THE POINT STUDY

GENERAL INFORMATION

About the POINT Study

- POINT is a clinical research study that looks at the effects and safety of adding ponesimod 20 mg treatment to dimethyl fumarate [trade name Tecfidera®] background therapy for patients with relapsing multiple sclerosis (RMS).
- The POINT study will have two treatment groups: one will take Tecfidera® plus ponesimod and one will take Tecfidera® plus placebo.
- A placebo tablet looks like real medicine but has no drug in it.
- Among approximately 600 participants taking Tecfidera® twice daily for at least 6 months, approximately 300 participants will take ponesimod 20 mg and approximately 300 participants will take placebo. You may be assigned to take ponesimod 20 mg or placebo in addition to Tecfidera®. Your treatment assignment will be chosen by chance, like tossing a coin, using a computer. There is about a 50% chance of taking ponesimod 20 mg or placebo (always in addition to Tecfidera®).
- Patients from more than 100 clinics in approximately 20 countries worldwide will be asked to participate in this research study for up to 3 years.
- This is a double-blind study. This means that you, your study doctor and Actelion representatives will not know if you are taking ponesimod or placebo in addition to Tecfidera®.
- The primary outcome measured in the POINT study is the number of confirmed relapses per patient per year.
- The POINT study also aims to determine if any changes occur in your fatigue symptoms if you are experiencing any.

About the investigational therapy ponesimod

- ✓ Ponesimod is not yet available for prescription. If randomized, you will be asked to take one tablet of study drug with ponesimod or placebo every day, in addition to Tecfidera®.
- ✓ If you are randomized to ponesimod taken once daily, it will slowly be increased from 2 mg to 10 mg during the first 14 days of treatment which will be referred to as the up-titration period. From Day 15 until the end of treatment, patients randomized to ponesimod will take 20 mg of ponesimod per day (maintenance period). The placebo will consist of tablets that will look the same but contain no ponesimod.

Additional Information

Your Responsibilities as a Study Participant. What is expected from you?

- ✓ Participating in the POINT study is completely voluntary
- ✓ Follow the instructions of the study doctor and study staff
- ✓ Attend all scheduled study visits
- ✓ Take the study drug as instructed
- ✓ Inform the study doctor of any changes in your health or medication
- ✓ Tell the study doctor before making changes to your existing medications,
- ✓ or taking any new medication, vitamin or supplement
- ✓ Tell the study doctor if you become pregnant

If you have any questions, please refer to a study doctor listed on clinicaltrials.gov

Thank you for taking time to learn about the POINT Study