Conclusions

• Regardless of the previous disease modifying therapy, fingolimod significantly suppresses clinical disease activity.

• Fingolimod demonstrated sustained efficacy in the treatment of RRMS.

• Long-term therapy with fingolimod has a high treatment persistence.

• The long-term reported adverse events is consistent with previous findings from clinical trials.

• The average fingolimod patient has a stable EDSS.

Introduction

Once daily oral fingolimod (FTY720; Gilenya®, Novartis Pharma AG, a sphingosine 1-phosphate receptor modulator) is approved for the treatment of relapsing-remitting multiple sclerosis (RRMS) in over 80 countries. As of May 2013, it is estimated that Gilenya® has been used to treat approximately 125,000 patients in clinical trials and the post-marketing setting. The total patient exposure now exceeds 240,000 patient-years.

Purpose

The PANGAEA registry records data of German patients with RRMS that are treated with fingolimod under real-life conditions for 5 years. Here, we present the results of an interim analysis after 36 months from February 2015.

Methods

PANGAEA is a prospective, multi-center, non-interventional, long-term study of fingolimod (0.5 mg) for the treatment of patients with RRMS. The observation period under PANGAEA is up to 60 months with follow-up visits every 3 months. Patients included the first time with fingolimod (n = 3121) and former study participants (n = 342) are documented in PANGAEA.

Results

A total of 3,951 patients documented up to 36 months at 342 sites were included in this analysis. The baseline characteristics are described in Table 1 and Figure 1a. Observation period under PANGAEA was 36.0 ± 37.2 days; average duration of therapy with Gilenya® was 88.8 ± 418.0 days (mean ± SD).

Safety

• Rates of study discontinuation remained stable with 13.9% (±12.1%) in years 1 and 2 respectively (Fig. 2a).

• The proportion of patients who discontinued due to an adverse event reduced from 4.3% in year 1 to 2.5% in year 2 (Fig. 2a).

• Patients discontinuing treatment due to lack of efficacy or disease progression remained low at 2.6% in year 1 and 3.1% at year 2 (Fig. 2a).

• Compared to baseline, the frequency of the most frequently reported adverse events in the first year of PANGAEA was decreased in phase III clinical trials.

• The average fingolimod patient has a stable EDSS.

Effectiveness and treatment satisfaction

• In the first year of PANGAEA more than 60% of the patients were disease free defined as patients without a relapse in the last 12 months and without a sustained EDSS progression (defined by a 6 months stable rise of the EDSS by 1 point for an EDSS 5.0 or 0.5 points for an EDSS 6.0) (Fig. 4b).

• This proportion increased to 70% at 3 years and was independent of prior treatment history.

• In a 34-month follow-up, the disability progression rate (a ≥4.0 EDSS increase at baseline) patients were asked to rate their treatment satisfaction with the Treatment Satisfaction Questionnaire for Medication (TSQM 9: 7 = low satisfaction, 9 = high satisfaction). The total score improved by more than 5 points from baseline to 36 months (Fig. 4b).

Disclosures

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