



May 11, 2009

Medication Safety Alert

MEDICATIONS: Tarceva® (erlotinib), Genentech/OSI Pharmaceuticals

DOSAGE FORMS: 25 mg, 100 mg, and 150 mg Tablets

ISSUE: New safety information has been added to the Warnings and Precautions sections of the prescribing information for Tarceva® (erlotinib) following clinical study and post-marketing reports.

The following was posted on the FDA Med Watch Web site on May 8, 2009:

“OSI, Genentech and (the) FDA notified healthcare professionals of new safety information added to the WARNINGS AND PRECAUTIONS sections of the prescribing information for Tarceva®. Gastrointestinal perforation (including fatalities), bullous, blistering and exfoliative skin conditions including cases suggestive of Stevens-Johnson syndrome/toxic epidermal necrolysis, in some cases fatal, and ocular disorders, including corneal perforation or ulceration have been reported during use of Tarceva®. The new safety information comes from routine pharmacovigilance activities of clinical study and post-marketing reports. Tarceva® monotherapy is 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® is also indicated for the first-line treatment of patients with locally advanced, unresectable, or metastatic pancreatic cancer.”

A complete copy of the accompanying “Dear Healthcare Professional Letter” dated April 2009 from Genentech/OSI Pharmaceuticals may be viewed at:

http://www.fda.gov/medwatch/safety/2009/Tarceva_DHCP_Letter_April09.pdf