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FDA Public Health Advisory Updated Safety Information about Raptiva (efalizumab)

This information is not current. For current information, please see <http://www.fda.gov/cder/drug/infopage/efalizumab/default.htm>

Since the approval of Raptiva (efalizumab) in October 2003, the FDA has received reports of three confirmed cases and one possible case of progressive multifocal leukoencephalopathy (PML) in patients who were 47 to 73 years of age who were using Raptiva for the treatment of moderate to severe plaque psoriasis. Two of the patients with confirmed PML and one patient with possible PML died. All four patients were treated with Raptiva continuously for more than three years. None of the patients were receiving other treatments that suppress the immune system while taking Raptiva.

PML is a rare, serious, progressive neurologic disease caused by a virus that affects the central nervous system. When PML occurs, it is usually in people whose immune systems have been severely weakened and often results in an irreversible decline in neurologic function and death. There is no known effective treatment for PML.

Raptiva works by affecting T-cells in the immune system. The effects of Raptiva also decrease the function of the immune system and increase susceptibility to infections.

Raptiva was approved for the treatment of moderate to severe plaque psoriasis in 2003. There were no cases of PML seen in the clinical trials that supported the approval of Raptiva. At the time of approval, a total of 2,764 patients had been treated with Raptiva. Of those 2,764 patients, 2400 had been treated for three months, 904 for six months, and 218 for one year or more.

In October 2008, the labeling for Raptiva was changed to highlight, in a Boxed Warning, the risks of life-threatening infections, including PML. In addition, FDA directed Genentech, the manufacturer of Raptiva, to develop a Risk Evaluation and Mitigation Strategy, or REMS, to ensure that patients receive risk information about Raptiva.

The FDA is reviewing this latest information. The agency will take appropriate steps to ensure that the risks of Raptiva do not outweigh its benefits, that patients prescribed Raptiva are clearly informed of the signs and symptoms of PML, and that health care professionals carefully monitor

patients for the possible development of PML.

Healthcare providers should, in the interim, be aware of the following information and advice:

- Raptiva increases the risk of PML. Longer, continuous use may further increase this risk.
- Inform patients using Raptiva of the potential risk of developing PML.
- There are no known screening tests that can reliably predict PML or medical interventions that can prevent or treat this disease.
- Monitor patients being treated with Raptiva for the onset of neurologic symptoms. Discontinue Raptiva if PML is suspected.
- Patients treated with Raptiva should be periodically re-evaluated to ensure that the benefit of treatment continues to outweigh the risks. Consideration should be given to use of other approved therapies to control the patients' psoriasis.
- The effects of periodic or intermittent use of Raptiva, or the concomitant use of other immunosuppressant drugs on the risk for PML is not known.

Patients using Raptiva should:

- Be aware that Raptiva increases the risk of developing PML. PML is a disease that is fatal or causes severe disability.
- Talk with their healthcare provider about the benefits and risks of treatment with Raptiva.
- Be aware of the symptoms of PML which may include unusual weakness, loss of coordination, changes in vision, difficulty speaking and sometimes personality changes.
- Contact their healthcare provider immediately if they experience these symptoms.
- Understand that there are no laboratory screening tests for PML or medical interventions that can prevent or treat PML

The FDA asks health care providers and patients to report possible cases of PML to the FDA through the MedWatch program by phone (1-800-FDA-1088) or by the Internet at <http://www.fda.gov/medwatch/index.html>.

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