



April 8, 2009

## **VOLUNTARY U.S. MARKET WITHDRAWAL OF RAPTIVA® (efalizumab)**

Dear Healthcare Professional:

**Genentech, Inc. would like to inform you of our decision to implement a phased voluntary withdrawal of the psoriasis medication RAPTIVA (efalizumab) from the United States market. We are taking this action due to an increased risk of progressive multifocal leukoencephalopathy (PML) in patients on RAPTIVA therapy.**

- PML is a rapidly progressive infection of the central nervous system caused by the JC virus that leads to death or severe disability.
- Although we believe there are many psoriasis patients who are deriving meaningful clinical benefit from RAPTIVA, the balance between benefit and risk in the psoriasis population for which RAPTIVA was approved has significantly changed.
- It is presently not possible to identify patients at increased risk of PML prior to or during RAPTIVA therapy.
- There are currently no effective therapeutic options to treat PML.

Effective today, Genentech is implementing a phased voluntary withdrawal; RAPTIVA will not be available after Monday June 8, 2009. The intent of the phased withdrawal is to provide sufficient time for prescribers to identify their patients on RAPTIVA, inform them that they need to discontinue treatment, and plan a careful transition to alternative psoriasis therapies as appropriate.

### **Guidance for Prescribers**

- Prescribers should not initiate RAPTIVA treatment for any new patients.
- **For current patients, RAPTIVA will only be available through Monday June 8, 2009.** All healthcare providers should continue to counsel patients about the risks associated with RAPTIVA use.
- Prescribers should review the treatment of all patients who are currently receiving RAPTIVA, with a goal of stopping treatment in a prompt but appropriate manner.
- Prescribers should carefully manage the transition of patients from RAPTIVA to other appropriate therapies, and should consider the risk that abrupt discontinuation of therapy could result in a worsening of psoriasis. The effect of concomitant or sequential use of other immunosuppressive drugs on the risk of PML is not known (see the enclosed RAPTIVA US Prescribing Information; WARNINGS, PSORIASIS WORSENING AND VARIANTS, PML).

## Guidance for Prescribers, continued

- After RAPTIVA discontinuation, prescribers should continue to closely monitor patients for any sign or symptom that is suggestive of PML, and for infections or other adverse events after stopping treatment.
- Healthcare professionals should report any serious adverse events suspected to be associated with the use of RAPTIVA to Genentech Drug Safety at 1-888-835-2555.
  - Alternatively, adverse event information may be reported to FDA's MedWatch reporting system online (<https://www.accessdata.fda.gov/scripts/medwatch/>), by phone (1-800-FDA-1088), by facsimile (1-800-FDA-0178), or by mail using the MedWatch Form FDA 3500 (FDA Medical Products Reporting Program, 5600 Fishers Lane, Rockville, MD 20852-9787).

A "Patient Letter" (enclosed) is being sent to patients from Genentech and Specialty Pharmacies informing them of the voluntary withdrawal. Patients are being encouraged to contact their physician to discuss transition strategies and have been advised to avoid stopping RAPTIVA abruptly. Please contact your patients promptly to discuss this matter.

Enclosed is a copy of the RAPTIVA US Prescribing Information and Medication Guide for your reference. Should you have any questions regarding the use of RAPTIVA, please call our Medical Information/Communications Department at 1-800-821-8590. For patients who may have non-clinical related questions about RAPTIVA, please direct them to call our Genentech Access Solutions call center at 1-866-480-7762.

Sincerely,



Hal Barron, M.D., FACC  
Senior Vice President, Development  
Chief Medical Officer  
Genentech, Inc.