CONCLUSIONS

• Patients with active disease and treated with baseline therapy (GA and IFN-beta) in the PEARL study show a stronger disease progression compared to patients treated with fingolimod (PANGAEA).

• Patients treated with fingolimod (PANGAEA) show a significantly higher occurrence of sustained EDSS improvement than those on first-line therapy showing disease activity (PEARL).

• Patients and physicians agree that Gilenya is well tolerated.

BACKGROUND

• Once daily oral fingolimod (FTY720; Gilenya®, Novartis Pharma AG, a sphingosine-1-phosphate receptor (S1PR) modulator, is approved for the treatment of relapsing multiple sclerosis. More than 71,000 patients have been treated with fingolimod in both the clinical trial and post-marketing settings; total patient exposure now exceeds 87,000 patient years.12

• To investigate the safety, tolerability and efficacy of fingolimod in daily practice, a large national prospective 5-year noninterventional study (NIS) is being conducted (PANGAEA). The study includes a subset of pharmaco-economic (PE) data (Fig. 1).

• A further prospective NIS (PEARL) collects analogous data in a first-line setting, i.e., Interferon beta (IFNa/betainterferon) (IFNa) (n = 1,140, 71.69 %) and Glatiramer acetate (GA) therapy (n = 450, 28.30 %), allowing comparison of efficacy, safety and treatment satisfaction between fingolimod and first-line therapy (Fig. 1).

METHODS

• PEARL patients were divided into those with disease activity (at least one relapse during the previous 12 months of documentation (PEARL, active n = 450) vs. PEARL patients that responded well to baseline therapy and did not have any relapse in the last 12 months of documentation (PEARL, inactive n = 1,193) (Fig. 1).

• PANGAEA patients (n = 2,239), all suffered from highly active RMS (as defined by the fingolimod label) during the 12 months before first dosing with fingolimod (Fig. 1).

• In the analysis depicted in Fig. 3 only fingolimod treatment naïve patients were included that took part in former fingolimod studies were excluded) to focus on patient development during the first year of fingolimod treatment. This population was compared with PEARL patients with disease activity.

RESULTS

• Here we report the results of interanalyses of both noninterventional studies PANGAEA (n = 2,239 in Fig. 2 and 4, and m = 2,300 in Fig. 3) and PEARL (n = 1,590) and compare efficiency, safety, tolerability and treatment satisfaction.

• PEARL inactive (n = 1,132), PEARL active (n = 455) and PANGAEA patients (n = 2,239) were first diagnosed with MS (47.6 %, 61.3 %, 61.8 % and 64.3 % and 62.3 %) years ago; their baseline EDSS was 2.2 (± 1.5), 2.6 (± 1.5), 3.1 (± 1.7) respectively (Fig. 2).

• PEARL inactive patients on average were 43.2 (± 10.3) years old, whilst PEARL active and PANGAEA patients were slightly younger: 40.7 (± 10.3) and 39.7 (± 9.8) respectively (Fig. 2).

• PANGAEA patients showed a higher T2 lesion load and a worse clinical global impression than CGI (severity score) than PEARL active patients (Fig. 2).

• Over the course of one year, PANGAEA patients showed a significantly higher probability of sustained EDSS improvement than PEARL patients with disease activity (Fig. 3).

• PEARL patients showed a higher probability of sustained EDSS progression than PANGAEA patients (Fig. 3).

• Patients and physicians agree on tolerability of fingolimod therapy, 9 out of 10 agree that Gilenya is well tolerated (Fig. 4).

DISCLOSURES

This study was sponsored by Novartis Pharma GmbH, Germany. Poster presented at the European Committee for Treatment and Research in Multiple Sclerosis | 2 - 5 October 2013, Copenhagen, Denmark

The approved indication may vary from country to country. In the EU, fingolimod is indicated for the treatment of relapsing/remitting MS and primary progressive MS. In the United States, it is approved for the treatment of patients with relapsing forms of MS. Data as of 31 May 2013, date of file in MS.