

## About clinical trials

Clinical trials aim to answer specific questions about how medicines work in the participants who take them. You should feel fully informed about what to expect from your participation in a clinical trial.

During the study, you will collaborate with a professional research team of study doctors, study nurses, and other research staff. Without your help and the commitment of the study team, the development of new medication choices would not be possible to help MS patients in the future.



## Why are clinical trials conducted?

Clinical trials may help researchers, doctors, and healthcare providers find new ways to prevent, detect, or treat diseases, syndromes, or conditions.

Clinical trials may include the study of:

- Investigational drugs or new drug combinations
- New surgical procedures or devices.
- New ways to use existing treatments to relieve symptoms and/or slow a disease from getting worse.

The goal of a clinical trial is to learn the effects of an investigational procedure, medication, or device under controlled conditions.



# HERCULES

## EFC16645

The Hercules clinical trial is part of the MyMSTrials symposium of multiple sclerosis clinical trials.

 **MyMSTrials.com**

MyMSTrials.com is a collection of phase III clinical trials designed to determine the efficacy, safety and tolerability of the study drug in patients with various forms of Multiple Sclerosis.

## Who can I contact to learn more about MyMSTrials?

For more information about MyMSTrials and the possible risks and benefits of participation, please visit:

**[www.MyMSTrials.com](http://www.MyMSTrials.com)**



## Seeking Participants with Non-Relapsing Secondary Progressive Multiple Sclerosis (nrSPMS) for Clinical Trial



 **MyMSTrials.com**

## We appreciate your interest in the Hercules Trial!

The information provided is intended to assist in your decision to participate in this clinical trial opportunity.



### About secondary progressive multiple sclerosis (SPMS)

Nearly 80% of people diagnosed with relapse-remitting multiple sclerosis (RMS) eventually develop secondary progressive MS (SPMS).

With SPMS, the relapses and remissions typical of RMS develop into symptoms that steadily worsen over time. This change typically occurs between 15 and 20 years after one is initially diagnosed with MS.

Even for healthcare professionals, it can be challenging to identify the changes that signal the onset of SPMS.

Common symptoms of secondary progressive multiple sclerosis include—but are not limited to—increased weakness, difficulty maintaining coordination, bowel and bladder problems, stiffness/tightness in the leg muscles, a lack of mental coherence, and depression and fatigue.

## What is the purpose of the Hercules Trial?



The Hercules Trial is a Phase III clinical trial designed to test how well the study drug works and whether it is safe. The study drug will be compared to placebo (a tablet that looks the same as the study drug but has no therapeutic effect). The main effect that is being tested is whether the study drug delays disability progression in patients diagnosed with secondary progressive multiple sclerosis (SPMS). Patients will be randomly selected to receive the study drug or placebo. The study drug is being compared to placebo because approved treatments specifically for non-relapsing SPMS (nrSPMS) are not available in all countries or covered by insurance in all patients. Comparing the study drug to another active treatment (eg, an approved MS drug) would require a larger number of patients to be studied (vs placebo control) and would increase the time it takes to finish the study. As only a small number of patients with nrSPMS, finding enough patients with nrSPMS would be difficult and would have delayed the availability of potentially effective treatment.

Additional goals of the trial will be to test the effect of the study drug on disability progression, magnetic resonance imaging (MRI) lesions, the ability to learn and process information, and quality of life, as well as the safety and tolerability of the study medication.

### You may be eligible for the trial if:

- You are a man or woman between the ages of 18 and 60
- You have a current diagnosis of secondary progressive multiple sclerosis (SPMS)

Additional requirements will be discussed with a study team's representative. Qualified patients may receive study-related care at no cost.

### What are the benefits and risks of taking part in this study?

This study is experimental research and there is no guarantee that you will get any benefit from participating in.

All medications and treatments have risks. One of the risks is that you might experience discomfort or side effects with the use of the SAR442168 or procedures. For SAR442168, these risks are still unknown at this stage. In some cases, side effects can be serious, long-lasting, permanent, or life-threatening. The study doctor is trained to take the appropriate measures to reduce risks and limit any discomforts you may experience. The study doctor will discuss with you risks in more detail such as those associated with drugs similar to the study drug and those that may be associated with study procedures.

## What will I be required to do to join the trial?

Participation in the Hercules Trial consists of three stages:

1

### SCREENING

to determine eligibility to participate

2

### TREATMENT

receive either the investigational drug or placebo.

3

### COMMON EOS VISIT

final procedures/assessments

*After the end of this study, and after completing this trial successfully, you may be offered the option to participate in the long-term extension study for an additional 2 years, or until the drug is approved in your respective country, whichever comes first. For more information, please discuss with your study doctor.*

### How long will participation last?

The duration of treatment (investigational drug) will be between 24 to 48 months. For patients completing the treatment per protocol, you may be offered to take part of an optional Long-Term extension study during which you will continue to receive the study drug.



The Hercules clinical trial is part of the MyMSTrials symposium of multiple sclerosis clinical trials. To learn more about this trial and find out if you qualify, visit [www.MyMSTrials.com](http://www.MyMSTrials.com).