Efficacy, costs and quality of life in the real world setting for patients with multiple sclerosis: intermediate results from the VIRGILE study

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Introduction

Multiple sclerosis (MS) is an auto-immune chronic disease affecting the central nervous system and causing a variety of motor and sensitive symptoms with an important impact on quality of life for patients.

- Fingolimod (FTY720; Gilenya®; Novartis Pharma AG), a sphingosine 1-phosphate receptor modulator, was the first approved oral disease-modifying therapy (DMT) in patients with relapsing-remitting MS in 2011.
- Fingolimod 0.5mg daily has an established efficacy, safety and tolerability profile with data from a large clinical development program and an increasingly large number of patients in real-world settings.
- The VIRGILE study is an observational prospective study which was launched at the request of French Health and Technology Assessment Authorities upon launch of fingolimod in France. Besides clinical endpoints, the study included collection of health care resource utilizations in order to evaluate the impact of fingolimod on health care organization.
- The intermediate results at 12 months follow up are presented in this poster on the main clinical endpoint, as well as the economic analysis derived from health care resource utilization.

Objectives

The objective of this economic analysis is to assess the evolution of health resources consumptions of patients treated with fingolimod at 12 months follow up from a payer’s perspective.

Methods

- Health resources consumptions data were extracted from the largest study in France to date evaluating fingolimod in real-world settings, a non-interventional, multicentre, and observational study including patients treated with fingolimod, with prospective follow up for 3 years. Besides efficacy and safety, endpoints include quality of life and health resource consumptions collected through patient questionnaires.
- Health resources use was collected through a patient questionnaire at 6 months and 12 months follow up.
- Disability was measured by EDSS and EQ-5D scales.
- The costs for health resources valorization were estimated from the public payer’s perspectives (social security), using healthcare system databases. Patients were considered under “long lasting affection” (ALD) regimen and therefore expenses related to the disease such as hospitalizations and neurologist consultations were considered 100% reimbursed.
- Mean hospitalizations costs in patients with MS were calculated using an extraction of DRG data of hospitalization expenses for patients presenting with MS as main, associated or related diagnosis.
- General practitioners (GP) consultation costs were extracted from AMELI database and considered reimbursed at 70% by social security.
- Neurologist consultation costs were extracted from AMELI database and considered reimbursed at 100% by social security.
- Work day losses reimbursed by the social security were estimated from the mean annual wage adjusted to the sex ratio observed in the VIRGILE population.
- Costs were updated to year 2015 using variation price index.
- All estimated costs are listed in table 1.

Results

• Clinical results:
  - A total of 1011 patients treated with fingolimod were enrolled in the study. At 12 months follow up, results confirmed the efficacy and safety profile of fingolimod with an increase of the proportion of relapse free patients (figure 1).
  - Disability was stable as assessed by EDSS scores (figure 2) and quality of life was maintained with a stable utility scores of 0.7 (EQ5D) and stable MusiQol scores (figure 3).

Discussion / Conclusion

The one year data analysis from this study evaluating fingolimod in real-world settings shows a reduction in health resources consumption and confirms long-term efficacy and safety profile of fingolimod with a maintained quality of life. Efficacy of fingolimod observed for clinical endpoints such as relapse rates and EDSS scores was consistent with the reductions of medical consultations, hospitalizations and sick leaves. These results are still preliminary, and should be confirmed at the end of VIRGILE study after a regular 2 years follow up. Upon completion of the VIRGILE study, health economics results and cost savings should be compared to the global costs of the disease as measured in VIRGILE, as well as in the general population of patients with MS in France.

References