Pfizer Announces FDA Accepts Supplemental New Drug Application for XELJANZ® (tofacitinib citrate) for the Treatment of Adult Patients with Moderately to Severely Active Ulcerative Colitis

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Pfizer Inc. announced today that the supplemental New Drug Application (sNDA) for XELJANZ® (tofacitinib citrate), an investigational oral treatment for adult patients with moderately to severely active ulcerative colitis (UC), has been accepted for filing by the U.S. Food and Drug Administration (FDA).

The FDA has provided an anticipated Prescription Drug User Fee Act (PDUFA) action date in March 2018 for the sNDA.

“Ulcerative colitis is a debilitating inflammatory disease that impacts the physical, emotional and social well-being of nearly one million people in the United States, many of whom are not able to manage their disease,” said Michael Corbo, Chief Development Officer, Inflammation & Immunology, Global Product Development, Pfizer Inc. “We look forward to working with the FDA as they consider the application for tofacitinib in UC, with the goal of offering, if approved, the first oral Janus kinase (JAK) inhibitor as a therapeutic option for people living with moderately to severely active UC.”

The sNDA submission package included data from three pivotal Phase 3 studies from the Oral Clinical Trials for tofAcitinib in ulceratiVE colitis global clinical development program (OCTAVE Induction 1, OCTAVE Induction 2 and OCTAVE Sustain) evaluating the safety and efficacy of tofacitinib in patients with moderately to severely active UC, and OCTAVE

Open, the open label long-term extension study of tofacitinib in patients who completed or who had treatment failure in OCTAVE Sustain, or who were non-responders in OCTAVE Induction 1 or 2. Full results from OCTAVE Induction 1, OCTAVE Induction 2 and OCTAVE Sustain were published in The New England Journal of Medicine in May 2017.

About Ulcerative Colitis

UC is a chronic, debilitating and often misunderstood inflammatory bowel disease that affects millions of people worldwide. Symptoms of UC can include chronic diarrhea with blood and mucus, abdominal pain and cramping, fever and weight loss. While the exact cause of UC is unknown, it is believed to be the result of complex interactions between multiple factors that include genetic predisposition and an exaggerated immune response to a microbial trigger. UC can have a significant effect on work, family and social activities. Despite receiving treatment, half of patients continue to experience symptoms. Under these circumstances, surgery to remove the colon (colectomy), may be considered for some patients.

About Tofacitinib Citrate

Tofacitinib citrate is a Janus kinase (JAK) inhibitor. It is not currently approved for the treatment of UC.

As the developer of tofacitinib, Pfizer is committed to advancing the science of JAK inhibition and enhancing understanding of tofacitinib through robust clinical development programs in the treatment of immune-mediated inflammatory conditions.

XELJANZ/XELJANZ XR U.S. Label Information

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

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

Important Safety Information

XELJANZ/XELJANZ XR can lower the ability of the immune system to fight infections. Some people can have serious infections while taking XELJANZ/XELJANZ XR, 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/XELJANZ XR, and monitor them closely for signs and symptoms of TB and other infections during treatment. People should not start taking XELJANZ/XELJANZ XR 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/XELJANZ XR may increase the risk of certain cancers by changing the way the immune system works. Lymphoma and other cancers, including skin cancers, can happen in patients taking XELJANZ/XELJANZ XR. The risks and benefits of treatment should be considered prior to initiating XELJANZ/XELJANZ XR 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/XELJANZ XR. Update immunizations in agreement with current immunization guidelines prior to initiating XELJANZ/XELJANZ XR 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/XELJANZ XR can 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/XELJANZ XR should be used with caution in patients who may be at increased risk for gastrointestinal perforation (e.g., patients with a history of diverticulitis), or who have a narrowing within their digestive tract. Some people taking XELJANZ have had 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/XELJANZ XR and while they are taking XELJANZ/XELJANZ XR, to check for these side effects. Normal cholesterol levels are important to good heart health. Healthcare providers may stop XELJANZ/XELJANZ XR treatment because of changes in blood cell counts or liver test results. Use of

XELJANZ/XELJANZ XR 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/XELJANZ XR will harm an unborn baby. To monitor the outcomes of pregnant women exposed to XELJANZ/XELJANZ XR, 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/XELJANZ XR 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/XELJANZ XR. Healthcare providers may do blood tests before and during treatment with XELJANZ/XELJANZ XR. Common side effects of XELJANZ/XELJANZ XR 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/XELJANZ XR, including BOXED WARNING and Medication Guide: http://labeling.pfizer.com/ShowLabeling.aspx?id=959.

Pfizer Inc.: Working together for a healthier world®

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 healthcare products. Our global portfolio includes medicines and vaccines as well as many of the world's best-known consumer healthcare 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. For more information, please visit us at www.pfizer.com.

In addition, to learn more, follow us on Twitter at @Pfizer and @Pfizer_News, LinkedIn, YouTube and like us on Facebook at Facebook.com/Pfizer.

DISCLOSURE NOTICE: The information contained in this release is as of July 13, 2017. 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 for the treatment of adult patients with moderately to severely active UC (the “potential indication”), 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 the ability to meet anticipated trial commencement and completion dates and regulatory submission dates, as well as the possibility of unfavorable clinical trial results, including unfavorable new clinical data and additional analyses of existing clinical data; uncertainties regarding the commercial success of XELJANZ and XELJANZ XR; whether and when any applications for the potential indication may be filed with regulatory authorities in any jurisdictions; whether and when the FDA will approve the sNDA for the potential indication and whether and when regulatory authorities in any jurisdictions may approve any such applications and/or any other applications that are pending or may be filed for XELJANZ or XELJANZ XR, 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 XELJANZ XR, including the potential indication; 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, 2016 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 U.S. Securities and Exchange Commission and available at www.sec.gov and www.pfizer.com.

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