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Real-world Change in Annualized Relapse Rate Following Initiation of Ofatumumab in Patients with Multiple Sclerosis

Author Block: M. Tai[1], Q. Shao[1], B. Brown[1], R. Taiji[2], R. Kyle[2], A. Gadkari[1];
[1]Novartis Pharmaceuticals Corporation, East Hanover, NJ, [2]STATLOG Inc., Quebec City, QC, CANADA.

Abstract:
Background: Ofatumumab (OMB) is a high-efficacy anti-CD20 monoclonal antibody that has demonstrated efficacy in reducing incidence of relapse in multiple sclerosis (MS) within clinical trials. Real-world (RW) data will help ascertain OMB's effectiveness in reducing relapse in a broader population of MS patients outside of clinical trials.
Objectives: To evaluate the change in annualized relapse rate (ARR) following initiation of OMB in a RW sample of patients with MS using U.S. administrative claims data.

Methods: A retrospective pre-post cohort study was conducted using Optum® Clinformatics® Data Mart Database (Aug 2019-May 2023). Adult patients with ≥1 MS diagnosis and first OMB claim (index date) between Aug 20, 2020 (FDA approval date) and May 31, 2022, were included. The sample was further refined to patients who were continuously enrolled in a healthcare plan ≥12 months before and after index date (study period) and persistent on OMB, defined as no gaps in treatment >60 days or treatment switch, for ≥12 months following index date. Using a validated claims-based algorithm (Ollendorf et al. [2002]), relapse was defined as an inpatient admission with primary MS diagnosis or outpatient or emergency department visit with MS diagnosis in primary or secondary position with a claim for high dose oral corticosteroids, intravenous methylprednisolone, corticotropin, or plasma exchange within 7 days. Multiple qualifying relapse events within 30 days were collapsed into a single relapse episode. The study period was divided into a 12-month pre- (before OMB initiation) and ≥12-month post-index period (from OMB initiation until end of follow up). ARR was assessed using negative binomial regression with an offset for person-years and compared between the pre- and post-index periods using unadjusted incidence rate ratio (IRR).
Results: Among 342 included patients, mean (standard deviation [SD]) age at index date was 49 (11) years, 75% were female, and 66% were White. In the pre-index period, 45% and 23% of patients received low- and high-efficacy disease-modifying therapies (DMTs), respectively, while 33% of patients did not receive any DMT. Mean (SD) follow-up in the post-index period was 1.65 (0.43) years. ARR (95% confidence interval [CI]; N relapse episodes / N person-years) in the pre-index period was 0.43 (0.36, 0.52; 147 / 342) compared to 0.09 (0.07, 0.13; 51 / 563) in the post-index period. This equated to a statistically significant 79% reduction in ARR following OMB initiation (IRR: 0.21; 95% CI: 0.16, 0.29; $p<0.001$). The significant reduction in ARR following OMB initiation was robust to varying the claims-based definition of relapse and the required period for persistence with OMB, as well as in an anti-CD20 naïve population.
Conclusions: In a RW sample of MS patients, OMB was highly effective in reducing incidence of relapses, consistent with efficacy demonstrated in clinical trials.

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