



FDA News

FOR IMMEDIATE RELEASE

P06-206
December 18, 2006

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FDA Warns of Safety Concern Regarding Rituxan in New Patient Population

The Food and Drug Administration (FDA) is alerting health care professionals and patients treated with Rituxan (rituximab) to reports of an emerging risk of a serious side effect in patients receiving or who have used Rituxan. FDA recently learned that two patients who were treated with Rituxan for systemic lupus erythematosus (SLE) developed progressive multifocal leukoencephalopathy (PML), a fatal viral infection of the central nervous system. This side effect has been reported in patients as late as 12 months after their last dose of Rituxan.

SLE is not an approved indication for Rituxan. Rituxan is approved only for the treatment of patients with non-Hodgkin's lymphoma and patients with rheumatoid arthritis whose disease no longer responds to other common treatments.

"Rituxan is used in both approved and off-label settings, and therefore it is very important for prescribers as well as patients to be aware of these new reports of the risk of PML," said Dr. Steven Galson, director of FDA's Center for Drug Evaluation and Research. "Patients who are being treated or have been treated with Rituxan who experience any major changes in vision, balance, or coordination, or who experience confusion, should promptly call their doctor."

Rituxan, which has been marketed since 1997, acts on the body's immune system by decreasing certain types of white blood cells. This makes the drug effective in treating lymphoma and rheumatoid arthritis, but it also increases the body's susceptibility to infection. The Rituxan label was updated in February 2006 to include postmarketing reports of cases of serious viral illnesses, including PML, in patients with lymphoma who received Rituxan. There have been 23 confirmed cases of PML in patients with lymphoid malignancies either during or after completion of treatment with Rituxan. The majority of these patients also had received other drugs known to affect the immune system.

Additionally, cases of PML have occurred in patients who have not received Rituxan. Most reports have been in patients with a compromised immune system, either due to medical conditions (lymphoma or blood cancers, HIV infection and congenital immunodeficiency syndromes) or medical treatments (cancer chemotherapy and immunosuppressive medications in organ transplant recipients). There also have been literature reports of PML in patients with SLE who did not receive Rituxan, but had received other immunosuppressive drugs. Currently FDA is working with Genentech, the drug's sponsor, to add this recent information on PML to the drug label.

Health care professionals should report any serious adverse events possibly associated with the use of Rituxan to FDA's MedWatch Adverse Event Reporting program online [at www.fda.gov/MedWatch/report.htm], by phone [1-800-FDA-1088], or by returning the postage-paid FDA form 3500 [which may be downloaded from www.fda.gov/MedWatch/getforms.htm] by mail [to MedWatch, 5600 Fishers Lane, Rockville, MD 20852-9787] or fax [1-800-FDA-0178].

Rituxan is manufactured by Genentech, Inc. of South San Francisco, Calif.

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