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Long-term Efficacy, Safety, tolerability and Quality of Life with Fingolimod Treatment in Patients with Multiple Sclerosis in Real-world Settings in France: VIRGILE Study Design

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Background: Once daily 0.5mg oral fingolimod is approved in the European Union for treatment of patients with highly active relapsing remitting multiple sclerosis (RRMS). The efficacy and safety profiles of fingolimod have been well established in a large clinical development programme; however, limited but increasing quantity of data available in real-world settings. The VIRGILE study was planned in response to a request by the French Health Authorities (HAS and CEPS) to assess the impact of fingolimod in the treatment of patients with highly active forms of RRMS in France.

Objective: To evaluate efficacy, safety and tolerability of fingolimod and its impact on quality of life (QoL) in patients with MS in real-world settings. A group of patients receiving natalizumab was also included in the study at the request of French Health Authorities.

Methods: VIRGILE, a non-interventional, multicentre, observational study, was planned in collaboration with the French Observatory of Multiple Sclerosis. Patients initiating either fingolimod or natalizumab treatment as per their physician's decision will be included in the study. Patients receiving disease modifying treatment other than fingolimod or natalizumab or those who received treatment with fingolimod or natalizumab previously will not be included in the study. All patients will be prospectively followed for 3 years. If the study is not finished at the completion of 3 years of follow-up, fingolimod cohort will have an additional follow up for a maximum period of 2 years. Approximately 1200 neurologists will be contacted to participate. VIRGILE will enrol ~1200 and 600 patients in the fingolimod and natalizumab cohorts, respectively. The primary endpoint is to assess changes in the annualised relapse rate at 2 years from baseline. Secondary end points include assessment of the impact of each treatment on relapse activity (% of relapse free patients and % of patients requiring corticosteroid/hospitalization), disability progression and QoL (Multiple Sclerosis International Quality of Life and EuroQoL5D scales). QoL parameters will be assessed at 3 years. Safety, pharmaco-economic aspects, and healthcare utilisation data will also be assessed.

Results: To date, 955 patients have been enrolled. The detailed study design will be presented.

Conclusion: VIRGILE is the largest study in France to date evaluating the long-term efficacy, safety, and tolerability profiles of fingolimod in real-world settings, thus aiding treatment decisions for MS patients.