Pfizer Announces FDA Acceptance for Review of New Drug Application for A Once-Daily Formulation of XELJANZ® (tofacitinib citrate) Modified Release Tablets

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“This filing underscores our commitment to helping advance patient care and our goal of providing innovative solutions for patients with RA."

Pfizer Inc. announced today that the United States Food and Drug Administration (FDA) accepted for review Pfizer’s new drug application (NDA) for XELJANZ® (tofacitinib citrate) 11 mg once daily modified release tablets for the treatment of moderate to severe rheumatoid arthritis (RA) in patients who have had an inadequate response or intolerance to methotrexate (MTX). The FDA has provided an anticipated Prescription Drug User Fee Act (PDUFA) action date in February 2016 for the NDA.

The NDA for XELJANZ 11 mg once daily modified release is based on data from a clinical pharmacology program designed to demonstrate equivalence in key pharmacokinetic parameters to XELJANZ 5 mg twice daily.

“This filing underscores our commitment to helping advance patient care and our goal of providing innovative solutions for patients with RA,” said Rory O’Connor, MD, senior vice president and head of Global Medical Affairs, Global Innovative Pharmaceuticals Business, Pfizer Inc. “If approved, it would bring us one step closer to offering the first and only once-daily oral Janus kinase inhibitor treatment for those living with moderate to severe RA who have had an inadequate response or intolerance to methotrexate.”

As the developer of XELJANZ, Pfizer is a leader in the research of this new class of medications. XELJANZ is approved in 40 countries around the world for the treatment of moderate to severe rheumatoid arthritis (RA). In the United States, XELJANZ has a boxed warning for serious infections and malignancies.

About the XELJANZ Clinical Development Program

Pfizer is committed to building on the science and understanding of JAK inhibition and XELJANZ through a robust clinical development program in a range of immune-mediated inflammatory conditions in the areas of rheumatology, dermatology and gastroenterology. A supplemental new drug application for XELJANZ 10 mg and 5 mg tablets twice daily is currently under review with the FDA for the treatment of adult patients with moderate to severe chronic plaque psoriasis who are candidates for systemic therapy or phototherapy. The benefit:risk profile of XELJANZ in RA has been studied in approximately 6,200 patients in the global clinical development program for XELJANZ in moderate to severe RA.

XELJANZ U.S. Label Information

XELJANZ is a prescription medicine called a Janus kinase (JAK) inhibitor. The recommended dose is 5 mg twice-daily (BID). XELJANZ is used to treat adults with moderately to severely active rheumatoid arthritis in which methotrexate did not work well. XELJANZ may be used as a single agent or in combination with MTX or other non-biologic disease-modifying antirheumatic drugs (DMARDs). Use of XELJANZ in combination with biologic DMARDs or potent immunosuppressants, such as azathioprine and cyclosporine is not recommended.

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.
People may be at a higher risk of developing shingles.

XELJANZ may increase the risk of certain cancers by changing the way the immune system works. Lymphoma and other cancers, including skin cancers, have happened in patients taking 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.

About Rheumatoid Arthritis

Rheumatoid arthritis (RA) is a chronic, inflammatory autoimmune disease that causes a range of symptoms, including stiffness and swelling in the joints,1,2 particularly those in the hands, feet and knees.3 Although the exact cause of RA is unknown,1 it is considered to be an autoimmune disease, because the immune system in people with RA mistakes the body’s healthy tissues for a threat and attacks them.3 Some people are at increased risk of developing RA, including people with a family history of RA, smokers and women.3 Three times as many women are affected by RA compared to men.2 RA affects approximately 23.7 million people4 worldwide and 1.6 million people in the United States.5,6 It can develop at any time during adulthood, but it usually occurs between 40 and 70 years of age.2

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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 July 2, 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 XELJANZ, including its potential benefits and a potential once daily formulation of XELJANZ 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 the possibility of unfavorable clinical trial results, including unfavorable new clinical data and additional analyses of existing clinical data; whether and when any applications for XELJANZ may be filed with regulatory authorities in any other jurisdictions; whether and when the FDA may approve the NDA or the supplemental new drug application and whether and when regulatory authorities in other jurisdictions in which such applications are pending or will be submitted may approve such 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, 2014 and in its subsequent reports on Form 10-Q, including in the sections thereof captioned "Risk Factors" and "Forward-Looking Information and Factors 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 and www.pfizer.com.

1 Lee DM, Weinblatt ME. Rheumatoid arthritis. Lancet. 2001; 358:903-911.

2 Medline Plus, "Rheumatoid Arthritis" Accessed 11 October 2011. Available athttp://www.nlm.nih.gov/medlineplus/ency/article/000431.htm.

3 Mayo Clinic, "Rheumatoid Arthritis." Accessed 14 September 2011. Available athttp://www.mayoclinic.com/health/rheumatoid-arthritis/DS00020/DSECTION=risk-factors.

4 World Health Organization, "The Global Burden of Disease, 2004 Update." Accessed 13 March 2012. Available athttp://www.who.int/healthinfo/global_burden_disease/GBD_report_2004update_full.pdf.

5 Sacks, J., Lou, Y., Helmick, C. Prevalence of Specific Types of Arthritis and Other Rheumatic Conditions in the Ambulatory Health Care System in the United States 2001-2005. Arthritis Care and Research. 2010. 62(4): 460- 464.

6 Howden, L., Meyer, J., 2010 U.S. Census Bureau results --- U.S. Census Bureau, 2010 Census Summary File 1.

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