# Pfizer Announces FDA Approval Of Supplemental Application To Expand XELJANZ® (tofacitinib citrate) Labeling To Include Additional Patient-Reported Outcomes Data For Adults With Moderately To Severely Active Rheumatoid Arthritis

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Pfizer Inc. (NYSE: PFE) announced today that the U.S. Food and Drug Administration (FDA) has approved the supplemental New Drug Application (sNDA) for XELJANZ® (tofacitinib citrate) to include additional Patient-Reported Outcomes (PRO) data in the label. These additional data show improvement in patients receiving XELJANZ based on health-related outcome measures reported by patients, including vitality, role emotional, physical function, bodily pain, social function, mental health, role physical and general health, which are the eight domains of the Medical Outcomes Study Short-Form (36-Item) Health Survey (SF-36). XELJANZ 5 mg twice-daily (BID) was approved by the FDA in November 2012 for the treatment of adults with moderately to severely active rheumatoid arthritis (RA) who have had an inadequate response or intolerance to methotrexate (MTX), and is the first approved RA treatment in the U.S. in a new class of medicines known as Janus kinase (JAK) inhibitors. In the U.S., XELJANZ may be used as monotherapy or in combination with MTX or other nonbiologic disease-modifying antirheumatic drugs (DMARDs). XELJANZ should not be used in combination with biologic DMARDs or potent

immunosuppressants, such as azathioprine and cyclosporine.

“The patient-reported outcomes data show the impact that XELJANZ can have on the daily lives of patients with RA, based on physical, mental and emotional measures,” said Dr. Steven Romano, senior vice president and the head of the Medicines Development Group for Pfizer Specialty Care. “Following the FDA approval of XELJANZ in November 2012, we are pleased with the agency’s decision to approve this sNDA and add to the growing body of knowledge about XELJANZ as an additional treatment option for patients with RA.”

The approval of the PRO sNDA expands the U.S. label to include the results of health-related outcome measures from three Phase 3 studies in the XELJANZ clinical development program (ORAL Solo, Scan and Step, also identified as Studies I, IV and V, respectively, in the XELJANZ label), as assessed by SF-36. The expanded U.S. label now includes results showing that, at three months, patients receiving XELJANZ 5 mg BID or XELJANZ 10 mg BID in these studies demonstrated greater improvement from baseline compared to placebo in all eight domains of the SF-36, as well as the physical component summary (PCS) and mental component summary (MCS) scores. This expands upon data already included in the U.S. label at the time of FDA approval that showed XELJANZ improved physical function as measured by the Health Assessment Questionnaire-Disability Index (HAQ-DI). The U.S. label specifies that 5 mg BID is the recommended dose. The 10 mg BID dose is not approved.

**About XELJANZ**

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. Lymphoma and other cancer can happen in patients taking XELJANZ. · Some people taking XELJANZ get tears in their stomach or intestines. 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 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. · 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 for hepatitis 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).

For full prescribing information, including boxed warning and Medication Guide, please visit www.XELJANZ.com.

**About Rheumatoid Arthritis**

Rheumatoid arthritis is a chronic inflammatory autoimmune disease that typically affects the hands and feet, although any joint lined by a synovial membrane may be affected. RA affects approximately 1.6 million Americans[1],[2] and 23.7 million people worldwide.[3] Although multiple treatments are available, many patients do not adequately respond. Specifically, up to one-third of patients do not adequately respond, and about half stop

responding to any particular DMARD within five years.[4],[5],[6],[7],[8],[9] As a result, there remains a need for additional options.

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**DISCLOSURE NOTICE:** The information contained in this release is as of November 18, 2013. 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 (tofacitinib citrate), including its potential benefits, that involves substantial risks and uncertainties. Such risks and uncertainties include, among other things, uncertainties related to the extent of market acceptance in the U.S.; whether and when the FDA will assess the benefit: risk profile of the 10 mg twice-daily dose and the impact of XELJANZ on the inhibition of structural damage; and competitive developments.

A further description of risks and uncertainties can be found in Pfizer’s Annual Report on Form 10-K/A for the fiscal year ended December 31, 2012, and in its reports on Form 10-Q and Form 8-K.

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