FDA investigating PML in patient taking MS drug

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(HealthDay)—The U.S. Food and Drug Administration is investigating the possible association between a rare brain infection and the multiple sclerosis (MS) drug Gilenya (fingolimod), according to a drug safety alert issued by the agency.

The FDA posted its public alert after a patient in Europe diagnosed with possible MS developed progressive multifocal leukoencephalopathy (PML) after taking the drug. The patient had not previously taken Tysabri (natalizumab), which is associated with a higher risk of PML.

This is the first reported case of PML, which usually leads to death or severe disability, in a patient taking Gilenya and not previously treated with Tysabri. The drug manufacturer, Novartis, reports that about 71,000 patients have taken the drug to treat relapsing forms of MS.

"Patients should not stop taking Gilenya without first discussing any questions or concerns with their health care professionals," the agency stated. "The FDA is providing this alert while continuing to investigate the PML case, and is working with Gilenya's manufacturer, Novartis, to obtain and review all available information about this occurrence. The FDA will communicate its final conclusions and recommendations after the evaluation is complete."

More information: More Information