Safety and Efficacy Study of Fingolimod in Taiwanese Adults (≥ 20years) With Relapsing Remitting Multiple Sclerosis

Last Update: Dec 27, 2024
A 12-month, Prospective, Multi-center Post-authorization Commitment (PAC) Study Monitoring Safety in Adult Patients With Relapsing-remitting Multiple Sclerosis Newly Initiated on Gilenya (Fingolimod) in Taiwan (SPRING)
ClinicalTrials.gov Identifier:
NCT04480853
Novartis Reference Number:CFTY720DTW03
See if you Pre-qualify
All compounds are either investigational or being studied for (a) new use(s). Efficacy and safety have not been established. There is no guarantee that they will become commercially available for the use(s) under investigation.

Study Description

The purpose of the study is to describe the safety profile of fingolimod in the Taiwanese multiple sclerosis population. This study aims to collect the safety data in patients newly initiated on fingolimod for one year. This is a 12-month, prospective, interventional, multi-center study to monitor safety in adult patients with relapsing-remitting multiple sclerosis (RRMS) in Taiwan who based on local practice are newly starting fingolimod at the time of study entry.

Thirty-four patients will be included in this study in line with the study inclusion and exclusion criteria. After entering this study, the participants will continue to be treated for MS based on local practice. The patient will be taking fingolimod 0.5mg per day. Protocol-mandated procedures and visits for safety data collection will be conducted in addition to the required examinations according to the clinical practice.

If a patient experienced an interruption of fingolimod treatment that requires a re-evaluation of FDO, the patient will be discontinued from the study. If the treatment interruption does not require a FDO when re-starting fingolimod, the patient can continue to participate in this study.

Condition
Multiple Sclerosis
Phase
Phase4
Overall Status
Recruiting
Number of Participants
30
Start Date
Oct 12, 2020
Completion Date

Jan 27, 2026
Gender
All
Age(s)
20 Years - 100 Years (Adult, Older Adult)

Interventions

Drug

Fingolimod

Fingolimod 0.5 mg QD, oral

Eligibility Criteria

Inclusion Criteria:

-Patients with relapsing-remitting multiple sclerosis that are fingolimod treatment naive at the time of study entry and are newly starting fingolimod based on physician judgement and according to Taiwan's fingolimod package insert (version TWI-090420)

Exclusion Criteria:

* Patients with the diagnosis of neuromyelitis optica.
* Patients who are being treated with any investigational drug at the time of study entry.
* In the last 6 months experienced myocardial infarction, unstable angina, stroke, transient ischemic attack, decompensated heart failure requiring hospitalization or Class III/IV heart failure
* A history or presence of Mobitz Type II second-degree or third-degree atrioventricular block or sick sinus syndrome, unless patient has a functioning pacemaker
* A baseline QTc interval ≥ 500 msec
* Cardiac arrhythmias requiring anti-arrhythmic treatment with Class Ia or Class III anti-arrhythmic drugs
* Patient with known immune deficiency, increased risk of opportunistic infection, severe active infection or chronic active infection.
* Patients with severe active malignancies, except for basal cell epithelioma
* Patients with severe hepatic insufficiency
* Pregnant or nursing (lactating) women or women of childbearing potential unless on contraception

Taiwan

Novartis Investigative Site

Recruiting

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Novartis Investigative Site

Recruiting

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Recruiting

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