Pfizer Announces FDA Acceptance For Review Of Supplemental New Drug Application For Oral XELJANZ® (tofacitinib citrate) For Adult Patients With Moderate To Severe Chronic Plaque Psoriasis

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Pfizer Inc. (NYSE:PFE) announced today that the U.S. Food and Drug Administration (FDA) has accepted for review the supplemental New Drug Application (sNDA) for XELJANZ® (tofacitinib citrate) 5 mg and 10 mg tablets, a Janus kinase (JAK) inhibitor, the first in a new class of oral medicines being investigated for the treatment of adult patients with moderate to severe chronic plaque psoriasis who are candidates for systemic therapy or phototherapy. The FDA has provided an anticipated Prescription Drug User Fee Act (PDUFA) action date in October 2015 for the sNDA.

The submission to the FDA is based on data from the Phase 3 Oral treatment Psoriasis T rials (OPT) Program, a global, multi-study, comprehensive clinical development program that consisted of five studies (including an ongoing long-term extension study), designed to evaluate oral XELJANZ 5 mg and 10 mg twice daily in patients with moderate to severe chronic plaque psoriasis. With more than 3,600 adult psoriasis patients enrolled across 36 countries, the OPT program has yielded one of the largest databases for a potential psoriasis indication at the time of registration.

XELJANZ is a small molecule that targets the JAK pathway, a signaling pathway inside the cells, thought to play a role in chronic inflammatory responses.

“This regulatory milestone demonstrates our commitment to the research of chronic inflammatory diseases with the goal of developing therapies, such as XELJANZ, that can help address unmet medical needs for patients,” said Steve Romano, MD, SVP and Head, Global Medicines Development for the Pfizer Global Innovative Pharmaceutical business. “We continue to play a leadership role in the evaluation of JAK inhibition across chronic inflammatory diseases, such as psoriasis.”

XELJANZ is approved in 37 countries around the world for the treatment of moderate to severe rheumatoid arthritis (RA). In the United States, XELJANZ 5 mg tablets are approved for the treatment of adults with moderate to severe RA who have had an inadequate response or intolerance to methotrexate (MTX). The benefit:risk profile of XELJANZ in RA has been characterized through the study of 6,192 RA patients representing 16,800 patient years of exposure in the global clinical development program for XELJANZ in moderate to severe RA.

About Plaque Psoriasis

Psoriasis is a chronic, immune-mediated inflammatory skin disease, affecting the skin and other parts of the body, such as nails. It affects approximately two-to-three percent of people worldwide and 7.4 million in the United States.1,2,3,4,5,6,7 The most common form is plaque psoriasis, which affects about 80 percent of people who have the condition.8 Of those, as many as 20 percent have moderate to severe chronic plaque psoriasis.6 A need for additional therapies remains. According to recently published surveys, approximately 50 percent of patients with psoriasis are dissatisfied with their treatment. Under-treatment also represents a significant problem. Even though guidelines typically state that patients with moderate to severe psoriasis are candidates for systemic therapy, many treated adult plaque psoriasis patients appear to be undertreated, with approximately 30 percent of treated moderate patients and 22 percent of treated severe patients receiving only topical therapy in the United States.9

XELJANZ® (tofacitinib citrate) RA U.S. Label Information

XELJANZ is a prescription medicine called a Janus kinase (JAK) inhibitor. XELJANZ is used to treat adults with moderately to severely active rheumatoid arthritis in which methotrexate did not work well.

It is not known if XELJANZ is safe and effective in people with Hepatitis B or C. XELJANZ is not for people with severe liver problems. It is not known if XELJANZ is safe and effective

in children.

Important Safety Information

XELJANZ can lower the ability of the immune system to fight infections. Some people have serious infections while taking XELJANZ, including tuberculosis (TB), and infections caused by bacteria, fungi, or viruses that can spread throughout the body. Some people have died from these infections. Healthcare providers should test patients for TB before starting XELJANZ, and monitor them closely for signs and symptoms of TB and other infections during treatment. People should not start taking XELJANZ if they have any kind of infection unless their healthcare provider tells them it is okay. XELJANZ may increase the risk of certain cancers by changing the way the immune system works. Malignancies were observed in clinical studies of XELJANZ. The risks and benefits of treatment should be considered prior to initiating XELJANZ in patients with chronic or recurrent infection; who have been exposed to tuberculosis; with a history of a serious or an opportunistic infection; who have resided or traveled in areas of endemic tuberculosis or endemic mycoses; or with underlying conditions that may predispose them to infection. Viral reactivation, including cases of herpes virus reactivation (e.g., herpes zoster), was observed in clinical studies with XELJANZ. Use of live vaccines should be avoided concurrently with XELJANZ. Update immunizations in agreement with current immunization guidelines prior to initiating XELJANZ therapy. Some people who have taken XELJANZ with certain other medicines to prevent kidney transplant rejection have had a problem with certain white blood cells growing out of control (Epstein Barr virus-associated post-transplant lymphoproliferative disorder). Some people taking XELJANZ get tears in their stomach or intestines. This happens most often in people who also take nonsteroidal anti-inflammatory drugs (NSAIDs), corticosteroids, or methotrexate. Patients should tell their healthcare provider right away if they have fever and stomach-area pain that does not go away, or a change in bowel habits. XELJANZ should be used with caution in patients who may be at increased risk for gastrointestinal perforation (e.g., patients with a history of diverticulitis). XELJANZ can cause changes in certain lab test results including low blood cell counts, increases in certain liver tests, and increases in cholesterol levels. Healthcare providers should do blood tests before starting patients on XELJANZ and while they are taking XELJANZ, to check for these side effects. Normal cholesterol levels are important to good heart health. Healthcare providers may stop XELJANZ treatment because of changes in blood cell counts or liver test results. Use of XELJANZ in patients with severe hepatic impairment is not recommended. Patients should tell their healthcare providers if they plan to become pregnant or are pregnant.

It is not known if XELJANZ will harm an unborn baby. To monitor the outcomes of pregnant women exposed to XELJANZ, a registry has been established. Physicians are encouraged to register patients and pregnant women are encouraged to register themselves by calling 1-877-311-8972.

Patients should tell their healthcare providers if they plan to breastfeed or are breastfeeding. Patients and their healthcare provider should decide if they will take XELJANZ or breastfeed. They should not do both.

In carriers of the hepatitis B or C virus (viruses that affect the liver), the virus may become active while using XELJANZ. Healthcare providers may do blood tests before and during treatment with XELJANZ. Common side effects include upper respiratory tract infections (common cold, sinus infections), headache, diarrhea, and nasal congestion, sore throat, and runny nose (nasopharyngitis).
Please click the direct link to the full prescribing information for XELJANZ, including boxed warning and Medication Guide:http://labeling.pfizer.com/ShowLabeling.aspx?id=959.

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At Pfizer, we apply science and our global resources to bring therapies to people that extend and significantly improve their lives. We strive to set the standard for quality, safety and value in the discovery, development and manufacture of health care products. Our global portfolio includes medicines and vaccines as well as many of the world's best-known consumer health care products. Every day, Pfizer colleagues work across developed and emerging markets to advance wellness, prevention, treatments and cures that challenge the most feared diseases of our time. Consistent with our responsibility as one of the world's premier innovative biopharmaceutical companies, we collaborate with health care providers, governments and local communities to support and expand access to reliable, affordable health care around the world. For more than 150 years, Pfizer has worked to make a difference for all who rely on us. To learn more, please visit us at www.pfizer.com.

DISCLOSURE NOTICE: The information contained in this release is as of February 4, 2015. Pfizer assumes no obligation to update forward-looking statements contained in this release as the result of new information or future events or developments.

This release contains forward-looking information about a potential new indication for XELJANZ (tofacitinib citrate) for the treatment of adult patients with moderate-to-severe chronic plaque psoriasis, including its potential benefits, that involves substantial risks and uncertainties that could cause actual results to differ materially from those

expressed or implied by such statements. Risks and uncertainties include, among other things, the uncertainties inherent in research and development, including, without limitation, the possibility of unfavorable clinical trial results, including unfavorable new clinical data and additional analyses of existing clinical data; whether and when any applications may be filed with regulatory authorities in other jurisdictions for XELJANZ for the potential treatment of moderate-to-severe chronic plaque psoriasis; whether and when the FDA may approve the supplemental new drug application and whether and when regulatory authorities in other jurisdictions may approve any such other applications, which will depend on the assessment by such regulatory authorities of the benefit-risk profile suggested by the totality of the efficacy and safety information submitted; decisions by regulatory authorities regarding labeling and other matters that could affect the availability or commercial potential of XELJANZ; and competitive developments.

A further description of risks and uncertainties can be found in Pfizer's Annual Report on Form 10-K for the fiscal year ended December 31, 2013 and in its subsequent reports on Form 10-Q, including in the sections thereof captioned "Risk Factors" and "Forward-Looking Information That May Affect Future Results", as well as in its subsequent reports on Form 8-K, all of which are filed with the SEC and available at www.sec.gov andwww.pfizer.com.

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