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## **Orchestra – Opera**

*The sound of a new research  
opportunity in multiple sclerosis*

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Dear Reader,

We understand the challenges of living with multiple sclerosis (MS) and would like to let you know that our center is currently participating in a new clinical research program, called Orchestra, which comprises three studies. We would like to ask if you would like to participate in either the Opera I or the Opera II Study for patients with relapsing MS. The third study is for patients with progressive MS. The Opera I & II Studies will include approximately 1600 patients across 440 study centers worldwide.

Each study is looking at whether patients treated with an investigational drug, called ocrelizumab, experience fewer relapses compared with patients who take a treatment that is already approved for MS, called Rebif®.

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- We are looking for patients who:
  - are between 18 and 55 years of age
  - have been diagnosed with relapsing MS – a relapse is a time when your symptoms rapidly get worse
  - have had at least two documented relapses within the past 2 years, or one within the past year.
- You will first need to visit the study center so the study team can see if you are eligible to participate. If you are eligible and decide to take part, you will receive either the investigational drug or an approved medication for MS to take for approximately 2 years. This will be decided at random, like the toss of a coin. All patients will receive infusions once every 6 months\* and will be trained to inject themselves three times per week.
- The study will require you to visit the study center usually every 10–12 weeks, for a total of at least 11 visits, at which you will undergo several assessments to monitor your neurologic status and general health. After that, you may be eligible to enter a separate long-term extension study. A member of the study team will call and ask you a few questions every 4 weeks.
- If you decide to discontinue study treatment or are not eligible for the extension study, you will enter into a safety follow-up period of at least 48 weeks in duration. You will be assessed at study center visits every 12 weeks. If prolonged B-cell monitoring is required beyond 48 weeks, you will be assessed at study center visits every 24 weeks until your B-cell count has returned to normal.

\*Given as two infusions of 300 mg on Days 1 and 15 of the first 24-week treatment cycle and one infusion of 600 mg on Day 1 of each 24-week treatment cycle thereafter.

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To find out more about taking part in an Opera Study, please contact me or a member of the study team using the details below. Thank you for your interest in this important research into treatments for MS.

Sincerely

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