

October 2008

IMPORTANT SAFETY INFORMATION

Dear Healthcare Professional:

Genentech, Inc would like to inform you of important new safety information regarding RAPTIVA® (efalizumab).

- A case of progressive multifocal leukoencephalopathy (PML) has been reported in a 70-year-old man who received RAPTIVA for greater than 4 years for treatment of plaque psoriasis. He has not received other systemic immunosuppressants. Other medical conditions reported to date include coronary artery disease and hyperlipidemia. PML was diagnosed based on the detection of JC viral DNA in the CSF, clinical symptoms, and MRI findings.
- Physicians should consider PML in any patient being treated with RAPTIVA who presents with new onset neurologic manifestations. Consultation with a neurologist, brain MRI and lumbar puncture should be considered as clinically indicated.

PML is a rare, progressive, demyelinating disease of the central nervous system that usually leads to death or severe disability. PML is caused by activation of the JC virus. JC virus resides in latent form in up to 80% of healthy adults, typically only causing PML in immunocompromised patients. The factors leading to activation of the latent infection are not fully understood, though abnormalities in T cells have been described as important for reactivation and PML. PML has been reported in HIV positive patients, immunosuppressed cancer patients, transplantation patients and patients with autoimmune diseases. There are no known interventions that can reliably prevent or adequately treat PML.

There are no other cases of confirmed PML in RAPTIVA treated patients in the worldwide safety database. There has been a report of a patient who developed progressive neurologic symptoms. This patient was a 62-year-old man with chronic plaque psoriasis treated with RAPTIVA for greater than 3 years. He had not received other systemic immunosuppressants. Other reported concurrent medical conditions included hypertension, hyperlipidemia, and coronary artery disease. The reported differential diagnoses included lymphoma, cerebrovascular disease, and PML. However, further diagnostic testing was not done, including a lumbar puncture and the patient subsequently died of unknown cause.

RAPTIVA is an immunosuppressive, humanized monoclonal antibody that binds to CD11a and in turn impacts T cell activation, adhesion and migration.

RAPTIVA is indicated for the treatment of adult patients (18 years or older) with chronic moderate to severe plaque psoriasis who are candidates for systemic therapy or phototherapy.

Since RAPTIVA was approved, we estimate that approximately 46,000 patients have been treated worldwide. In the United States as of July 2008, approximately 23,500 patients have been exposed to RAPTIVA for up to 2 years, approximately 1,850 have been exposed between 2 and 3 years, approximately 700 have been exposed between 3 and 4 years, and at least 400 have been exposed for greater than 4 years.

In patients who develop PML, RAPTIVA should be discontinued and appropriate treatment including antiviral therapy should be considered. Worsening of psoriasis can occur during or after discontinuation of RAPTIVA. Following discontinuation, patients should be closely observed and appropriate psoriasis treatment instituted as necessary. Please refer to the Warnings section of the RAPTIVA package insert (enclosed).

Health care professionals should report any serious adverse events possibly associated with the use of RAPTIVA to Genentech Drug Safety at 1-888-835-2555. Alternatively, this information may be reported to the FDA's MedWatch reporting system by phone (1-800-FDA-1088), facsimile (1-800-FDA-1078) or the MedWatch website at www.fda.gov/medwatch or mailed to MedWatch, HF-2, 5600 Fishers Lane, Rockville, MD 20852-9787.

If you have any questions regarding the use of RAPTIVA, please call Genentech Medical Information/Communications Department toll free at 1-800-821-8590.



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