.

Results:
A total of 175 patients initiated OMB with mean age 44.9 (SD 10.4) and mean disease duration 13.6 (SD 9.6) years. This cohort was 74% female, and included 81% White and 13% Black American patients. Most (87%) had prior DMT exposure, median 2 agents, with 38% switching from high efficacy DMT, most commonly ocrelizumab (36%). The injection-related reaction (IRR) reports were primarily from the initial injections (i.e., 1st, 2nd, and 3rd injection) – 25%, 15%, and 11%, respectively; only 8 patients (5%) reported IRR between months 6-12. Over the course of 12 months, 90% of patients had remained on OMB (mean 101 days, SD 78.9). Sixty-two (35%) patients experienced an infection, with 24% having upper respiratory infection, 8% urinary tract infection, and 3.4% other types. Total IgG levels were stable and mostly within normal range ($p=0.892$). Thirty-nine (22%) patients had relapses in the year before starting OMB. By 6 months, only 1 relapse ($p<0.001$) had occurred with no relapses between months 6-12. In the subset of patients with available data, 52 (33%)/27 (17%) patients had new T2/GdE lesions at baseline (n=159) with 13 (15%)/2 (2%) and 9 (13%)/0 (0%) lesions at 6 and 12 months, respectively (6 months, n=87; 12 months, n=67; $p=0.001$). There were no significant differences in Patient Determined Disease Steps (PDDS) at months 6 and 12 versus baseline, with majority of patients remaining mild to moderate disability.

Conclusion:
This real-world study demonstrated that OMB is highly effective with robust persistence and good safety and tolerability by 12-month follow-up. Continuing analyses are planned to examine longer-term outcomes.

Disclosures: Moein Amin has received Novartis fellowship award NGC44741.
Tucker Harvey has no disclosures.
Brandon Moss has received research support paid to his institution from Novartis and Genentech. He has received consulting fees from Biogen. He has ownership interest in Pfizer.
Devon Conway has received research support paid to his institution from Novartis Pharmaceuticals, EMD Serono, Biogen, and Horizon Therapeutics. He has received speaking fees from Biogen and consulting fees from Novartis and Alexion.
Carrie M. Hersh has received speaking, consulting, and advisory board fees from Genentech, Genzyme, Biogen, Novartis, EMD-Serono, Bristol Myers Squibb, TG Therapeutics, and Alexion. She has received research support paid to her institution by Biogen, Novartis, Genentech, Patient-Centered Outcomes Research Institute (PCORI) and NIH - NINDS 1U01NS111678-01A1 sub-award.
Abhijit Gadkari, Brandon Brown, and Ming-Hui Tai are employees of Novartis Pharmaceuticals Corporation.

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

Which one would you like to apply to:

Date of Birth: