March 14, 2016

Xalkori Granted Second Indication

The U.S. Food and Drug Administration (FDA) approved a new indication for Pfizer’s Xalkori® (crizotinib) capsules on March 11, 2016. Xalkori, a kinase inhibitor, was originally approved in 2011 to treat metastatic non-small cell lung cancer (NSCLC) that has been detected by an FDA-approved genetic test to be anaplastic lymphoma kinase (ALK)-positive. Now, it is also approved to treat patients with ROS1-positive metastatic NSCLC. Last year, it had been given Breakthrough Therapy and Priority Review designations for treating ROS1-positive NSCLC tumors, pending results of a clinical trial. Of the 50 patients in the Phase 1 study, one patient had a complete response and 32 responded partially to treatment with 250mg of Xalkori twice a day. Median response lasted for 18.3 months. According to the American Cancer Society, about 1% of newly diagnosed NSCLC patients in the world, or around 15,000 individuals annually, have ROS1 genetic mutations. A companion diagnostic test for ROS1 is being developed. Updated prescribing information for Xalkori is available at:


Generic to Oxistat Approved

The FDA announced on March 11, 2016, that it has approved Taro Pharmaceutical’s oxiconazole cream 1%, the first generic alternative to Fougera Pharmaceuticals’ Oxistat®. A topical antifungal drug, it is applied to affected areas once or twice a day to treat athlete’s foot (tinea pedis), jock itch (tinea cruris), ringworm (tinea corporis) and tinea versicolor (generalized rash or discolored patches) that are caused by specific types of fungus. Patients should be evaluated for improvement in the infection after two weeks to four weeks of treatment. Patients or caregivers should wash their hands thoroughly after applying oxiconazole to prevent its touching the eyes or the mucus membranes. Taro has not yet released its plans for pricing or marketing. Prescribing information for the generic is at:

http://www.accessdata.fda.gov/drugsatfda_docs/label/2016/205076Orig1s000lbl.pdf