July 12, 2004

Genentech BIOONCOLOGY | biogen idec

IMPORTANT DRUG WARNING
UPDATED SAFETY INFORMATION

Dear Healthcare Professional:

Genentech, Inc., and Biogen Idec Inc., wish to inform you of an update to the WARNINGS section of the prescribing information (PI) for Rituxan® (Rituximab). Rituxan is indicated for the treatment of patients with relapsed or refractory low-grade or follicular, CD-20 positive, B-cell non-Hodgkin's lymphoma.

Since Rituxan was introduced to the market, Genentech, Inc., and Biogen Idec Inc., have continued to gather information on the safety and efficacy of Rituxan. Based upon review of recent post marketing and clinical safety reports, the WARNINGS section of the Rituxan PI was revised to include the following information:

WARNINGS

Hepatitis B Reactivation with Related Fulminant Hepatitis: Hepatitis B virus (HBV) reactivation with fulminant hepatitis, hepatic failure, and death has been reported in some patients with hematologic malignancies treated with RITUXAN. The majority of patients received RITUXAN in combination with chemotherapy. The median time to the diagnosis of hepatitis was approximately 4 months after the initiation of RITUXAN and approximately one month after the last dose.

Persons at high risk of HBV infection should be screened before initiation of RITUXAN. Carriers of hepatitis B should be closely monitored for clinical and laboratory signs of active HBV infection and for signs of hepatitis during and for up to several months following RITUXAN therapy.

In patients who develop viral hepatitis, RITUXAN and any concomitant chemotherapy should be discontinued and appropriate treatment including antiviral therapy initiated. There are insufficient data regarding the safety of resuming RITUXAN therapy in patients who develop hepatitis subsequent to HBV reactivation.

Persons at high risk of HBV infection should be screened before initiation of Rituxan. Carriers of hepatitis B should be closely monitored for clinical and laboratory signs of active HBV infection and for signs of hepatitis during and for up to several months following Rituxan therapy. Healthcare professionals should report any serious adverse events possibly associated with the use of Rituxan to Genentech Drug Safety at 1-888-835-2555. Alternatively, this information may be reported to FDA's MedWatch reporting system by phone (1-800-FDA-1088), facsimile (1-800-FDA-1078), or the MedWatch web site at www.fda.gov/medwatch or mailed to MedWatch, HF-2, 5600 Fishers Lane, Rockville, MD 20852-9787.

The revised full prescribing information is enclosed for your review. If you have any questions about Rituxan, please call the toll-free number for Genentech Medical Information Department at 1-800-821-8590.

Sincerely,

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