



Medicare Part D Pharmacy Updates

TARCEVA (erlotinib) Safety Alert

On May 8, 2009 the **FDA** made public a letter that was sent in April 2009 by the makers (Genentech, OSI) of TARCEVA (erlotinib) to healthcare professionals, notifying them of **new safety information** that was added to the *Warnings and Precautions* section of the medication's prescribing information. Incidents of gastrointestinal (GI) perforation, bullous, blistering and exfoliative skin conditions (e.g. suggestive of Steven-Johnson syndrome/toxic epidermal necrolysis), and ocular disorders including corneal perforation or ulceration have been reported through routine pharmacovigilance activities during clinical studies or through post-marketing reports. These safety monitoring reports included a number of undisclosed fatalities. TARCEVA (erlotinib) monotherapy is currently indicated for the treatment of patients with locally advanced or metastatic non-small cell lung cancer after failure of at least one prior chemotherapy regimen. In combination with gemcitabine, TARCEVA (erlotinib) is also indicated for the first-line treatment of patients with locally advanced, unresectable, or metastatic pancreatic cancer.

Patients known to be at a higher risk of these side effects include:

- Patients receiving concomitant anti-angiogenic agents (e.g. GLEEVEC, SPRYCEL, TASIGNA, TYKERB) corticosteroids, NSAIDs, taxane based chemotherapy, or who have a prior history of peptic ulceration or diverticular disease.
- Patients with other ocular disorders including abnormal eyelash growth, keratoconjunctivitis sicca or keratitis as these conditions are known risk factors for corneal ulceration/perforation.

Medical providers are asked to monitor their patients carefully for unusual GI, skin and ophthalmic signs and symptoms while taking TARCEVA (erlotinib) and to report all suspected adverse drug reactions to the FDA's MedWatch Program by phone at 800.FDA.1088, by fax at 800.FDA.0178, by mail at MedWatch, HF-2, FDA, 5600 Fishers Lane, Rockville, M.D. 20852-9787, or on the MedWatch Web site at www.fda.gov/medwatch.

References:

1. U.S. Food and Drug Administration MedWatch. Tarceva. 5/8/2009. Accessed on 5/14/2009 at: <http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm150596.htm>
2. Dear Healthcare Professional. OSI Pharmaceuticals and Genentech. April 2009. Accessed on 5/14/2009 at: <http://www.fda.gov/downloads/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/UCM150610.pdf>

RAPTIVA (efalizumab) Withdrawn from Market

On April 8, 2009 Genentech and the Food and Drug Administration (FDA) notified healthcare professionals of the voluntary, phased withdrawal of RAPTIVA (efalizumab), a medication for treatment of psoriasis, from the U.S. market due to a potential risk to patients of developing progressive multifocal leukoencephalopathy (PML). PML is typically seen in patients with compromised immune system and has been previously reported in both RITUXAN (rituximab) and TYSABRI (natalizumab). The move comes only about six months after the company updated the drug's labeling to carry warnings regarding links to PML. A total of four cases of PML (three confirmed, one suspected) have been reported. Regulators in the European Union recommended in February that the drug therapy should be banned.

The company estimated that about 2,000 patients in the U.S. were taking the drug at the time of the announcement and accounted for \$108 million out of Genentech's \$13.42 billion sales in 2008.

After June 8, 2009, RAPTIVA (efalizumab) will no longer be available in the United States. Prescribers are being asked not to initiate RAPTIVA (efalizumab) treatment for any new patients. Prescribers should immediately begin discussing with patients currently using RAPTIVA (efalizumab) how to transition to alternative therapies.

References:

1. U.S. Food and Drug Administration MedWatch. Raptiva. 4/8/2009. Accessed on 4/9/2009 at <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm149561.htm>.
2. Anon. Genentech pulls drug from market for safety. Associated Press/AP Online (www. Yellowbrix). April 8, 2009.