



# Pfizer Announces U.S. FDA Filing Acceptance of Supplemental New Drug Application for XELJANZ® (tofacitinib citrate) for the Treatment of Adult Patients with Active Psoriatic Arthritis

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Pfizer Inc. announced today that the United States Food and Drug Administration (FDA) has accepted for review the supplemental New Drug Application (sNDA) for XELJANZ® (tofacitinib citrate) 5 mg twice daily (BID) for the treatment of adult patients with active psoriatic arthritis (PsA). A separate sNDA was also accepted for XELJANZ XR® (tofacitinib citrate) extended release 11 mg once daily use in PsA. The sNDA submission is based on data from the Phase 3 Oral Psoriatic Arthritis Trials (OPAL) clinical development program, which consisted of two pivotal trials and a long-term extension study, evaluating the safety and efficacy of XELJANZ in patients with active PsA who had failed prior PsA treatments. The FDA has provided an anticipated Prescription Drug User Fee Act (PDUFA) action date in December 2017 for the sNDAs.

“Psoriatic arthritis is a complex disease involving joint inflammation and damage, psoriasis, and musculoskeletal inflammation, which may limit physical functioning for people living with the disease. Despite advances in the treatment of psoriatic arthritis in recent years, many people are still living with active disease and are in need of additional therapeutic options,” said Michael Corbo, Chief Development Officer, Inflammation & Immunology, Global Product Development. “We believe that XELJANZ has the potential to

provide patients with psoriatic arthritis and their physicians a new treatment option that also offers oral administration. If approved, XELJANZ or once-daily XELJANZ XR would be the first and only Janus kinase inhibitor for the treatment of this chronic inflammatory disease.”

Two pivotal Phase 3 studies were included in the submission package. OPAL Broaden was conducted in conventional synthetic disease-modifying antirheumatic drug (csDMARD) inadequate response (IR) and tumor necrosis factor inhibitor (TNFi)-naïve patient populations. The study included an active control arm of adalimumab. However, the study was not designed for non-inferiority or superiority comparisons between adalimumab and XELJANZ. OPAL Beyond was conducted in TNFi-IR patients and was the first PsA study focused exclusively in this population. Both studies met their primary efficacy endpoints showing a statistically significant improvement with XELJANZ 5 mg and 10 mg BID compared to treatment with placebo at three months as measured by American College of Rheumatology 20 (ACR20) response and change from baseline in Health Assessment Questionnaire Disability Index (HAQ-DI) score. In both studies adverse events were more frequent with XELJANZ 5 mg and 10 mg BID versus placebo. Overall safety findings were consistent with those observed in the broader rheumatology clinical development program for XELJANZ. Interim results from OPAL Balance, the long-term extension study of XELJANZ in patients with active PsA, were also included in the submission package.

#### About Psoriatic Arthritis

Psoriatic Arthritis (PsA) is a chronic inflammatory multisystem disease. PsA can cause joint pain and stiffness, skin and nail psoriasis, swollen toes and fingers, persistent painful tendonitis, and irreversible joint damage. There are an estimated three million people in the U.S. and Europe combined with active PsA. Real world disease prevalence may be even higher because it is often misdiagnosed or goes undiagnosed altogether.

About XELJANZ (tofacitinib citrate) and XELJANZ XR (tofacitinib citrate) extended-release

XELJANZ®/XELJANZ XR® (tofacitinib citrate) is a prescription medicine called a Janus kinase (JAK) inhibitor. XELJANZ is not currently approved for the treatment of PsA.

As the developer of XELJANZ/XELJANZ XR, Pfizer is a leader in JAK innovation. The XELJANZ RA development program includes more than eight years of safety data from the long-term extension studies representing over 21,100 patient-years of drug exposure to date.

XELJANZ is approved in more than 80 countries around the world for the treatment of moderately to severely active rheumatoid arthritis (RA). In the United States, Argentina, and Macau, XELJANZ XR is the first once-daily oral JAK inhibitor approved for the treatment of moderately to severely active RA.

Pfizer is committed to advancing the science of JAK inhibition and enhancing understanding of XELJANZ 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. 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. 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. 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 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/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 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 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, we have worked to make a difference for all who rely on us. We routinely post information that may be important to investors on our website at [www.pfizer.com](http://www.pfizer.com). In addition, to learn more, please visit us on [www.pfizer.com](http://www.pfizer.com) and follow us on Twitter at @Pfizer and @PfizerNews, LinkedIn, YouTube and like us on Facebook at [Facebook.com/Pfizer](https://www.facebook.com/Pfizer)

DISCLOSURE NOTICE: The information contained in this release is as of May 3, 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 and XELJANZ XR for the treatment of adult patients with active psoriatic arthritis (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, without limitation, 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 other applications for the potential indication or any other potential indications for XELJANZ or XELJANZ XR may be filed with regulatory authorities in any jurisdictions; whether and when the FDA may approve the supplemental new drug applications for XELJANZ and XELJANZ XR for the potential indication and whether and when regulatory authorities in any jurisdictions may approve any other applications that 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](http://www.sec.gov) and [www.pfizer.com](http://www.pfizer.com).

Media: Steven Danehy, 978-273-3946 [Steven.Danehy@pfizer.com](mailto:Steven.Danehy@pfizer.com) or Investors: Chuck Triano, 212-733-3901 [Charles.E.Triano@pfizer.com](mailto:Charles.E.Triano@pfizer.com)