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BACKGROUND: Delayed-release dimethyl fumarate (DMF) has demonstrated efficacy and a stable benefit/risk profile in studies of patients with relapsing-remitting multiple sclerosis (RRMS). ESTEEM is an ongoing phase 4 5-year observational study characterizing long-term effectiveness and safety of DMF in real-world clinical practice. Evidence suggests that MS clinical course and disability outcomes may vary according to ethnicity and race. DMF was efficacious in a small sample of Black/African American (AA) and Hispanic/Latino (H/L) patients in DEFINE/CONFIRM. A previous analysis of these subgroups in ESTEEM demonstrated effectiveness across 3 years of DMF treatment; however, longer-term data are limited. **OBJECTIVES:** To evaluate real-world effectiveness and safety of DMF in Black/AA, non-Black/non-AA, H/L, and non-Hispanic/non-Latino (non-H/non-L) patients with RRMS. **METHODS:** ESTEEM included patients newly prescribed DMF in routine practice at approximately 390 sites globally. Effectiveness and safety of DMF were evaluated in a post hoc subgroup analysis in Black/AA, non-Black/non-AA, H/L, and non-H/non-L patients. Annualized relapse rates (ARRs) were obtained by negative binomial model. **RESULTS:** Overall, 220 (4.2%) Black/AA, 5031 non-Black/non-AA, 105 (2.0%) H/L, and 5146 non-H/non-L patients received at least 1 dose of DMF and were included in the analysis, with follow-up of 60 months. Unadjusted ARRs (95% CI) up to 5 years were as follows: Black/AA, 0.054 (0.038-0.078); non-Black/non-AA, 0.077 (0.072-0.081); H/L, 0.069 (0.043-0.112), and non-H/non-L, 0.076 (0.072-0.081), representing reductions ranging from 90.6% to 92.1% compared with ARRs 12 months before study entry ($P < .0001$ for all subgroups). Gastrointestinal disorders were the most common reason for discontinuation in both subgroups. In the first year, median lymphocyte counts declined 24.4% in Black/AA, 35.8% in non-Black/non-AA, 28.2% in H/L, and 35.6% in non-H/non-L patients, and then remained stable. **CONCLUSIONS:** These data demonstrate real-world treatment benefit of DMF in Black/AA and H/L patients. Compared with the 12 months before DMF initiation, ARRs were significantly lower up to 5 years after DMF initiation in Black/AA and H/L patients. The safety profile of DMF in these subgroups was consistent with the overall ESTEEM population, although lymphopenia was less pronounced in the black/AA and H/L subgroups; these lymphocyte findings should be interpreted with caution as this study was not designed to compare lymphocyte changes between different patient subgroups.

SUPPORTED BY: *Biogen.*

DISCLOSURES: *Mitzi J. Williams: Biogen, Celgene, EMD Serono, Genentech, Sanofi Genzyme, Teva Neuroscience. (consulting fee); Biogen, Genentech, Sanofi Genzyme, Teva (speakers' bureau). Lilyana Amezcua: Biogen, MedDay (contracted research); EMD Serono, Genzyme, Novartis (consulting fee). Angel Chinea: Biogen, Genentech, Novartis, Sanofi Genzyme, Teva (speakers' bureau); Biogen, Genentech, Novartis, Sanofi Genzyme, Teva Neuroscience (consulting fee); Biogen, Novartis, Sanofi Genzyme (contracted research). Stanley L. Cohan: AbbVie, Adamas, Alithios, Biogen, EMD Serono, Genentech/Roche, MedDay, Novartis, Sanofi Genzyme (contracted research); Biogen, Celgene, Genentech/Roche, Novartis, Pear Therapeutics, Sage Therapeutics, Sanofi Genzyme (consulting fee); Biogen, Genentech/Roche, Sanofi Genzyme (speakers' bureau). Annette Okai: Biogen, Celgene, EMD Serono, Genentech, Novartis, Sanofi Genzyme (consulting fee); Biogen, Genentech, Novartis, Sanofi Genzyme, Teva (speakers' bureau); Biogen, Novartis, Sanofi Genzyme, TG Therapeutics (contracted research). Darin T. Okuda: Biogen, EMD Serono/Merck (contracted research); Biogen, Bristol Myers Squibb/Celgene, EMD Serono, Genentech, Genzyme, Janssen Pharmaceuticals, Novartis, Osmotica Pharmaceuticals, RVL Pharmaceuticals, Inc, TG Therapeutics, Viela Bio (consulting fee); The Board of Regents of The University of Texas System (receipt of intellectual property rights/patent holder). Wendy Vargas: Alexion, Biogen, Genentech, Octapharma (consulting fee); Teva (contracted research). Nicholas Belviso, Ivan Bozin, Xiaotong Jiang, James B. Lewin, Jennifer Lyons, Changyu Shen, Sarah M. England, Nydjie Grimes: Biogen (ownership interest, salary).*

KEYWORDS: Dimethyl fumarate, Disease-modifying treatments in MS

(DMT47) Ofatumumab Improves NEDA-3 Likelihood in Patients With Relapsing MS Identifying As Black or African American: Subgroup Analysis of the ASCLEPIOS Studies

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BACKGROUND: Ofatumumab (OMB), a fully human anti-CD20 monoclonal antibody, is approved by the US Food and Drug Administration for the treatment of adults with relapsing multiple sclerosis (RMS). Black/African American people with MS may experience a different disease course, and it is well established that drug effect can vary by race/ethnicity. **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 ASCLEPIOS who identified as Black/African American. **METHODS:** This analysis included pooled data from the phase 3 ASCLEPIOS I/II studies. 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 66 (3.5%) as Black/African American. Mean ± SD age was 38.4 ± 9.1 years for White patients and 37.8 ± 9.2 years for Black/African American patients; 67% and 79% were female, respectively. Mean ± SD time since MS diagnosis was 5.7 ± 6.3 years and 5.4 ± 5.7 years and median Expanded Disability Status Scale scores were 2.5 and 2.8, respectively. In the Black/African American subgroup, OMB increased odds of achieving NEDA-3 vs TER during months 0 to 12 (odd ratio [OR] [95% CI], 5.7 [1.5-21.8]; $P = .013$), months 12 to 24 (9.5 [2.5-36.4]; $P = .0006$), and months 0 to 24 (8.7 [1.7-45.8]; $P = .007$). Corresponding numbers in the White subgroup were as follows: months 0 to 12 (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 $P < .0001$). The AE rates were balanced between OMB and TER in both subgroups, with at least 1 AE reported in 92.4% of the Black/African American subgroup vs 84.5% of the White subgroup; there were no significant differences in reported types of AEs between subgroups. In the Black/African American subgroup, serious AE rates were 10.7% OMB (7.9% TER), and rates of AEs resulting in discontinuations were 0% OMB (5.3% TER); corresponding numbers in the White subgroup were 9.4% OMB (8.1% TER) and 6.3% OMB (5.3% TER). **CONCLUSIONS:** NEDA-3 achievement and the safety profile of OMB in the Black/African American subgroup are consistent with those in the White subgroup in the ASCLEPIOS studies.

DISCLOSURES: *Mitzi J. Williams: AbbVie, Alexion, Biogen Idec, Bristol Myers Squibb, TG Therapeutics (consulting fee); EMD Serono, Genentech, Janssen, Novartis, Sanofi Genzyme (consulting fee, research support). Lilyana Amezcua: Biogen, MedDay (contracted research); EMD Serono, Genzyme, Novartis (consulting fee). Stanley L. Cohan: AbbVie, Adamas, Alithios, Biogen, EMD Serono, Genentech/Roche, MedDay, Novartis, Sanofi Genzyme (contracted research); Biogen, Celgene, Genentech/Roche, Novartis, Pear Therapeutics, Sage Therapeutics, Sanofi Genzyme (consulting fee); Biogen, Genentech/Roche, Sanofi Genzyme (speakers' bureau). Jeffrey A. Cohen: Adamas, Atara, Bristol Myers Squibb, Convelo, MedDay, Mylan (consulting fee); Multiple Sclerosis Journal (editor). Silvia R. Delgado: Mapi Pharma (contracted research); Novartis (consulting fee, contracted research). Le H. Hua: Biogen, Celgene, EMD Serono, Genentech, Genzyme, Novartis (consulting fee). Elisabeth B. Lucassen, Xiangyi Meng, James Stankiewicz: Novartis (employee).*

KEYWORDS: Disease-modifying treatments in MS

(DMT48) NurOwn (MSC-NTF) Cells Maintain Neurotrophic and Immunomodulatory Effects With Sphingosine-1-phosphate Modulator Siponimod

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BACKGROUND: MSC-NTF cells (NurOwn) are autologous bone marrow–derived mesenchymal stem cells (MSCs) induced to secrete high levels of neurotrophic factors (NTFs). MSC-NTF cells were evaluated in a phase 2 clinical study in progressive MS (trial registration: NCT03799718) demonstrating consistent increases in cerebrospinal fluid biomarkers of neuroprotection (VEGF-A, HGF, LIF, fetuin-A, follistatin,