Background

Minority patients with multiple sclerosis (MS), including those of African ancestry (AA) and Hispanic and Latino ethnicity (HA), have greater disease severity and faster progression than Whites. Minorities are vastly underrepresented in clinical trials, owing to poor access and cultural, economic and other participation barriers. Ocrelizumab (OCR), an anti-CD20 therapy targeting B cells, reduced the rates of disease activity and progression in patients with relapsing MS (RMS) and primary progressive MS in pivotal studies; however, minority participation was <10%.

Objectives

To investigate the efficacy and safety of OCR in AA and HA patients with RMS (2017 McDonald criteria) who meet the US prescribing information criteria in a single-arm Phase IV clinical study designed exclusively to meet the needs of these specific demographic groups.

Methods

An industry-sponsored collaborative approach rooted in minority needs and known knowledge gaps was used.

Results

Key differences between CHIMES (NCT04377555) and other MS trials are as follows:

1. CHIMES was developed in collaboration with patients with MS, patient advocacy groups and investigators.
2. Inclusion criteria allow for ≈150–200 participants with specific, well-controlled, pre-existing comorbidities and baseline creatinine levels within race-specific limits; these factors may disproportionately limit minority patient qualification in other trials.
3. OCR was chosen because of the indications that AA patients with MS may have greater B-cell–mediated pathology, such as a higher CSF IgG index.
4. Written materials will be available in English and Spanish and will be reviewed by a minority patient panel to ensure that they are easy to understand.
5. To enable early results, the primary endpoint is disease activity, defined by the proportion of patients free of protocol-defined events (clinical relapses, CDP or MRI activity) at the end of year 1.
6. All patients may participate in the second-year extension to study disease progression and various biomarker endpoints.

7. One-third of patients will participate in a substudy to assess CSF-specific biomarkers at two time points.

Conclusions

Findings from CHIMES are expected to improve current understanding of MS disease biology, treatment response and clinical trial participation among AA and HA patients with MS, with the ultimate goals of increasing high-quality standard of care to traditionally underserved populations and enhancing equality through clinical research.