



Wednesday, Apr 8, 2009

## **Genentech Announces Voluntary Withdrawal of Raptiva from the U.S. Market**

**South San Francisco, Calif. -- April 8, 2009 --** Genentech, Inc. announced today a phased voluntary withdrawal of the psoriasis drug Raptiva® (efalizumab) from the U.S. market. The company's decision is based on the association of Raptiva with an increased risk of progressive multifocal leukoencephalopathy (PML), a rare and usually fatal disease of the central nervous system. Raptiva is indicated for the treatment of chronic moderate-to-severe plaque psoriasis in adults 18 years or older who are candidates for systemic therapy or phototherapy.

Effective immediately, physicians should not issue prescriptions for Raptiva for any new patients and should promptly contact patients currently receiving Raptiva to assess the most appropriate treatment alternatives. Raptiva will no longer be available after June 8, 2009. This transition period is intended to allow patients, who are currently taking Raptiva, enough time to work with their doctors to appropriately discontinue use of Raptiva. Because of the potential for severe psoriasis worsening with abrupt discontinuation of Raptiva, it is important that patients talk with their doctor before stopping treatment.

Genentech estimates that approximately 2,000 patients in the United States may currently be receiving Raptiva for chronic plaque psoriasis. Since FDA approval in 2003, approximately 46,000 patients worldwide have been treated with Raptiva.

"Our decision to remove Raptiva from the market reflects Genentech's commitment to patient safety," said Hal Barron, M.D., Genentech's senior vice president, development and chief medical officer. "Although we believe that many psoriasis patients are benefiting from Raptiva, the balance between benefit and risk in the psoriasis population for which Raptiva was approved has significantly changed."

The Raptiva prescribing information was updated in October 2008 to include a boxed warning on the risk of serious infections, including PML, in patients receiving Raptiva. The Raptiva prescribing information was further updated in March 2009 to include additional information on the risk of PML and a new Medication Guide for patients.

There have been three cases of diagnosed PML in patients receiving Raptiva and one patient treated with Raptiva who developed progressive neurologic symptoms and died of unknown cause. It is not known whether other, unreported cases have occurred. Dear Healthcare Provider letters were issued to inform prescribers about the risk of PML with Raptiva as these cases were identified.

The company has taken immediate steps to inform potential prescribers, patients, clinical trial investigators, and distributors of the decision to withdraw Raptiva from the market in the United States. Copies of these letters have been posted today to the Genentech web site <http://www.gene.com/> and are available on the Raptiva page at <http://www.gene.com/gene/products/information/immunological/raptiva/index.html>. Physicians with questions about Raptiva use may contact Genentech Medical Communications at 1-800-821-8590.

The company's actions have been taken after consultation with the U.S. Food and Drug Administration. Genentech is working with Merck Serono, its licensee outside the U.S. and Japan to inform regulatory authorities outside of the United States of Genentech's decision to withdraw Raptiva from the U.S. market.

For the full year 2008, U.S. sales of Raptiva were approximately \$108 million. As a result of the phased withdrawal and resultant excess Raptiva inventories, the company will be reporting a one-time cost-of-sales charge of approximately \$125 million in its results for the first half of 2009. After taking into account taxes and non-controlling interests, the impact on the Group's net income and EPS will not be significant, and Roche's previously communicated targets for 2009 are not affected by this.

### **About PML**

PML is a rare, progressive, demyelinating disease of the central nervous system that leads to death or severe

disability. PML is caused by activation of the John Cunningham, (JC) virus. The JC virus resides in latent form in up to 80 percent 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 may be important for reactivation and PML. PML has been reported in the published literature in HIV-positive patients, as well as immunosuppressed cancer patients (including patients with hematologic malignancies), organ transplant recipients, and patients with autoimmune diseases. There are no known interventions that can reliably prevent or adequately treat PML.

**About Psoriasis**

Psoriasis occurs when new skin cells grow abnormally, resulting in thick, red, and scaly, inflamed patches. Plaque psoriasis, the most common form of the disease, affects approximately 2.3 million Americans and is characterized by inflamed patches of skin ("lesions") topped with silvery white scales. Psoriasis can be limited to a few spots or involve extensive areas of the body, appearing most commonly on the scalp, knees, elbows and trunk. Although it is highly visible, psoriasis is not a contagious disease. While there are a number of medications that may help control the symptoms of psoriasis, there currently is no known cure.

**About Genentech**

Founded more than 30 years ago, Genentech is a leading biotechnology company that discovers, develops, manufactures and commercializes medicines to treat patients with serious or life-threatening medical conditions. The company, a wholly-owned member of the Roche Group, has headquarters in South San Francisco, California. For additional information about the company, please visit <http://www.gene.com/>.

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