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Serum Neurofilament Light Chain Levels and Neda-3 Status with Ofatumumab Treatment in Diverse Racial/Ethnic Subgroups with Relapsing Multiple Sclerosis: 5-Year Results from Alithios
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Abstract Text:

Background: In the Phase 3 ASCLEPIOS I/II trials (NCT02792218/NCT02792231), ofatumumab (OMB) lowered serum neurofilament light chain (sNFL) levels from Month 3 to Month 24 and increased the likelihood of achieving 3-parameter no evidence of disease activity (NEDA-3) vs teriflunomide (TER) in people with relapsing multiple sclerosis (pwRMS). The effect of long-term OMB on sNFL levels and NEDA-3 in diverse racial/ethnic subgroups has not been investigated.

Objectives: To assess the long-term effect of OMB on sNFL levels and NEDA-3 in Asian, Black, Hispanic, Caucasian, and Other (racial subgroups originally described as "other" or "unknown") subgroups entering the ALITHIOS open-label extension study (NCT03650114).

Methods: Of 1882 participants randomized in ASCLEPIOS I/II, 1367 (72.6%) participants entered ALITHIOS (Asian, n=46; Black, n=31; Hispanic, n=105; Caucasian, n=1142; Other, n=43) and received OMB for up to 5 years. Due to small numbers in the racial/ethnic subgroups except Caucasian, summary statistics were provided. Geometric means for sNFL and the proportion of participants achieving NEDA-3 over time were reported. Data were analyzed up to 5 years in those randomized to OMB and continuing OMB in ALITHIOS (OMB-OMB) and those randomized to TER and switching to OMB in ALITHIOS (TER-OMB).

Results: Lower mean sNFL levels vs baseline were recorded up to Year 5 in Asian, Black, Hispanic, Caucasian, and Other subgroups in the OMB-OMB group (baseline/Year 5): 13.1/8.5; 10.9/7.2; 11.9/8.1; 10.9/8.9; 12.3/8.9 pg/mL, respectively), and in the TER-OMB group (10.8/7.4, 11.4/9.5, 9.9/8.5, 10.6/9.2; 12.9/8.3 pg/mL, respectively). Higher rates of NEDA-3 were achieved earlier across all racial/ethnic subgroups in the continuous (OMB-OMB) vs switch (TER-OMB) groups. NEDA-3 rates at Year 1/Year 5 in the OMB-OMB group were 48.3%/91.7%, 52.2%/85.7%, 50.0%/98.4%, 47.9%/93.3%, and 40.5%/89.3% in the Asian, Black, Hispanic, Caucasian, and Other subgroups, respectively. In the TER-OMB group, NEDA-3 rates at Year 1/Year 5 by ethnicity were 32.4%/96.7%, 13.8%/78.9%, 30.0%/97.5%, 24.7%/90.2%, and 30.0%/100%, respectively. sNFL and NEDA-3 results for racial/ethnic subgroups were consistent with those of the overall population.

Conclusions: The earlier and sustained benefit of OMB-OMB treatment on sNFL levels and NEDA-3 vs TER-OMB support the value of earlier initiation of high-efficacy therapy in pwRMS irrespective of racial/ethnic background.

Title:

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Category:

Non-imaging biomarkers

Would you give CMSC and International Journal of MS Care the first preference to any article that is submitted for publication based on this abstract presentation?:

Yes

Late Breaking Reason:

The data outputs for this study were ready in January 2024, and the abstract could not therefore be developed in time to meet the original deadline of January 15th.

Category: Non-imaging biomarkers

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