

April 2009

Important Safety Information

Dear Healthcare Professional:

OSI Pharmaceuticals, Inc. and Genentech would like to inform you of new safety information regarding Tarceva[®] (erlotinib) and are issuing this letter to ensure that you have the most recent information available when considering Tarceva as a treatment option for its approved uses.

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.

The new safety information comes from routine pharmacovigilance activities of clinical study and postmarketing reports.

The following new information has been added to the **WARNINGS AND PRECAUTIONS** section in the full prescribing information:

- Gastrointestinal perforation (including fatalities) has been reported in patients receiving TARCEVA. Patients receiving concomitant anti-angiogenic agents, corticosteroids, NSAIDs, and/or taxane-based chemotherapy, or who have prior history of peptic ulceration or diverticular disease are at increased risk. Permanently discontinue TARCEVA in patients who develop gastrointestinal perforation.
- Bullous, blistering and exfoliative skin conditions have been reported, including cases suggestive of Stevens-Johnson syndrome/toxic epidermal necrolysis, which in some cases were fatal. Interrupt or discontinue TARCEVA treatment if the patient develops severe bullous, blistering or exfoliating conditions.
- Ocular Disorders: Corneal perforation or ulceration have been reported during use of Tarceva. Other ocular disorders including abnormal eyelash growth, keratoconjunctivitis sicca or keratitis have been observed with Tarceva treatment and are known risk factors for corneal ulceration/perforation. Interrupt or discontinue TARCEVA therapy if patients present with acute/worsening ocular disorders such as eye pain.

The **DOSAGE AND ADMINISTRATION** section of the labeling has been updated to reflect the dose interruption and/or discontinuation instructions included in the **WARNINGS AND PRECAUTIONS** section, described above.

Our primary concern is the safety and well-being of patients who receive Tarceva treatment. For any questions, or to report adverse events suspected to be associated with the use of Tarceva, please call 1-877-TARCEVA (1-877-827-2382). Alternatively, adverse event information may be reported to the FDA's MedWatch reporting system by phone at 1-800-FDA-1088, by facsimile at 1-800-FDA-0178, by mail to MedWatch, HF-2, FDA, 5600 Fishers Lane, Rockville, MD 20857, or by the internet at <http://www.fda.gov/medwatch/index.html>.

The complete wording of these changes can be found in the enclosed copy of the full prescribing information for Tarceva, superseding all previous versions. The most current version of the full prescribing information can always be found at www.tarceva.com.

Sincerely,



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