CHIMES: FIRST-OF-ITS-KIND STUDY IN BLACK AND HISPANIC PEOPLE LIVING WITH MS[1]

Results from the Phase IV CHIMES (Characterization of Ocrelizumab in Minorities with Multiple Sclerosis) trial

The patients pictured were not enrolled in the CHIMES study.

Indications

OCREVUS is indicated for the treatment of:

- Relapsing forms of multiple sclerosis (RMS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults
- Primary progressive MS (PPMS), in adults

Contraindications

OCREVUS is contraindicated in patients with active hepatitis B virus infection and in patients with a history of life-threatening infusion reaction to OCREVUS.

Select Important Safety Information

The warnings and precautions for OCREVUS are infusion reactions, and infections, which include respiratory tract infections, herpes, hepatitis B virus (HBV) reactivation, and a warning for progressive multifocal leukoencephalopathy (PML). Additional warnings are possible increased risk of immunosuppressant effects with other immunosuppressants, reduction in immunoglobulins, malignancies, and immune-mediated colitis.

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For additional safety information, please see pages 8 through 11 and the accompanying full **Prescribing Information** and **Medication Guide**.

Background on the OPERA trials

SUPERIOR EFFICACY vs REBIF[2]

OCREVUS demonstrated superior efficacy in 2 RMS trials vs an active comparator (Rebif) at Year 2 (controlled period)[2]

PROVEN EFFICACY vs REBIF[2,3]

ARR	T1 Gd+	T2 ACTIVITY	CDP
Reduced relapse rates by nearly half	Near complete suppression[a]	Superior reductions	Superior reduction in risk
46% OPERA I | **47%** OPERA II **RELATIVE REDUCTIONS** $p<0.0001$	**94%** OPERA I | **95%** OPERA II **RELATIVE REDUCTIONS** $p<0.0001$	**77%** OPERA I | **83%** OPERA II **RELATIVE REDUCTIONS** $p<0.0001$	**40%** RISK REDUCTION HR (95% CI): 0.60 (0.45, 0.81) $p=0.0006$ 12-week CDP (proportion of patients): **Prespecified, pooled analysis 9.8% OCREVUS vs 15.2% Rebif** **40%** RISK REDUCTION HR (95% CI): 0.60 (0.43, 0.84) $p=0.003$ 24-week CDP (proportion of patients): **Prespecified, pooled analysis 7.6% OCREVUS vs 12% Rebif**
Annualized relapse rate with OCREVUS vs Rebif: **OPERA I: 0.156 vs 0.292** **OPERA II: 0.155 vs 0.290**	Mean number of T1 Gd+ lesions with OCREVUS vs Rebif: **OPERA I: 0.016 vs 0.286** **OPERA II: 0.021 vs 0.416**	Mean number of new or enlarging hyperintense T2 lesions with OCREVUS vs Rebif: **OPERA I: 0.323 vs 1.413** **OPERA II: 0.325 vs 1.904**	

[a]The precise mechanism by which OCREVUS exerts its therapeutic effects in MS is unknown.

OPERA I and II (RMS): Two randomized, double-blind, double-dummy, active comparator-controlled clinical trials of identical design vs Rebif in 1656 patients (OCREVUS; OPERA I [n=410], OPERA II [n=417]; Rebif; OPERA I [n=411], OPERA II [n=418]) with RMS treated for 96 weeks. Both studies included patients who had experienced ≥1 relapse within the prior year, or 2 relapses within the prior 2 years, and had an Expanded Disability Status Scale (EDSS) score between 0 and 5.5. The primary outcome of both studies was the annualized relapse rate.[2]

Baseline demographics of Black patients in the OPERA trials[4]

In the OCREVUS pivotal trials for RMS, 72 out of 1656 patients (4.3%) were of African descent. A post hoc subgroup analysis showed that these Black patients had a higher T2 lesion volume at baseline despite being younger and with a shorter disease course on average than OPERA participants who were not of African descent.

A subanalysis of Hispanic patients in the OPERA trials was not performed.

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Background on the OPERA trials

NEDA BY WEEK 96 (POST HOC ANALYSIS)

No evidence of disease activity (NEDA) in the controlled period including re-baselined analysis

NEDA IS THE PROPORTION OF RMS PATIENTS WITH[3]:

NO PROTOCOL-DEFINED RELAPSES ■ NO 3-MONTH CDP ■ NO T1 GD+ MRI ACTIVITY ■ NO NEW OR ENLARGING T2 LESIONS

Controlled Period NEDA[3]
Pooled Analysis

48% OCREVUS vs **27%** Rebif

Weeks 0-96

Re-baselined NEDA[5]
Pooled Analysis

72% OCREVUS vs **42%** Rebif

Weeks 24-96
(re-baselined to 24 weeks)

82% OCREVUS vs **57%** Rebif

Weeks 48-96
(re-baselined to 48 weeks)

ASSESSMENT AND LIMITATIONS

- The predefined secondary endpoint of NEDA in the OPERA studies was considered nonconfirmatory because it fell below the break in the statistical hierarchy at change in Multiple Sclerosis Functional Composite Scale score from baseline to Week 96
- Exploratory result based on modified intent-to-treat population
- During Weeks 48 to 96, the lower frequency of MRI scans compared with other time periods may have influenced the proportions of patients maintaining NEDA
- Moving into the clinical practice setting, the optimal timing of re-baselining should reflect the anticipated timing for reaching complete disease-modifying therapy (DMT) efficacy, to give a more reliable indication of subsequent drug failure
- Conclusions from cross-trial comparisons are limited because of differences including comparators, patient populations, MRI techniques, frequency of assessments, analysis methods, and definitions of NEDA

Why re-baseline NEDA data?

NEDA analyses are often re-baselined, or calculated at a later timepoint, in order to minimize any confounding impact of pretreatment disease activity and to better reflect the steady state of DMT impact on disability worsening and disease activity.[5]

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Our commitment to health equity

FURTHERING THE UNDERSTANDING OF MS

Advancing inclusive research with the goal of improving outcomes for Black and Hispanic people living with MS

Limited data[6-12]

Some studies suggest that Black and Hispanic MS patients accrue disability more rapidly than White patients. Black and Hispanic people continue to be underrepresented in clinical trials, which means there are limited data on what drives greater disability in these populations.

Clinical trial representation[13,14]

According to a report:

- Black people make up 13% of the US population, but account for only ~5% of participants in clinical trials overall
- Hispanic people make up 19% of the US population, but account for only ~1% of participants in clinical trials overall

A first-of-its-kind study[1]

As part of our commitment to advancing health equity, Genentech has conducted CHIMES, the first-ever clinical trial focused exclusively on broadening our knowledge of how MS impacts Black and Hispanic people.

> Being Black I faced many challenges getting diagnosed with MS, I think, to be honest, it was because **in the Black and Brown community, MS wasn't suspected.**
>
> **—PASTELL, loving mom**
> RMS diagnosis, 2016
> Started OCREVUS, 2018 at age 34
>
> The patient quoted was not enrolled in the CHIMES study.

OCREVUS in the CHIMES trial

WHO ARE CHIMES PATIENTS?

Select baseline characteristics of RMS patients in the CHIMES trial[1]

36 years
mean age

38%
Hispanic

62%
Black

2.4
mean EDSS score

1.9
mean number of T1 Gd+ lesions

49.3
mean number of T2 lesions

5 years
mean time since symptom onset

3 years
mean time since diagnosis

63%
previously untreated with an MS DMT

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OCREVUS in the CHIMES trial

A UNIQUE STUDY DESIGN

Prospective open-label, single-arm study of OCREVUS in Black and Hispanic people living with RMS[1,15]

182 patients studied

- 113 Black patients, 69 Hispanic patients
- 18 to 65 years of age with relapsing MS
- Enrolled at study centers across the US, including Puerto Rico, and 1 site in Kenya
- All treated with OCREVUS[a]

Select study endpoints[1,15]

NEDA (primary endpoint)

Proportion of patients free of a protocol-defined relapse

24W — 24-week CDP

T1-weighted contrast-enhancing lesions

New/enlarging T2-weighted lesions

Supporting inclusive enrollment in CHIMES[1,15]

The CHIMES study was developed in collaboration with MS patients, patient advocacy groups, and other industry leaders to help address common barriers in order to support participation of Black and Hispanic MS patients.

- Language/cultural barriers
- Scheduling
- Transportation
- Childcare

LIMITATIONS

- CHIMES is an ongoing, single-arm, open-label, Phase IV study in Black and Hispanic patients with the primary analysis conducted at Year 1
  - Because there is no comparator arm in the study, no comparisons can be made
- OPERA and CHIMES are separate studies; no direct comparisons can be made
  - The OPERA Phase III clinical trials were conducted in RMS patients of any race/ethnicity while CHIMES is studying RMS patients who self-identify as Black or Hispanic
  - The CHIMES study and OPERA trials were conducted in different locations, at different timepoints, and using different methodologies

[a] 600-mg IV infusion of OCREVUS administered every 24 weeks, with the first dose administered as two 300-mg IV infusions given 14 days apart.

OCREVUS in the CHIMES trial

NEDA AT WEEK 48

No evidence of disease activity (NEDA) in CHIMES participants

NEDA IS THE PROPORTION OF RMS PATIENTS WITH[1]:

NO PROTOCOL-DEFINED RELAPSES ■ NO 6-MONTH CDP ■ NO T1 GD+ MRI ACTIVITY ■ NO NEW OR ENLARGING T2 LESIONS

CHIMES RESULTS: **NEDA AT WEEK 48** (PRIMARY ANALYSIS)[1]

NEDA data from this 1-year study have not yet been re-baselined.

NEDA at Week 48
(primary endpoint)

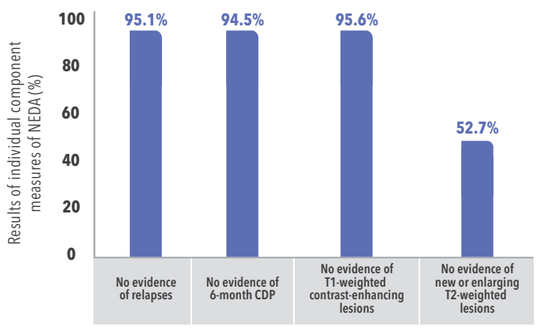
50.5%
(92 out of 182 total patients)

NEDA in Black vs Hispanic RMS patients

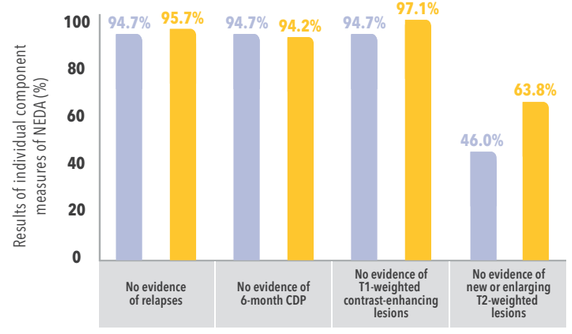
46%
Black patients
(52 out of 113)

58%
Hispanic patients
(40 out of 69)

Components of NEDA



Components of NEDA



Select Important Safety Information

Infusion Reactions

OCREVUS can cause infusion reactions, which can include pruritus, rash, urticaria, erythema, bronchospasm, throat irritation, oropharyngeal pain, dyspnea, pharyngeal or laryngeal edema, flushing, hypotension, pyrexia, fatigue, headache, dizziness, nausea, tachycardia, and anaphylaxis.

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Contraindications

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Important Safety Information

Warnings and Precautions

Infusion Reactions

OCREVUS can cause infusion reactions, which can include pruritus, rash, urticaria, erythema, bronchospasm, throat irritation, oropharyngeal pain, dyspnea, pharyngeal or laryngeal edema, flushing, hypotension, pyrexia, fatigue, headache, dizziness, nausea, tachycardia, and anaphylaxis. In multiple sclerosis (MS) clinical trials, the incidence of infusion reactions in OCREVUS-treated patients [who received methylprednisolone (or an equivalent steroid) and possibly other pre-medication to reduce the risk of infusion reactions prior to each infusion] was 34-40%, with the highest incidence with the first infusion. There were no fatal infusion reactions, but 0.3% of OCREVUS-treated MS patients experienced infusion reactions that were serious, some requiring hospitalization.

Observe patients treated with OCREVUS for infusion reactions during the infusion and for at least one hour after completion of the infusion. Inform patients that infusion reactions can occur up to 24 hours after the infusion. Administer pre-medication (e.g., methylprednisolone or an equivalent corticosteroid, and an antihistamine) to reduce the frequency and severity of infusion reactions. The addition of an antipyretic (e.g., acetaminophen) may also be considered. For life-threatening infusion reactions, immediately and permanently stop OCREVUS and administer appropriate supportive treatment. For less severe infusion reactions, management may involve temporarily stopping the infusion, reducing the infusion rate, and/or administering symptomatic treatment.

Infections

Serious, including life-threatening or fatal, bacterial, viral, parasitic and fungal infections have been reported in patients receiving OCREVUS. An increased risk of infections (including serious and fatal bacterial, fungal, and new or reactivated viral infections) has been observed in patients during and following completion of treatment with anti-CD20 B-cell depleting therapies.

A higher proportion of OCREVUS-treated patients experienced infections compared to patients taking REBIF or placebo. In RMS trials, 58% of OCREVUS-treated patients experienced one or more infections compared to 52% of REBIF-treated patients. In the PPMS trial, 70% of OCREVUS-treated patients experienced one or more infections compared to 68% of patients on placebo. OCREVUS increased the risk for upper respiratory tract infections, lower respiratory tract infections, skin infections, and herpes-related infections. OCREVUS was not associated with an increased risk of serious infections in MS patients in controlled trials. Delay OCREVUS administration in patients with an active infection until the infection is resolved.

Respiratory Tract Infections

A higher proportion of OCREVUS-treated patients experienced respiratory tract infections compared to patients taking REBIF or placebo. In RMS trials, 40% of OCREVUS-treated patients experienced upper respiratory tract infections compared to 33% of REBIF-treated patients, and 8% of OCREVUS-treated patients experienced lower respiratory tract infections compared to 5% of REBIF-treated patients. In the PPMS trial, 49% of OCREVUS-treated patients experienced upper respiratory tract infections compared to 43% of patients on placebo and 10% of OCREVUS-treated patients experienced lower respiratory tract infections compared to 9% of patients on placebo. The infections were predominantly mild to moderate and consisted mostly of upper respiratory tract infections and bronchitis.

Herpes

In active-controlled (RMS) clinical trials, herpes infections were reported more frequently in OCREVUS-treated patients than in REBIF-treated patients, including herpes zoster (2.1% vs. 1.0%), herpes simplex (0.7% vs. 0.1%), oral herpes (3.0% vs. 2.2%), genital herpes (0.1% vs. 0%), and herpes virus infection (0.1% vs. 0%). Infections were predominantly mild to moderate in severity. In the placebo-controlled (PPMS) clinical trial, oral herpes was reported more frequently in the OCREVUS-treated patients than in the patients on placebo (2.7% vs 0.8%).

Serious cases of infections caused by herpes simplex virus and varicella zoster virus, including central nervous system infections (encephalitis and meningitis), intraocular infections, and disseminated skin and soft tissue infections, have been reported in the postmarketing setting in multiple sclerosis patients receiving OCREVUS. Serious herpes virus infections may occur at any time during treatment with OCREVUS. Some cases were life-threatening.

If serious herpes infections occur, OCREVUS should be discontinued or withheld until the infection has resolved, and appropriate treatment should be administered.

Hepatitis B Virus (HBV) Reactivation

Hepatitis B reactivation has been reported in MS patients treated with OCREVUS in the postmarketing setting. Fulminant hepatitis, hepatic failure, and death caused by HBV reactivation have occurred in patients treated with anti-CD20 antibodies. Perform HBV screening in all patients before initiation of treatment with OCREVUS. Do not administer OCREVUS to patients with active HBV confirmed by positive results for HBsAg and anti-HB tests. For patients who are negative for surface antigen [HBsAg] and positive for HB core antibody [HBcAb+] or are carriers of HBV [HBsAg+], consult liver disease experts before starting and during treatment.

Possible Increased Risk of Immunosuppressant Effects with Other Immunosuppressants

When initiating OCREVUS after an immunosuppressive therapy or initiating an immunosuppressive therapy after OCREVUS, consider the potential for increased immunosuppressive effect. OCREVUS has not been studied in combination with other MS therapies.

Vaccinations

Administer all immunizations according to immunization guidelines at least 4 weeks prior to initiation of OCREVUS for live or live-attenuated vaccines and, whenever possible, at least 2 weeks prior to initiation of OCREVUS for non-live vaccines. OCREVUS may interfere with the effectiveness of non-live vaccines. The safety of immunization with live or live-attenuated vaccines following OCREVUS therapy has not been studied, and vaccination with live-attenuated or live vaccines is not recommended during treatment and until B-cell repletion.

Vaccination of Infants Born to Mothers Treated with OCREVUS During Pregnancy

In infants of mothers exposed to OCREVUS during pregnancy, do not administer live or live-attenuated vaccines before confirming the recovery of B-cell counts as measured by CD19+ B-cells. Depletion of B-cells in these infants may increase the risks from live or live-attenuated vaccines.

You may administer non-live vaccines, as indicated, prior to recovery from B-cell depletion, but should consider assessing vaccine immune responses, including consultation with a qualified specialist, to assess whether a protective immune response was mounted.

Progressive Multifocal Leukoencephalopathy (PML)

Cases of progressive multifocal leukoencephalopathy (PML) have been reported in patients with MS treated with OCREVUS in the postmarketing setting. PML is an opportunistic viral infection of the brain caused by the JC virus (JCV) that typically only occurs in patients who are immunocompromised, and that usually leads to death or severe disability. PML has occurred in OCREVUS-treated patients who had not been treated previously with natalizumab, (which has a known association with PML), were not taking any immunosuppressive or immunomodulatory medications, associated with risk of PML prior to or concomitantly with OCREVUS, and did not have any known ongoing systemic medical conditions resulting in compromised immune system function.

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Important Safety Information (continued)

Progressive Multifocal Leukoencephalopathy (PML) (continued)

JCV infection resulting in PML has also been observed in patients treated with other anti-CD20 antibodies and other MS therapies.

At the first sign or symptom suggestive of PML, withhold OCREVUS and perform an appropriate diagnostic evaluation. Typical symptoms associated with PML are diverse, progress over days to weeks, and include progressive weakness on one side of the body or clumsiness of limbs, disturbance of vision, and changes in thinking, memory, and orientation leading to confusion and personality changes.

Magnetic resonance imaging (MRI) findings may be apparent before clinical signs or symptoms of PML. Monitoring with MRI for signs consistent with PML may be useful, and any suspicious findings should lead to further investigation to allow for an early diagnosis of PML, if present.

If PML is confirmed, treatment with OCREVUS should be discontinued.

Reduction in Immunoglobulins

As expected with any B-cell depleting therapy, decreased immunoglobulin levels are observed with OCREVUS treatment. The pooled data of OCREVUS clinical studies (RMS and PPMS) and their open-label extensions (up to approximately 7 years of exposure) have shown an association between decreased levels of immunoglobulin G (IgG<LLN) and increased rates of serious infections. Monitor the levels of quantitative serum immunoglobulins during OCREVUS treatment and after discontinuation of treatment, until B-cell repletion, and especially in the setting of recurrent serious infections. Consider discontinuing OCREVUS therapy in patients with serious opportunistic or recurrent serious infections, and if prolonged hypogammaglobulinemia requires treatment with intravenous immunoglobulins.

Malignancies

An increased risk of malignancy with OCREVUS may exist. In controlled trials, malignancies, including breast cancer, occurred more frequently in OCREVUS-treated patients. Breast cancer occurred in 6 of 781 females treated with OCREVUS and none of 668 females treated with REBIF or placebo. Patients should follow standard breast cancer screening guidelines.

Immune-Mediated Colitis

Immune-mediated colitis, which can present as a severe and acute-onset form of colitis, has been reported in patients receiving OCREVUS in the postmarketing setting. Some cases of colitis were serious, requiring hospitalization, with a few patients requiring surgical intervention. Systemic corticosteroids were required in many of these patients. The time from treatment initiation to onset of symptoms in these cases ranged from a few weeks to years. Monitor patients for immune-mediated colitis during OCREVUS treatment, and evaluate promptly if signs and symptoms that may indicate immune-mediated colitis, such as new or persistent diarrhea or other gastrointestinal signs and symptoms, occur.

Use in Specific Populations

Pregnancy

There are no adequate data on the developmental risk associated with use of OCREVUS in pregnant women. There are no data on B-cell levels in human neonates following maternal exposure to OCREVUS. However, transient peripheral B-cell depletion and lymphocytopenia have been reported in infants born to mothers exposed to other anti-CD20 antibodies during pregnancy. OCREVUS is a humanized monoclonal antibody of an immunoglobulin G1 subtype and immunoglobulins are known to cross the placental barrier.

Lactation

There are no data on the presence of ocrelizumab in human milk, the effects on the breastfed infant, or the effects of the drug on milk production. Ocrelizumab was excreted in the milk of ocrelizumab-treated monkeys. Human IgG is excreted in human milk, and the potential for absorption of ocrelizumab to lead to B-cell depletion in the infant is unknown. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for OCREVUS and any potential adverse effects on the breastfed infant from OCREVUS or from the underlying maternal condition.

Females and Males of Reproductive Potential

Women of childbearing potential should use effective contraception while receiving OCREVUS and for 6 months after the last infusion of OCREVUS.

Most Common Adverse Reactions

RMS: The most common adverse reactions in RMS trials (incidence ≥10% and >REBIF) were upper respiratory tract infections (40%) and infusion reactions (34%).

PPMS: The most common adverse reactions in PPMS trials (incidence ≥10% and >placebo) were upper respiratory tract infections (49%), infusion reactions (40%), skin infections (14%), and lower respiratory tract infections (10%).

You may report side effects to the FDA at **(800) FDA-1088** or **www.fda.gov/medwatch**. You may also report side effects to Genentech at **(888) 835-2555**.

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References: 1. Williams MJ, Vartanian T, Reder AT, et al. One-year analysis of efficacy and safety data from Black and Hispanic patients with relapsing multiple sclerosis receiving ocrelizumab treatment in the CHIMES trial. Poster presented at: 39th Congress of the European Committee for Treatment and Research in Multiple Sclerosis (ECTRIMS); October 11-13, 2023; Milan, Italy. **2.** OCREVUS [prescribing information]. South San Francisco, CA: Genentech, Inc; 2024. **3.** Hauser SL, Bar-Or A, Comi G, et al. Ocrelizumab versus interferon beta-1a in relapsing multiple sclerosis. *N Engl J Med.* 2017;376(3):221-234. **4.** Cree BAC, Pradhan A, Pei J, Williams MJ, et al. Efficacy and safety of ocrelizumab vs interferon beta-1a in participants of African descent with relapsing multiple sclerosis in the Phase III OPERA I and OPERA II studies. *Mult Scler Relat Disord*. 2021;52:103010. **5.** Havrdová E, Arnold D, Bar-Or A, et al. No evidence of disease activity (NEDA) analysis by epochs in patients with relapsing multiple sclerosis treated with ocrelizumab vs interferon beta-1a. *Mult Scler J Exp Transl Clin*. 2018;4(1):1-11. **6.** Okai AF, Howard AM, Williams MJ, et al. Advancing care and outcomes for African American patients with multiple sclerosis. *Neurology*. 2022;98(24):1015-1020. **7.** Amezcua L, Rivera VM, Vazquez TC, Baezconde-Garbanati L, Langer-Gould A. Health disparities, inequities, and social determinants of health in multiple sclerosis and related disorders in the US. *JAMA Neurol*. 2021;78(12):1515-1524. **8.** Cree BAC, Khan O, Bourdette D, et al. Clinical characteristics of African Americans vs Caucasian Americans with multiple sclerosis. *Neurology*. 2004;63(11):2039-2045. **9.** Gray-Roncal K, Fitzgerald KC, Ryerson LZ, et al. Association of disease severity and socioeconomic status in Black and White Americans with multiple sclerosis. *Neurology*. 2021;97(9):e881-e889. **10.** Kister I, Bacon T, Cutter GR. How multiple sclerosis symptoms vary by age, sex, and race/ethnicity. *Neurol Clin Pract*. 2021;11(4):335-341. **11.** Orlando CM, Pérez CA, Agyei P, et al. Social determinants of health and disparate disability accumulation in a cohort of Black, Hispanic, and White patients with multiple sclerosis. *Mult Scler*. 2023;29(10):1304-1315. **12.** Ventura RE, Antezana AO, Bacon T, Kister I. Hispanic Americans and African Americans with multiple sclerosis have more severe disease course than Caucasian Americans. *Mult Scler*. 2017;23(11):1554-1557. **13.** Trinity Life Sciences. Diversity in clinical trials participation: A life sciences perspective. https://trinitylifesciences.com/wp-content/uploads/2022/05/Trinity-Whitepaper-Diversity-in-Clinical-Trials-Participation.pdf. Accessed December 19, 2023. **14.** US Census Bureau. Quick facts United States. https://www.census.gov/quickfacts/fact/table/US/IPE120221. Accessed December 19, 2023. **15.** Williams MJ, Okai AF, Cross AH, et al. Demographics and baseline disease characteristics of Black and Hispanic patients with multiple sclerosis in the open-label, single-arm, multicenter, phase IV CHIMES trial. *Mult Scler Relat Disord*. 2023;76:104794.

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“We know that **Black and Hispanic people with MS often experience more severe disease and greater disability** compared with their White counterparts. But until now, there has been limited research conducted in these populations.”

—**Mitzi J. Williams, MD**
Lead investigator for
the CHIMES trial

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