



July, 2005

Re: **Important Drug Warning Regarding RAPTIVA® [efalizumab]**

Dear Healthcare Provider:

Genentech would like to inform you of important new safety information regarding RAPTIVA® [efalizumab], which 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. This safety information includes a new WARNING regarding events of immune-mediated hemolytic anemia, an updated Warnings regarding postmarketing reports of serious infections and thrombocytopenia. Accompanying this letter you will find a new package insert for RAPTIVA.

Two cases of hemolytic anemia were observed in RAPTIVA clinical trials. Two additional cases were reported in the postmarketing setting. In two severe cases the hemoglobin decreased to 6 and 7 g/dL. A causal relationship between RAPTIVA and these events has not been established but cannot be excluded.

Based on this data, the following WARNING has been added to the prescribing information:

#### **Immune-Mediated Hemolytic Anemia**

Reports of hemolytic anemia, some serious, diagnosed 4-6 months after the start of RAPTIVA treatment have been received. RAPTIVA should be discontinued if hemolytic anemia occurs.

This information has also been included in the ADVERSE REACTIONS section and Patient Information sheet (see enclosed prescribing information).

The WARNINGS section concerning serious infections has been updated to include rare postmarketing reports of necrotizing fasciitis, tuberculous pneumonia, bacterial sepsis with seeding of distant sites, severe pneumonia with neutropenia, and worsening of infection (e.g. cellulitis, pneumonia) despite antimicrobial treatment.

The WARNINGS section concerning thrombocytopenia has been relabeled Immune-Mediated Thrombocytopenia and has been updated to include postmarketing reports.

Genentech is committed to ensuring that RAPTIVA is used safely and effectively. Should you have any questions regarding the use of RAPTIVA, please contact Genentech's Medical Communications department at 1-800-821-8590 or in the "Contact Us" section of the Genentech corporate website (<http://www.gene.com/gene.contact/>).



Healthcare professionals should report any serious adverse events suspected to be associated with the use of RAPTIVA to Genentech at 1-888-835-2555. Alternatively, this information may also be reported to FDA's MedWatch reporting system by phone (1-800-FDA-1088), by facsimile (1-800-FDA-0178), online (<https://www.accessdata.fda.gov/scripts/medwatch/>) or mailed, using the MedWatch form FDA 3500, to the FDA Medical Products Reporting Program, 5600 Fishers Lane, Rockville, MD 20852-9787.

Sincerely,

Hal Barron, MD  
Senior Vice President, Development  
Chief Medical Officer  
Genentech, Inc.