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BACKGROUND: Ofatumumab (OMB) is a fully human anti-CD20 monoclonal antibody approved by the US Food and Drug Administration for the treatment of adults with relapsing multiple sclerosis (RMS). Hispanic people with MS may experience a different disease course, and it is well established that race/ethnicity plays a role in drug response variability. **OBJECTIVES:** To report findings of a post hoc analysis assessing achievement of no evidence of disease activity-3 (NEDA-3) with subcutaneous OMB vs oral teriflunomide (TER) in a subgroup of patients with RMS from the phase 3 ASCLEPIOS I/II studies who identified as Hispanic/Latino. **METHODS:** ASCLEPIOS trials included patients aged 18 to 55 years with RMS, Expanded Disability Status Scale (EDSS) score of 0 to 5.5, randomized to receive OMB or TER for up to 30 months. Patients achieving NEDA-3 (defined as no 6-month confirmed disability worsening, no confirmed MS relapse, no new/enlarging T2 lesions, and no gadolinium-enhancing T1 lesions) were assessed via Fisher Exact test according to patient-reported race/ethnicity. No adjustment was made for multiple comparisons. Rates of adverse events (AEs) are also reported. **RESULTS:** Of 1882 patients in the overall ASCLEPIOS population, 1658 (88.1%) identified as White and 147 (7.8%) as Hispanic/Latino. Mean ± SD age was 38.4 ± 9.1 years for White participants and 37.7 ± 9.4 years for Hispanic/Latino participants; 67% were female in both subgroups. Mean ± SD time since MS diagnosis was 5.7 ± 6.3 and 5.5 ± 5.5 years, and median EDSS scores were 2.5 and 3.0, respectively. In the Hispanic/Latino subgroup, OMB significantly increased the odds of achieving NEDA-3 vs TER during months 0 to 12 (odds ratio [OR] [95% CI]: 2.5 [1.2-5.1]; $P = .02$], months 12 to 24 (11.5 [3.7-35.7]; $P < .0001$), and months 0 to 24 (2.7 [1.3-5.8]; $P = .01$). Corresponding numbers in the White subgroup were as follows: months 0 to 12 (OR [95% CI]: 2.8 [2.2-3.5]), months 12 to 24 (7.6 [5.8-9.9]), and months 0 to 24 (3.1 [2.5-3.9]) (all $P < .0001$). At least 1 AE was reported in 83.0% of Hispanic/Latino patients vs 84.5% of White patients; there were no significant differences in reported types of AEs between subgroups. In the Hispanic/Latino subgroup, serious AE rates were 6.6% OMB (8.5% TER), and rates of AEs resulting in discontinuations were 7.9% OMB (8.5% TER); corresponding numbers in the White subgroup were 9.4% OMB (8.1% TER) and 6.3% OMB (5.3% TER), respectively. **CONCLUSIONS:** NEDA-3 efficacy data and the safety profile of OMB in the Hispanic/Latino subgroup are suggested to be consistent with those in the White subgroup in the ASCLEPIOS studies.

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(DMT57) Diroximel Fumarate in Young Adults With Relapsing-Remitting Multiple Sclerosis: Interim Safety and Efficacy Results from the Phase 3 EVOLVE-MS-1 Study

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BACKGROUND: Diroximel fumarate (DRF) is an oral fumarate for the treatment of relapsing multiple sclerosis (MS). DRF has better gastrointestinal (GI) tolerability and lower rates of discontinuation due to GI adverse events (AEs) compared with dimethyl fumarate (DMF). Outcomes have not previously been reported for young adult patients with MS treated with DRF. **OBJECTIVES:** To assess interim safety, GI tolerability, and efficacy of DRF in young adults (age 18-25 years) participating in the EVOLVE-MS-1 study (trial registration: NCT02634307). **METHODS:** Patients entered the open-label, 96-week EVOLVE-MS-1 study either as newly diagnosed patients or after completing the randomized, double-blind, 5-week phase 3 EVOLVE-MS-2 study (trial registration: NCT03093324) of DRF or DMF. **RESULTS:** As of September 2020, 1057 patients were enrolled in EVOLVE-MS-1, of which 65 were young adults aged 18 to 25 years (mean ± SD age, 22.6 ± 2.0 years; female, 61.5%). At baseline, mean ± SD time since diagnosis was 1.6 ± 2.0 years, and mean ± SD Expanded Disability Status Scale score was 1.66 ± 1.10. Treatment-emergent AEs occurred in 59 (90.8%) patients; the most common AEs were flushing (n = 21, 32.3%), MS relapse (n = 15, 23.1%), and nasopharyngitis (n = 16, 24.6%). Serious AEs were reported in 10 patients (15.4%); 1 death (1.5%) was reported and was deemed by the investigator not to be related to study treatment. The GI AEs occurred in 40.0% of patients; no GI AEs led to treatment discontinuation. Mean absolute lymphocyte count was 1.52 x 10^9/L (n = 56) at week 48 vs 1.86 x 10^9/L (n = 65) at baseline, corresponding to an 18% reduction in absolute lymphocyte count from baseline to week 48. The annualized relapse rate was 0.206 (95% CI, 0.11-0.38) at 2 years, representing a 78.6% (95% CI, 61.6%-88.0%; $P < .0001$) reduction from the 12 months before study entry (0.961 [95% CI, 0.79-1.17]). At week 48, the estimated proportion of patients who were relapse free was 79.0%, and the estimated proportion who had no evidence of disease activity was 54.7%. The percentage of patients who were gadolinium-enhancing lesion free at week 48 was 73.2% compared with 46.2% at baseline. **Conclusions:** Safety, GI tolerability, and efficacy in the young adult population of EVOLVE-MS-1 were consistent with those in the overall adult study population. Clinical and radiologic (gadolinium-enhancing lesion counts) outcomes significantly improved, and no discontinuations due to GI AEs were seen. These data suggest that DRF is an effective treatment option for young adults with MS. Data for patients aged 18 to 29 years will also be assessed.

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(DMT58) Real-world Findings in an Oral Cladribine Cohort Study in Patients With Multiple Sclerosis

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BACKGROUND: Cladribine is an oral synthetic purine nucleoside analogue approved for the treatment of patients with relapsing-remitting multiple sclerosis (RRMS). The most common reported adverse events (AEs) are upper respiratory tract infection, headache, and lymphopenia. Cladribine may increase the risk of malignancy based on clinical trial data, although follow-up studies have not confirmed this increased risk. In this single-center study, we report on 50 patients treated with oral cladribine. **OBJECTIVES:** To monitor patients with RRMS on oral cladribine therapy and obtain real-world data on medication efficacy and safety **METHODS:** A cohort of 50 cladribine-treated patients were evaluated at a single MS center. Clinical data included annualized relapse rate (ARR), AEs, serum