About Gilenya® (fingolimod) & Measures of Relapsing MS Disease Activity
MEDIA FACT SHEET

What is Gilenya?
• Gilenya® (fingolimod) is a once-daily oral disease-modifying therapy (DMT) indicated for the treatment of patients with relapsing forms of multiple sclerosis*.

What is Gilenya indicated for?
• In the EU, Gilenya is indicated for adult patients with highly active relapsing-remitting MS (RRMS) defined as either high disease activity despite treatment with at least one DMT (including interferons, glatiramer acetate and newly-approved DMTs), or rapidly evolving severe RRMS.
• In the US, Gilenya may be used first line for the treatment of relapsing forms of MS (RMS)².

What is Relapsing Multiple Sclerosis (RMS)?
• Relapsing MS is characterized by attacks (relapses) where there is a sudden appearance of previous and/or new symptoms.
• Types of RMS include:
  o Relapsing remitting MS (RRMS), which is characterized by relapses with worsening symptoms, followed by periods of remission where patients may partially or fully recover. Around 85% of people with MS are initially diagnosed with RRMS.
  o Secondary progressive MS (SPMS), which is characterized by gradual worsening of symptoms and accumulation of disability between attacks. The majority of people with RRMS will develop SPMS over time. The transition from RRMS to SPMS is usually gradual.
• In both types of RMS, patients can experience a cumulative loss of physical (e.g. walking) and/or cognitive (e.g. memory) function over time, which impacts their daily and working lives.
• This loss of function in RMS is driven by two types of damage that result in the loss of neurons and brain tissue - distinct inflammatory lesions (referred to as focal damage) which is caused by infiltration of immune cells into the central nervous system (CNS), and more widespread inflammatory neurodegenerative processes (referred to as diffuse damage), which are caused by activation of resident CNS cells.
• Focal damage results in the loss of brain tissue and can clinically present as relapses. Diffuse damage starts early in the disease, often goes unnoticed and is also associated with loss of brain tissue and accumulated loss of function.
• It is important to address both focal and diffuse damage in RMS to effectively impact disease activity and help preserve an individual’s physical (e.g. walking) and cognitive (e.g. memory) function.

What are 4 key measures of RMS disease activity?
• Four key measures of RMS disease activity are relapses, MRI lesions, brain shrinkage (brain volume loss) and disability progression.
• Assessing these four measures gives physicians a complete picture of a patient’s disease and response to treatment, which is crucial to identify the optimal therapy.
• When these four key measures of RMS disease activity are effectively impacted, the patient is known to have ‘no evidence of disease activity’ (NEDA4).

How does Gilenya work in RMS?
• Gilenya targets both focal and diffuse CNS damage that drive loss of function in RMS. Gilenya prevents cells that cause focal inflammation from reaching the brain (referred to as ‘peripheral’ action), but also enters the CNS and reduces the diffuse damage by preventing the activation of harmful cells residing in the CNS (referred to as ‘central action’), as evidenced by animal studies and in vitro experiments.
• Gilenya is the only oral DMT to impact the course of RMS with high efficacy across four key measures of disease activity (relapses, MRI lesions, brain shrinkage and disability progression).
What is the efficacy profile of Gilenya in RMS?

1. Reduction of relapses\(^\text{19}\)

Three in five patients had no relapses when continuously treated with Gilenya for up to 4.5 years\(^{16,18}\)

*Why this is significant:* Relapses may have a disabling impact on an individual's life, and incomplete recovery from a relapse can significantly advance their level of disability\(^{19}\).

2. Reduction of MRI lesions\(^{20-21}\)

Patients treated with Gilenya had five times fewer Gd+ T1 lesions** compared to placebo-treated patients at two years\(^{15,16,\text{b}}\)

*Why this is significant:* During the course of RMS, inflammation driven focal damage can cause lesions (areas of damage) in the brain\(^{20}\). The number and volume of lesions have been shown to be associated with relapses and disability\(^{21}\).

3. Reduced rate of brain shrinkage\(^{22-23,24-25,26}\)

Gilenya is the only oral treatment with consistent, early and sustained reduction in brain volume loss\(^{17,18}\)

*Why this is significant:* RMS patients lose brain volume up to three to five times faster than people without MS\(^{22-23,24-25}\). This acceleration starts early in the course of RMS, even before symptoms are apparent. Brain shrinkage is associated with loss of function and can predict a patient’s disability over time\(^{26}\).
4. Reduced disability progression

Four in five patients remained free of disability progression when continuously treated with Gilenya for up to four years19,20

Why this is significant:
People with RMS may increasingly lose their independence due to accumulating disability; some people may lose their ability to walk21. Only ~50% of people with MS will be employed 10 years after diagnosis22 and two-thirds say having MS has affected their jobs23. Early treatment is key to giving a person with RMS as much time free of disability progression as possible.

Real-world use and confirmed tolerability of Gilenya

- Gilenya’s efficacy is confirmed both through clinical trials and in the real-world setting29.
- Patients can stay on Gilenya for the long term, due to favorable tolerability and once-daily dosing15,17,30,31.
- The most common side effects were headache, hepatic enzymes increased, influenza, sinusitis, diarrhea, back pain, and cough15,32.
- Gilenya is approved in over 80 countries, and has been used to treat more than 119,000 patients in clinical trials and the post-marketing setting29.
- The positive benefit-risk profile of Gilenya in relapsing MS is based on experience of more than 218,500 patient years and accumulation of real-world efficacy and safety data29.

References: