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

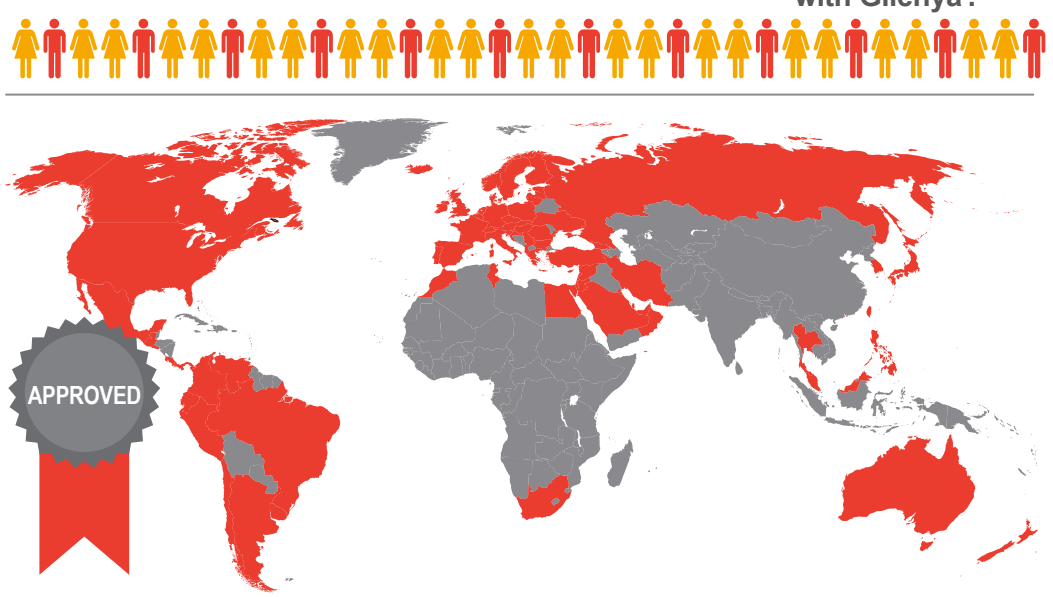
Gilenya is a once-daily oral disease-modifying therapy (DMT) indicated for the treatment of patients with relapsing forms of multiple sclerosis (RMS)*

Approximately 155,000 patients

have been treated in clinical trials and in a post-marketing setting[1].

Cumulative exposure of approximately 343,000 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

Gilenya was approved based on the largest phase III clinical trial program in RMS at the time of submission[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

Analyses from large, real-world databases have confirmed the benefits of Gilenya in the real world setting[7]. Data from 264 patients with RMS from the IMS PharMetrics Plus™ Database, showed that treatment with Gilenya resulted in

62% fewer relapses per year

compared to interferons or glatiramer acetate[7].

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[8-15]:

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

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

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