GILENYA SUMMARY

Gilenya (aka fingolimod and FTY720, previously known as Gilenia) was approved by the US FDA on Wed 9/22/10 to treat relapsing forms of MS. It is administered as a once-per-day 0.5 mg capsule.

Gilenya is the first approved oral disease modifying treatment for MS. Combined data from a Phase II study and two Phase III trials showed that Gilenya reduces relapses, disability progression, MRI lesion activity, and brain atrophy progression (loss of brain tissue).

Gilenya is generally safe and well tolerated. However, there are several safety issues that have been noted:

1. Slowing of heart rate. Heart rate typically slows following administration of the 1st dose of Gilenya. Slowed heart rate typically is asymptomatic, reaches a maximum 4-5 hours after the 1st dose, subsequently improves even with continued dosing, and returns to baseline over the 1st 1-2 weeks. Very rarely, patients develop symptoms (lightheadedness, dizziness, etc) or more worrisome abnormalities on the EKG (cardiogram), and rarely require treatment. Monitoring patients in a physician’s office for 6 hours after the 1st dose will be required. How we will do this is still being discussed. If one stops Gilenya for 2 weeks, monitoring will be required again when it is restarted.

2. Infections. Gilenya is a potent immunomodulatory drug and reversibly lowers blood lymphocyte counts (the white blood cells that cause inflammation in the brain in MS but also help fight infections). As a result, Gilenya can increase the risk of serious infections.

3. Macular edema. Rarely, patients treated with Gilenya develop macular edema (fluid swelling of the retina in the back of the eye) that causes blurred vision. It usually develops within 3-6 months after starting Gilenya and improves or resolves with discontinuation of Gilenya. Patients will be required to have an eye exam including a test called optical coherence tomography (OCT) prior to starting Gilenya, and 3-4 months after starting treatment. Patients with diabetes and uveitis are at increased risk for macular edema from Gilenya.

4. Increased blood pressure. Blood pressure typically increases mildly during the first 6 months of treatment with Gilenya then stabilizes.

5. Other rare side effects include abnormal liver blood tests, shortness of breath, cough, headache, diarrhea, and back pain.

6. Fetal harm. Based on animal studies, Gilenya possibly can cause harm to the fetus, so women taking Gilenya should not get pregnant.

FAQS

How do I pronounce Gilenya?
“jih-len-ee-ah”

When will it be available?
We do not know this with certainty but we expect within the next 1-2 months.

Are there any restrictions on who can take Gilenya?
There are no absolute restrictions. In general, care will be needed for patients with certain heart conditions, history of fainting, recurrent infections, no history of chicken pox, certain eye problems particularly uveitis, diabetes, breathing problems, liver problems, and high blood pressure, and women planning to become pregnant. Also, certain medications should not be taken with Gilenya. The effectiveness and safety of Gilenya in pediatric and geriatric patients is not known.

*Does Gilenya replace other disease therapies or is it combined with them?*
Gilenya will be used alone for disease treatment.

*Should I switch from my current medication to Gilenya?*
Although switching from an injection to an oral medication is attractive, in general, we recommend not switching until we have more experience with Gilenya. For patients who are not tolerating their current medication or not obtaining good control of their MS, Gilenya is a viable option. These considerations should be discussed with your care team.

*Can Gilenya be combined with MS symptom medications?*
Gilenya can be combined with most MS symptom medications without problem. There are some medications used for other conditions that should be combined with Gilenya with caution, for example certain anti-arrhythmics, beta-blockers, and the anti-fungal ketoconazole (Nizoral). You and your care team should review your medical history and medications in detail prior to starting Gilenya.

*What testing will be required?*
Our plans for testing prior to starting Gilenya and monitoring safety during Gilenya therapy are still being developed. Most likely testing will include:

- Prior to starting: blood tests (blood count and liver enzymes), eye exam with OCT, EKG (cardiogram).
- 1st day of therapy: monitoring for 6 hours in a physician’s office.
- During therapy: periodic blood tests (blood count and liver enzymes), eye exam with OCT at 3-4 months. Pulmonary testing (breathing tests) will be done when clinically indicated.