ForPatients
by Roche

Multiple Sclerosis (MS)Progressive Multiple Sclerosis (PMS)

A Clinical Trial of Ocrelizumab in Patients with Progressive Multiple Sclerosis (CONSONANCE)

A Study to Evaluate Ocrelizumab Treatment in Participants With Progressive Multiple Sclerosis (CONSONANCE)

Trial Status	Trial Runs In	Trial Identifier
Active, not recruiting	24 Countries	NCT03523858 MN39159

The information is taken directly from public registry websites such as ClinicalTrials.gov, EuClinicalTrials.eu, ISRCTN.com, etc., and has not been edited.

Official Title:

An Open-Label, Single-Arm 4-Year Study to Evaluate Effectiveness and Safety of Ocrelizumab Treatment in Patients With Progressive Multiple Sclerosis

Trial Summary:

This study is a prospective, multicenter, open-label, single-arm effectiveness and safety study in participants with progressive multiple sclerosis (PMS).

Hoffmann-La Roche Sponsor	**Phase 3** Phase

NCT03523858 MN39159
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	# 18 Years & # 65 Years	No

How does the CONSONANCE clinical trial work? This clinical trial is recruiting people who have a progressive form of ‘multiple sclerosis’ or MS, which is a disabling disease of the brain and spinal cord.

The aim of this clinical trial is to see if the trial medicine, ocrelizumab, will stop the signs and symptoms of your progressive form of MS from getting worse.

How do I take part in this clinical trial? If you think this clinical trial may be suitable for you and would like to take part, please talk to your doctor.

If your doctor thinks that you might be able to take part in this clinical trial, he/she may refer you to the closest clinical trial doctor who will give you all the information you need to make your decision about taking part in the clinical trial. You will also find the clinical trial locations at the top of this page.

If you agree to take part in the clinical trial, you will have some further tests to make sure you will be able to take the treatments given in this clinical trial. Some of these tests and procedures may be part of your regular medical care and may be done even if you do not take part in the clinical trial. If you have had some of the tests recently, they may not need to be done again.

Before starting the clinical trial, you will be told about any risks and benefits of taking part in the trial and what other treatments are available so that you may decide if you still want to take part.

What treatment will I be given if I join this clinical trial? Everyone who joins this clinical trial will be given the treatment ocrelizumab into their vein (this is called an ‘intravenous infusion’).

Patients will also be given two additional medicines, one called methylprednisolone and an antihistamine drug, about 30–60 minutes before the start of the ocrelizumab. Your doctor might also give you other medicines such as acetaminophen/paracetamol before the ocrelizumab. You will be given the first two doses of ocrelizumab on Day 1 and Day 14 of the clinical trial, and then another dose every 6 months after that for up to about 3 years.

How often will I be seen in follow-up appointments, and for how long? During this clinical trial, you will have 11 visits at the clinical trial site, including the screening visit. At every visit, you will need to stay at the clinical trial site for at least 1 hour after the ocrelizumab infusion has finished. You will also need to come to a follow-up visit around 12 months after your last infusion to check on any side effects. At your final clinical trial visit, if you and your doctor decide to continue your treatment, you may be able to move onto another Roche clinical trial or continue with ocrelizumab.

Your total time in the clinical trial will be about 5 years. You can leave the clinical trial at any time. If you decide to no longer take part in the clinical trial, you will need to return to the clinical trial site for at least 12 months, to check that you are not having any side effects.

What happens if I'm unable to take part in this clinical trial? If this clinical trial is not suitable for you, you will not be able to take part. Your doctor will suggest other treatments for you that you can be given or other clinical trials that you may be able to take part in. You will not lose access to any of your regular care.

For more information about this clinical trial see the **For Expert** tab on this page or follow this link to ClinicalTrials.gov

Trial-identifier: NCT03523858

Inclusion Criteria:

- Have a definite diagnosis of PMS (as per the revised McDonald 2010 criteria for PPMS or Lublin et al. 2014 criteria for PMS)
- EDSS (Expanded Disability Status Scale)
- Have a documented evidence of disability progression independent of relapse at any point over the 2 years prior to the screening visit. In case relapse(s) have occurred in the last 2 years, disability progression will have to be considered as independent of relapse activity as per treating physician's judgment
- Fulfill at least one of the 21 criteria assessing the evidence of disability progression independent of relapse activity in the last 2 years using the pre-baseline disability progression rating system checklist
- Have experience of having used a smartphone and connecting a smartphone to Wi-Fi network providers
- For women of childbearing potential: agreement to remain abstinent or use acceptable contraceptive methods during the treatment period and for at least 6 months, or longer if the local label is more stringent after the last dose of study drug

Exclusion Criteria:

- Relapsing-remitting multiple sclerosis (RRMS) at screening
- Inability to complete an MRI
- Gadolinium (Gd) intolerance
- Known presence of other neurological disorders

Exclusions Related to General Health:

- Pregnancy confirmed by positive serum # human chorionic gonadotropin (hCG) measured at screening
- Lactation
- Any concomitant disease that may require chronic treatment of systemic corticosteroids or immunosuppressants during the course of the study
- History or currently active primary or secondary immunodeficiency
- Lack of peripheral venous access
- Significant or uncontrolled somatic disease or any other significant disease that may preclude participant from participating in the study.
- Active infections must be treated and resolved prior to the first infusion of ocrelizumab
- Participants in a severely immunocompromised state until the condition resolves
- Participants with known active malignancies or being actively monitored for recurrence of malignancy
- Participants who have or have had confirmed progressive multifocal leukoencephalopathy (PML)

Exclusions Related to Laboratory Findings:

- Positive screening tests for hepatitis B
- CD4 count <250/µL
- ANC <1.0 × 103/µL
- AST/SGOT or ALT/SGPT #3.0 × ULN in combination with either an elevated total bilirubin (>2 X ULN) or clinical jaundice

Exclusions Related to Medications:

- Hypersensitivity to ocrelizumab or to any of its excipients
- Previous treatment with ocrelizumab
- Previous treatment with B-cell targeted therapies (i.e., atacicept, tabalumab, belimumab, ofatumumab, or obinutuzumab). Note: previous treatment with rituximab is allowed as long as the last dose was administered more than 6 months before the ocrelizumab infusion AND if discontinuation was due to adverse events or immunogenicity AND if Bcell levels are above the lower limit of normal (LLN) prior to screening.
- Any previous treatment with alemtuzumab (Campath/Mabcampath/Lemtrada), total body irradiation, or bone marrow transplantation
- Previous treatment with natalizumab where PML has not been excluded according to specific algorithm
- Contraindications to or intolerance of oral or intravenous (IV) corticosteroids, including methylprednisolone administered IV, according to the country label
- Systemic corticosteroid therapy within 4 weeks prior to screening
- All vaccines should be given at least 6 weeks before the first infusion of ocrelizumab, unless the local regulations allow for a shorter interval. Live/live attenuated vaccines should be avoided during treatment and safety follow-up period until B cells are peripherally repleted
- Previous treatment with daclizumab, ozanimod or figolimod in the last 8 weeks
- Previous treatment with siponimod in the last 2 weeks
- Treatment with fampridine/dalfampridine (Fampyra)/Ampyra) or other symptomatic MS treatment unless on stable dose for #30 days prior to screening
- Previous treatment with natalizumab in the last 12 weeks.
- Previous treatment with teriflunomide in the last 12 weeks. This washout period can be shortened if an accelerated elimination procedure is implemented before screening visit. One of the following elimination procedures can be used:
- Cholestyramine 8 g administered 3 times daily for a period of at least 7 days (cholestyramine 4 g three times a day can be used, if cholestyramine 8 g three times a day is not well tolerated)
- Alternatively, 50 g of activated powdered charcoal is administered every 12 hours for a period of at least 7 days.
- Previous treatment with azathioprine, cyclophosphamide, mycophenolate mofetil or methotrexate in the last 12 weeks
- Treatment with any investigational agent within 24 weeks of screening (Visit 1) or five half-lives of the investigational drug (whichever is longer) or treatment with any experimental procedures for MS
- Previous treatment with mitoxantrone, cyclosporine or cladribine in the last 96 weeks
- Participants previously treated with teriflunomide within the last two years, unless measured plasma concentrations are less than 0.02 mg/l. If above or not known, an accelerated elimination procedure should be implemented before screening visit