About Gilenya® (fingolimod) Media Fact Sheet

What is Gilenya?

- Gilenya® (fingolimod) is a once-daily oral treatment approved to treat relapsing forms of multiple sclerosis (MS).
- Gilenya is the only oral disease-modifying therapy (DMT) to impact the course of MS with high efficacy across the four measures of disease activity (disability progression, relapses, MRI activity, brain volume loss)[1-5].
- Gilenya is approved in 75 countries, and has been used to treat more than 71,000 patients in clinical trials and the post-marketing setting with more than 87,000 patient years of experience[6].

What is Gilenya indicated for?

- In the EU, Gilenya is approved for people with highly active relapsing remitting multiple sclerosis (RRMS) despite treatment with beta interferon, or in patients with rapidly evolving severe RRMS[7].
- In the US, Gilenya is approved to treat relapsing forms of MS[8].

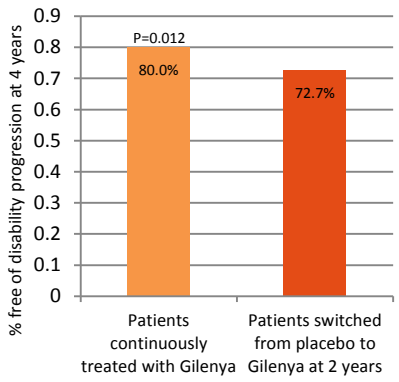
How does Gilenya work?

Gilenya is the first in a new class of compounds called sphingosine 1-phosphate (SP1) receptor modulators[9,10], a type of compound that binds to a receptor present on lymphocytes and on nerve cells in the central nervous system (CNS). It is thought that Gilenya works in two ways against the destructive processes that drive MS disease progression:

- **On the immune system:** Gilenya is thought to act by preventing lymphocytes (the cells that cause inflammation and damage in the CNS) from leaving the lymphoid tissues, thus reducing their entry into the CNS and potential for damage[9,10].
- **On the central nervous system:** Gilenya crosses the blood-brain barrier and can directly act on S1P receptors[9,10].

What is the efficacy profile of Gilenya?

- Early and long term improvements in disease status have been observed in patients who started on Gilenya[1,2,4,11,12] and also in those who were switched from standard interferon treatment (interferon beta 1a) to Gilenya[3,13]:
  - Almost one out of two patients remain disease-free* at one year on Gilenya vs. one out of three with standard interferon treatment (P<0.001; n=1292)[14].
  - In patients continuously treated with Gilenya for up to four years, four in five remained free of disability progression, compared to 7 out of 10 patients switched from placebo at two years (P=0.012)[4].
  - Post hoc analyses demonstrated that Gilenya provided a 61% relative reduction in annualized relapse rate versus standard interferon at one year in patients** failing on standard interferon (P<0.01; n= 160, n=149 respectively)[15].
  - Gilenya is the only oral treatment proven to consistently limit brain volume loss: seen within 6 months, and sustained for up to 4 years in Phase III studies and up to 7 years in a Phase II study[4,5,12].
- Gilenya is the only oral disease-modifying therapy (DMT) with high efficacy across the four measures of disease activity, including brain volume loss[1-5].



Patients were either treated continuously with Gilenya for up to 4 years, or treated first with a placebo for 2 years, followed by Gilenya for up to 2 years. In patients continuously treated with Gilenya for up to 4 years, 80%, were free of disability progression compared to 72.7% of patients switched from placebo at 2 years[10]

Real-world confirmed tolerability of Gilenya

- To date, more than 71,000 patients have been treated with Gilenya, demonstrating a positive benefit-risk profile in clinical study and real-world settings[6].
- Patients can stay on Gilenya for the long term, due to very good tolerability and once-daily dosing[1,2,16-18].
- The most common side effects reported were headache, hepatic enzymes increased, influenza, sinusitis, diarrhoea, back pain, and cough[6].

* Free of relapse, disability progression, and MRI activity
** In patients with high disease activity despite standard interferon treatment.

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