FDA issues multiple sclerosis drug alert

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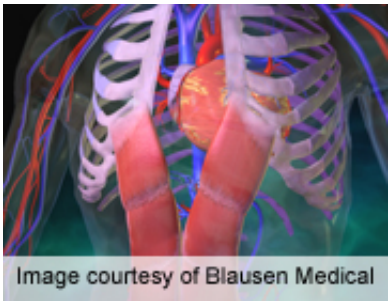

Heart risks spur warning about Gilenya.

(HealthDay) -- The multiple sclerosis drug Gilenya (fingolimod) should not be given to patients with certain pre-existing or recent heart conditions or stroke, or those taking certain medications to correct heart rhythm problems, says a U.S. Food and Drug Administration safety announcement issued Monday.

The warning follows the FDA's evaluation of a report of a patient who died within 24 hours after receiving the first dose of Gilenya. The agency also reviewed additional clinical trial and post-approval data for the drug, including reports of patients who died of cardiovascular or unknown causes.

While it couldn't definitively conclude that Gilenya was related to any of the deaths, the FDA said it has concerns about the cardiovascular effects of the drug after the first dose. The data analysis showed that even though the maximum heart rate-lowering effect of the drug usually

occurs within six hours of taking the first dose, this effect can occur as late as 20 hours after the first dose.

Along with the other recommendations, the FDA said that all patients starting Gilenya should be monitored for signs of a slow heart rate for at least six hours after the first dose and have hourly pulse and blood pressure measurements.

Patients should undergo electrocardiogram testing before receiving the drug and at the end of the observation period. In addition, extended cardiovascular monitoring should continue overnight in patients who are at higher risk for, or who may not tolerate, a slow heart rate (bradycardia).

These high-risk patients include those:

- Who develop severe bradycardia after receiving the first dose of Gilenya.
- With certain pre-existing conditions in whom bradycardia may be poorly tolerated.
- Receiving therapy with other drugs that slow the heart rate or electrical impulses that regulate the heartbeat.
- Who have a heart rhythm abnormality called QT interval prolongation prior to starting Gilenya or at any time during the cardiovascular monitoring period after they take the first dose.
- Who are taking other drugs that prolong the QT interval and that can cause a serious and life-threatening abnormal heart rhythm called Torsades de pointes.

Patients taking Gilenya should seek immediate medical care if they develop dizziness, tiredness, irregular heartbeat or palpitations -- signs of a slowing heart rate, the FDA said. Patients should not stop taking

Gilenya without talking to their doctor.

Gilenya is prescribed to prevent MS flare-ups and slow progression of the nervous system disorder.

More information: The National Multiple Sclerosis Society has more about MS treatments.