Abstract Number: 711/P691

One-year analysis of efficacy and safety in Black and Hispanic patients with relapsing multiple sclerosis receiving ocrelizumab treatment in the CHIMES trial

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Introduction:

Black and Hispanic patients are underrepresented in multiple sclerosis (MS) trials but may have higher MS incidence, faster disease progression and/or an increased risk of progression to disability vs White patients.

Objectives/Aims:

The CHIMES trial (NCT04377555) was designed to evaluate disease activity and the efficacy and safety of ocrelizumab (OCR) treatment in Black and Hispanic patients with relapsing multiple sclerosis (pwRMS).

Methods:

This prospective, open-label, single-arm, Phase IV study included pwRMS who self-identified as Black or Hispanic, were aged 18-65 yrs and had Expanded Disability Status Scale (EDSS) scores of 0-5.5 points at screening. Patients received two 300-mg OCR infusions 14 days apart and 600 mg every 24 wks for 1 yr, with an optional 3-yr extension. The primary outcome was no evidence of disease activity (NEDA), defined as proportion of patients at Wk 48 free from a protocol-defined event (relapse, confirmed disability progression at Wk 24, T1 gadolinium [Gd]-enhancing[+] lesion or new/enlarging T2 lesions). Additional outcomes were clinical evaluations and adverse events (AEs).

Results:

A total of 182 patients were included; 113 patients (62%) were Black and 69 (38%) were Hispanic. Mean (SD) age was 35.5 (10.5) yrs, BMI was 31.0 (7.4) kg/m2 and 72.5% of patients were female.* Patients had a mean (SD) time since first MS symptoms of 4.9 (5.7) yrs, and time since RMS diagnosis was 2.9 (4.5) yrs. Baseline mean (SD) EDSS score was 2.4 (1.4).* Approximately half (46.0%) of Black patients and over half (58.0%) of Hispanic patients achieved NEDA at Wk 48. The majority of patients had no relapses (Black 94.7%; Hispanic, 95.7%), no 24-Wk confirmed disability progression (Black, 94.7%; Hispanic, 94.2%) and no T1 Gd+ lesions (Black, 94.7%; Hispanic, 97.1%). No new/enlarging T2 lesions were observed in 46.0% of Black patients and 63.8% of Hispanic patients. Overall, 80.2% of patients experienced ≥1 AE, 5.5% had ≥1 serious AE and 29.1% had an infusion-related reaction. No deaths occurred.

Conclusion:
Black and Hispanic patients have been consistently underrepresented in MS clinical trials. This study found that approximately half of all patients enrolled in the CHIMES trial achieved NEDA at 1 yr, and no new safety signals were reported. These data are consistent with results from other OCR clinical studies and suggest the suitability of OCR as a treatment option in this underserved population.

Disclosures:

Sponsored by F. Hoffmann-La Roche Ltd. Writing and editorial assistance was provided by Health Interactions, Inc. and funded by F. Hoffmann-La Roche Ltd. MJ Williams has received consulting fees from Alexion, Biogen Idec, Bristol Myers Squibb, EMD Serono, Genentech, Inc., Janssen, Novartis, Sanofi Genzyme and TG Therapeutics and serves on speakers bureaus for Biogen, Bristol Myers Squibb, EMD Serono, Janssen, Genentech and TG Therapeutics. T Vartanian reports personal compensation for consulting, speaking, or serving on steering committees or advisory boards for Biogen Idec, Novartis, Genentech, Inc., EMD Serono, the National Multiple Sclerosis Society and the National Institutes of Health. AT Reder has received consulting fees from Bayer, Biogen, F. Hoffmann-La Roche Ltd, Genentech, Inc., Merck Serono, Novartis and TG Therapeutics; is an editor for MedLink; and has received unrestricted research grant support from Bayer, Biogen, F. Hoffmann-La Roche Ltd, Genentech, Inc., Mallinckrodt, Merck Serono and Novartis. NL Monson has received consulting fees from EMD Serono and Genentech, Inc.; is a founder of GenRab; and holds patent US 8,394,583 B2 on MSPreciseTM, a diagnostic tool for predicting conversion to multiple sclerosis. K Pandey has served as a consultant for: Biogen, BMS, Genentech-Roche and Sanofi-Genzyme. She has served as a speaker for: Biogen, Genentech/Roche, BMS, Sanofi-Genzyme, Alexion and Horizon Therapeutics. K Rammohan has received honoraria from, Biogen, Genentech, Inc., Genzyme, EMD Serono, Novartis and TG Therapeutics and has received research grant support from Biogen, Genentech, EMD Merck Serono, Novartis, Alexion and TG Therapeutics.

B Hendin has served on advisory and speakers bureau for EMD Serono, Genentech, Genzyme, Novartis, TG Therapeutics, Banner, Horizon, Alexion and Biogen and received research support from Novartis, Genentech, EMD Serono and Genzyme. DS Sokhi has received speaker fees from F. Hoffmann-La Roche Ltd. L Amezcua reports personal compensation for consulting or serving on steering committees or advisory boards for Biogen Idec, Novartis, Genentech, Inc., and EMD Serono, and has received research support from the National Multiple Sclerosis Society, NIH NINDS and Biogen. E Bernitsas has received grant support from F. Hoffmann-La Roche Ltd, Genentech, Inc., Sanofi Genzyme, MedImmune, Novartis, EMD Merck Serono, Chugai, Mallinckrodt and TG Therapeutics; is a Chief Editor for the “Brain Sciences” Neuroimaging section; and has received consulting fees/honoraria from Biogen, Merck Serono, Bristol Myers Squibb, Horizon, Janssen Pharmaceuticals and Genentech, Inc. R Parekh, J Pei, I Abioye, and J Acosta are employees of Genentech, Inc., and shareholders of F. Hoffmann-La Roche Ltd. GF Wu has received honoraria for consulting from Novartis, Sangamo and Genentech, Inc., and research funding from Biogen, EMD Serono and F. Hoffmann-La Roche Ltd.