Thursday, April 9, 2009

Genentech voluntarily withdraws psoriasis drug Raptiva®

On April 8, 2009, Genentech announced the voluntary withdrawal of Raptiva® (efalizumab) in the United States. The limited distribution specialty drug is indicated for the treatment of chronic moderate-to-severe plaque psoriasis in adults. Genentech's decision was based on Raptiva's association with an increased risk of progressive multifocal leukoencephalopathy (PML), a rare and usually fatal disease of the central nervous system.

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. Because of the potential for severe psoriasis worsening with abrupt discontinuation of Raptiva, it is essential that patients talk with their doctor before stopping treatment.

- **Background and Statistics:** Genentech estimates that approximately 2,000 patients in the United States may be receiving Raptiva for chronic plaque psoriasis currently. Raptiva's prescribing information was updated in October 2008 to include a Black Box Warning on the risk of serious infections, including PML, in patients receiving Raptiva. The drug's prescribing information was updated again in March 2009 to include additional information on the risk of PML and a new Medication Guide for patients.
- **Safety:** Genentech previously disclosed that three cases of PML had developed in patients taking Raptiva since October 2008, including two that were fatal. A fourth patient died of unknown cause after developing neurologic symptoms. All had been taking the drug for more than three years. Genentech has determined that there is no way to mitigate the risk. There is no treatment or cure for PML. People who do live with PML are severely disabled.
- **Withdrawal date:** June 8, 2009.
- **Peak sales:** For the full year 2008, U.S. sales of Raptiva were approximately $108 million, according to Genentech.
- **Implications:** Raptiva is being voluntary withdrawn from the market by Genentech. 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. Patients should not abruptly discontinue treatment with Raptiva. Raptiva will no longer be available beginning June 8, 2009. Accredo is a provider of Raptiva and is currently determining next steps to protect patient safety and to assist patients in transitioning to a different therapy.