Pfizer Logo

Pfizer’s XALKORI® Granted Regular FDA Approval

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Standard of Care for Patients With Metastatic ALK-Positive Non-Small Cell Lung Cancer

Pfizer Inc. announced today that the U.S. Food and Drug Administration (FDA) has granted Pfizer’s XALKORI® (crizotinib) regular approval for the treatment of patients with metastatic ALK-positive non-small cell lung cancer (NSCLC) as detected by an FDA-approved test. XALKORI was previously granted accelerated approval in August 2011 due to the critical need for new agents for people living with ALK-positive NSCLC.

Lung cancer is the leading cause of cancer death worldwide[1] with an estimated 1.4 million deaths each year.[2] To date, globally more than 6,000 patients have been treated with XALKORI, including those who received XALKORI in clinical trials. ALK testing rates in the U.S. have increased more than 5-fold from 11 percent before the XALKORI launch to more than 60 percent.[3]

"XALKORI has dramatically changed the treatment landscape for patients with advanced ALK-positive NSCLC," said Garry Nicholson, president and general manager, Pfizer Oncology Business Unit. "Achievement of this milestone underscores Pfizer’s commitment to provide physicians with effective cancer therapies for their patients.”

The FDA’s action marks the conversion of an accelerated approval to regular approval and is based on data from the pivotal Phase 3 PROFILE 1007 confirmatory trial comparing XALKORI to standard chemotherapy in previously treated patients. The results of this study were recently published in the June 20, 2013 issue of the *New England Journal of Medicine.*

In addition to the U.S., XALKORI has received approval in more than 60 countries, including EU, Canada, China, Korea, Japan and Australia.

For more information and full prescribing information visit www.XALKORI.com

XALKORI® (crizotinib) Indication and Important Safety Information

XALKORI is a kinase inhibitor indicated for the treatment of patients with metastatic non-small cell lung cancer (NSCLC) whose tumors are anaplastic lymphoma kinase (ALK)-positive as detected by an FDA-approved test.

Hepatotoxicity: Across three main clinical trials fatal hepatotoxicity occurred in 0.2% of patients. Monitor with periodic liver testing. Temporarily suspend, dose reduce, or permanently discontinue XALKORI.

Pneumonitis: Across three main clinical trials interstitial lung disease (ILD)/pneumonitis occurred in 2% of patients. Permanently discontinue in patients with ILD/pneumonitis.

QT Interval Prolongation: Across three main clinical trials QT interval prolongation occurred in 2.7% of patients. Monitor with electrocardiograms and electrolytes in patients who have a history of or predisposition for QTc prolongation, or who are taking medications that prolong QT. Temporarily suspend, dose reduce, or permanently discontinue XALKORI.

Bradycardia: Xalkori can cause bradycardia. Across three main clinical trials 11% of patients experienced a heart rate of less than 50 beats per minute. Monitor heart rate and blood pressure regularly. Temporarily suspend, dose reduce, or permanently discontinue XALKORI.

Embryofetal Toxicity: XALKORI can cause fetal harm when administered to a pregnant woman. Women of childbearing potential should be advised to avoid becoming pregnant while receiving XALKORI.

Adverse Reactions: Across three main clinical trials the most common adverse reactions (?25%) were vision disorders, nausea, diarrhea, vomiting, constipation, edema, elevated transaminases, and fatigue.

In a phase 3 study in patients with ALK-positive metastatic NSCLC randomized to XALKORI (n=172) or chemotherapy (n=171), serious adverse reactions were reported in 37.2% of patients treated with XALKORI. The most frequent serious adverse reactions reported in patients treated with XALKORI were pneumonia (4.1%), pulmonary embolism (3.5%), dyspnea (2.3%), and ILD (2.9%). Fatal adverse reactions in XALKORI-treated patients occurred in 9 (5%) patients, consisting of: acute respiratory distress syndrome, arrhythmia, dyspnea, ILD, pneumonia, pneumonitis, pulmonary embolism, respiratory failure, and sepsis. Grade 3 or 4 events occurring at a higher incidence with XALKORI than with chemotherapy and at greater than 2%, were syncope (3%), QT prolongation (3%), and pulmonary embolism (5%). Elevation of ALT of any grade occurred in 76% of patients and grade 3 or 4 in 17% of patients. Neutropenia of any grade occurred in 49% of patients and grade 3 or 4 in 12% of patients. Lymphopenia of any grade occurred in 51% of patients and grade 3 or 4 in 9% of patients. Renal cysts occurred in 4% and neuropathy occurred in 19% of patients treated with XALKORI.

Drug Interactions: Exercise caution with concomitant use of moderate CYP3A inhibitors. Avoid grapefruit or grapefruit juice which may increase plasma concentrations of crizotinib. Avoid concomitant use of strong CYP3A inducers and inhibitors. Dose reduction may be needed for co-administered drugs that are predominantly metabolized by CYP3A.

Nursing Mothers: Given the potential for serious adverse reactions in nursing infants, consider whether to discontinue nursing or discontinue XALKORI.

Hepatic Impairment: XALKORI has not been studied in patients with hepatic impairment. As crizotinib is extensively metabolized in the liver, hepatic impairment is likely to increase plasma crizotinib concentrations. Use caution in patients with hepatic impairment.

Renal Impairment: Administer XALKORI at a starting dose of 250 mg taken orally once daily in patients with severe renal impairment (CLcr<30 mL/min) not requiring dialysis. No starting dose adjustment is needed for patients with mild and moderate renal impairment.

About Pfizer Oncology

Pfizer Oncology is committed to the discovery, investigation and development of innovative treatment options to improve the outlook for cancer patients worldwide. Our strong pipeline of biologics and small molecules, one of the most robust in the industry, is studied with precise focus on identifying and translating the best scientific breakthroughs into clinical application for patients across a wide range of cancers. By working collaboratively with academic institutions, individual researchers, cooperative research groups, governments, and licensing partners, Pfizer Oncology strives to cure or control cancer with breakthrough medicines, to deliver the right drug for each patient at the right time. For more information please visit www.Pfizer.com.

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[1] The International Agency for Research on Cancer, the World Health Organization, GLOBOCAN 2008, Available at: http://globocan.iarc.fr/ (select ‘World’ from the drop down menu under ‘Fact Sheets)’. Accessed August 8, 2013.

[2] The International Agency for Research on Cancer, the World Health Organization, GLOBOCAN 2008. Available at: http://globocan.iarc.fr/burden.asp?selection_pop=220900&Text-

p=World&selection_cancer=14110&Text-c=Lung&pYear=2&type=1&window=1&submit=%A0Execute%A0. Accessed August 8, 2013.

[3] Pfizer data on file

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