# The Growing Experience with Gilenya® (fingolimod) in Relapsing Multiple Sclerosis

## Gilenya® is a once-daily oral disease-modifying therapy (DMT) indicated for the treatment of patients with relapsing forms of multiple sclerosis (RMS)*

**MORE THAN**

204,000

**PATIENTS HAVE BEEN TREATED WITH GILENYA**

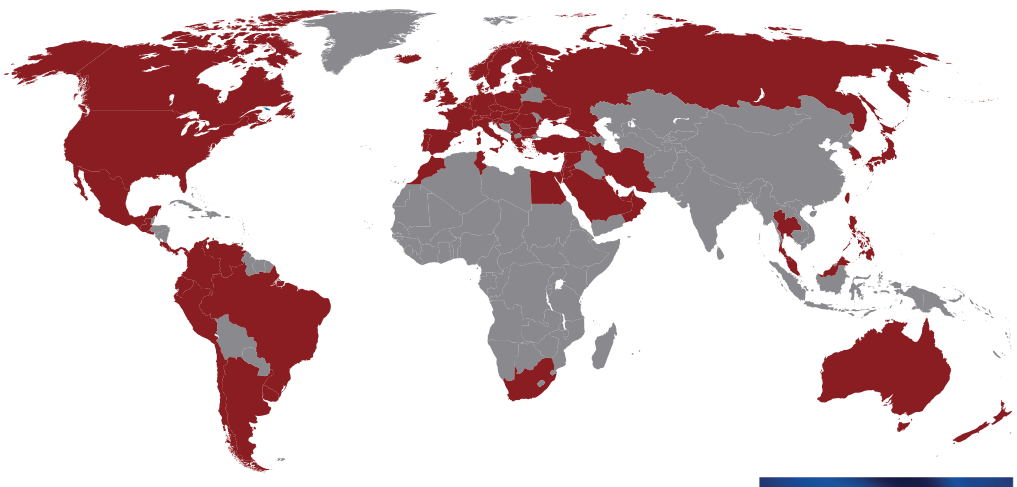
in both clinical trials and the post-marketing setting worldwide[1]

**CUMULATIVE EXPOSURE OF APPROXIMATELY**

424,000

**PATIENT YEARS WITH GILENYA[1]**

## Gilenya is now approved in over 80 countries[1]



In June 2014 the European Commission endorsed the CHMP positive opinion recommending to expand the EU label for Gilenya in relapsing-remitting MS (RRMS) to include patients not responding to DMTs beyond interferon.

## Growing Clinical Trial Evidence With Gilenya

One of the largest Phase III clinical trial programs in RMS was conducted with Gilenya[2-6]. Accumulation of efficacy and safety data post-marketing continues to reinforce the positive benefit-risk profile of Gilenya.

| | Patients | Clinical Trial Centers | Countries |
|---|---|---|---|
| **FREEDOMS** | **1272** | **138** | **22** |
| **TRANSFORMS** | **1292** | **172** | **18** |
| **FREEDOMS II** | **1083** | **126** | **8** |

## Growing Real World Evidence With Gilenya

Real-world evidence continues to confirm the benefits of Gilenya in the real-world setting[7-9].

Data from 264 patients with RMS from the IMS PharMetrics Plus™ Database showed that treatment with Gilenya resulted in **63% fewer relapses per year** compared to interferons or glatiramer acetate[7].

Data from the Phase IV MS-MRIUS study, of 590 patients with RRMS, showed that **approximately 38% of patients achieved NEDA-4** at 16 months, and **around 58% of patients** showed **brain shrinkage levels broadly within the range expected for people without MS[8].**

**Long-term experience has shown Gilenya treatment to be convenient for individuals to incorporate into everyday life, leading to high treatment satisfaction, long-term persistence, and ultimately improving the long-term outcomes for people with RMS[9,10]**

In clinical trials the most common side effects were headache, increased hepatic enzymes, influenza, sinusitis, diarrhea, back pain, cough[2,3,11].

*Approved indication may differ between countries based on local prescribing information


**References**

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