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

Gilenya is a once-daily oral disease-modifying therapy (DMT) approved to treat relapsing forms of multiple sclerosis (MS).

Growing Clinical Trial Evidence With Gilenya
Gilenya was approved based on the largest phase III clinical trial program in MS at the time of submission. Accumulation of efficacy and safety data post marketing continues to reinforce the positive benefit-risk profile of Gilenya.

Growing Real World Evidence With Gilenya
Analyses from large, real-world databases have confirmed the benefits of Gilenya in the real world setting. Data from 264 patients with MS from the IMS PharMetrics Plus™ Database, showed that treatment with Gilenya resulted in 62% fewer relapses per year compared to interferons or glatiramer acetate.

Gilenya is the only oral DMT to impact the course of relapsing-remitting MS with high efficacy across four key measures of disease activity:
- Relapses
- MRI lesions
- Brain shrinkage
- Disability progression

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

More than 100,000 patients have been treated in clinical trials and in a post-marketing setting.

Cumulative exposure of more than 147,000 patient years with Gilenya.

Gilenya is now approved in OVER 80 COUNTRIES.

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

REFERENCES