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U.S. Food And Drug Administration Approves Pfizer's XELJANZ® (tofacitinib citrate) for Adults with Moderately to Severely Active Rheumatoid Arthritis (RA) Who Have Had an Inadequate Response or Intolerance to Methotrexate

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First RA Treatment Approved in a New Class of Medicines Known as JAK Inhibitors First New Oral Disease-Modifying Antirheumatic Drug (DMARD) for RA in More Than 10 Years

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NEW YORK--(BUSINESS WIRE)--Pfizer Inc. (NYSE: PFE) announced today that the U.S. Food and Drug Administration (FDA) has approved XELJANZ® (tofacitinib citrate) 5 mg twice daily for the treatment of adults with moderately to severely active rheumatoid arthritis (RA) who have had an inadequate response or intolerance to methotrexate. XELJANZ may be used as monotherapy or in combination with methotrexate or other non-biologic disease-modifying antirheumatic drugs (DMARDs). XELJANZ should not be used in combination with biologic DMARDs or with potent immunosuppressives, such as azathioprine and cyclosporine.

XELJANZ (ZEL' JANS') is the first approved RA treatment in a new class of medicines known as Janus kinase (JAK) inhibitors and the first new oral DMARD for RA in more than 10 years. XELJANZ is approved as a second-line medicine for RA, which means treatment with a biologic is not required before taking XELJANZ.

"XELJANZ is an important new option that could potentially change the way rheumatologists treat this serious autoimmune disease," said Ian Read, chairman and chief executive officer of Pfizer. "With its novel mechanism of action, the discovery and development of XELJANZ by Pfizer scientists reflects our commitment to R&D innovation and our dedication to bringing important and meaningful medicines to patients."

XELJANZ is specifically designed to inhibit the JAK pathways, which are signaling pathways inside the cell that play an important role in the inflammation involved in RA. With one of the largest clinical databases of any RA drug ever submitted to the FDA for review, the comprehensive, multi-study, global clinical development program evaluated approximately 5,000 patients who represent a broad cross-section of the RA patient population.

"RA is a serious and disabling disease that affects people in their everyday lives, and many patients do not adequately respond or are intolerant to currently available therapies," said study investigator Stanley Cohen, MD, clinical professor of rheumatology at the University of Texas Southwestern Medical School; co-director,

Division of Rheumatology, Presbyterian Hospital Dallas; and co-medical director, Metroplex Clinical Research Center. “In clinical trials, XELJANZ significantly reduced the signs and symptoms of RA and improved physical function. As a physician, I am pleased that we have another choice for patients living with inadequately controlled, moderately to severely active RA.”

“In clinical trials, XELJANZ demonstrated consistent efficacy across a broad range of clinical measures and patient types, including patients who inadequately responded to non-biologic DMARDs and anti-TNF agents, and it has a safety profile that is well-characterized to date,” said Geno Germano, president and general manager, Specialty Care and Oncology, Pfizer. “We are proud of the comprehensive data that support the use of XELJANZ, and we are excited to make it available to patients in the U.S. as a powerful oral option that can be taken as a second-line treatment with or without methotrexate.”

Safety findings observed in the overall XELJANZ RA program include serious and other important infections, including tuberculosis and herpes zoster; malignancies, including lymphoma; gastrointestinal perforations; decreased neutrophil and lymphocyte counts; decreased hemoglobin; liver enzyme elevations; and lipid elevations.

The most common serious adverse events were serious infections. The most commonly reported adverse events were upper respiratory tract infections, headache, diarrhea and nasopharyngitis.

Regarding the potential for further assessment by the FDA of the inhibition of structural damage, Pfizer plans to immediately discuss with the FDA the submission of the results of the previously disclosed ORAL Start (A3921069) study, which demonstrated significant efficacy of XELJANZ taken as monotherapy versus methotrexate, including inhibiting structural damage. The ORAL Start study was ongoing at the time of the New Drug Application submission and was not included in the original application to the FDA.

In the clinical trials, XELJANZ was studied in both a 5 mg and 10 mg twice-daily dosing regimen. The FDA has approved the 5 mg twice-daily dose in the second-line setting and has indicated that further data are required to assess the benefit: risk profile of the 10 mg twice-daily dose. Pfizer will continue to generate additional clinical data on the 10 mg twice-daily dose and work with the FDA to understand the additional data needed for further assessment of the 10 mg twice-daily dose.

FDA has approved XELJANZ with a Risk Evaluation and Mitigation Strategy (REMS) designed to inform healthcare providers and patients about the serious risks associated with XELJANZ treatment. The approved REMS includes a Medication Guide for patients, a communication plan for healthcare providers and pharmacists, and periodic submissions of assessments of the REMS. Pfizer has agreed to conduct post-marketing clinical trials to evaluate the long-term safety of XELJANZ and to assess XELJANZ in the pediatric population with polyarticular juvenile idiopathic arthritis (JIA).

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

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 whom 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.**
- **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. 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 pregnancy 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, nasal congestion, sore throat, and runny nose (nasopharyngitis).

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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At Pfizer, we apply science and our global resources to improve health and well-being at every stage of life. We strive to set the standard for quality, safety and value in the discovery, development and manufacturing of medicines for people and animals. Our diversified global healthcare portfolio includes human and animal biologic and small molecule medicines and vaccines, as well as nutritional products and many of the world's best-known consumer 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 the world's leading biopharmaceutical company, we also collaborate with healthcare 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 about our commitments, please visit us at www.pfizer.com.

DISCLOSURE NOTICE: The information contained in this release is as of November 6, 2012. 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 for the fiscal year ended December 31, 2011, and in its reports on Form 10-Q and Form 8-K.

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