Pfizer Announces Over 10 Abstracts for XELJANZ® (Tofacitinib Citrate) in Rheumatoid Arthritis to be Presented at the European League Against Rheumatism (EULAR) 2014 Annual Meeting

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Additional Data Further Characterizes the Safety Profile of XELJANZ

Pfizer Inc. announced today that over 10 abstracts have been accepted for presentation at the European League Against Rheumatism (EULAR) 2014 Annual Meeting (June 11-14, Paris, France), seven of which are focused on further characterizing the safety profile of XELJANZ (tofacitinib citrate) in treating moderately to severely active rheumatoid arthritis. Notably, an abstract titled, “Integrated safety analysis of tofacitinib in rheumatoid arthritis clinical trials with a cumulative exposure of 12,664 patient-years,” will be presented as an oral abstract session (OP0154) on June 13, 2014 at 11:30 a.m. CEST. This analysis describes safety data for XELJANZ in patients from the integrated rheumatoid arthritis clinical trial database, which is based on cumulative exposure in Phase 2, Phase 3, and open-label long-term extension studies. The analysis includes 5,671 patients with a median exposure of 2.4 years including more than 500 patients followed for greater than four years.

“Pfizer is proud to showcase our commitment to the ongoing study of XELJANZ, with a focus on further establishing its benefit:risk profile in rheumatoid arthritis, a disease

which affects more than 23 million people worldwide," said Dr. Steven Romano, Global Medicines Development Lead for the Pfizer Global Innovative Pharmaceutical business.

XELJANZ is now approved in more than 20 countries for the treatment of patients with moderately to severely active rheumatoid arthritis who had an inadequate response to existing therapies. Most recently, Health Canada approved XELJANZ 5 mg twice daily in combination with methotrexate for reducing the signs and symptoms of rheumatoid arthritis in adult patients with moderately to severely active rheumatoid arthritis who have had an inadequate response or intolerance to methotrexate. In cases of intolerance to methotrexate, physicians may consider the use of XELJANZ as monotherapy. Regulatory applications for XELJANZ for the treatment of moderately to severely active rheumatoid arthritis remain under review in more than 35 additional countries. In Europe, XELJANZ is approved in Russia, Switzerland and Turkey, and Pfizer is working on next steps to re-file an application with the European Medicines Agency (EMA).

The following additional abstracts focused on further characterizing the efficacy and safety profile of XELJANZ have also been accepted for presentation at the EULAR 2014 Annual Meeting:

Safety and Epidemiology

"Tofacitinib, An Oral Janus Kinase Inhibitor: Analysis Of Malignancies Across The Rheumatoid Arthritis Clinical Programme." Mariette X, Curtis JR, Lee EB et. al. [THU0147; June 12, 2014 11:45 a.m.; Poster Session] "Tofacitinib, An Oral Janus Kinase Inhibitor: Analysis Of Malignancies In Japanese Patients Across The Rheumatoid Arthritis Clinical Programme." Tanaka Y, Takeuchi T, Yamanaka H et. al. [THU0148; June 12, 2014 11:45 a.m.; Poster Session] "Association Of Mean Changes In Laboratory Safety Parameters With C-Reactive Protein At Baseline And Week 12 In Rheumatoid Arthritis Patients Treated With Tofacitinib." Strand V, Issacs JD, Beal J et. al. [THU0145; June 12, 2014 11:45 a.m.; Poster Session] "Evaluation Of The Effect Of Tofacitinib On Measured Glomerular Filtration Rate In Patients With Active Rheumatoid Arthritis." Kremer J, Kivitz AJ, Simon-Campos JA et. al. [THU0126; June 13, 2014 11:45 a.m.; Poster Session] "Changes In T And B Lymphocyte Subsets With Tofacitinib Do Not Translate From Nonclinical Species To Humans." Ball D J, Kawabata T, Vogel W M et. al. [AB0474; Abstract Book Only] "Contextualisation Of Safety Endpoints In The Tofacitinib Rheumatoid Arthritis (Ra) Development Programme: Collaboration With The Consortium Of Rheumatology Researchers Of North America (CORRONA) Registry." Geier J, KC Saunders, G Reed G. [AB1057; Abstract Book Only]
Efficacy

“Effects Of Tofacitinib Monotherapy Versus Methotrexate On Patient-Reported Outcomes In The 2-Year Phase 3 Oral Start Trial In Methotrexate-Naïve Patients With Rheumatoid Arthritis.” Alten RE, Strand V, Fleischmann R et al. [OP0152; June 13, 2014 11:10 a.m.; Oral Presentation].

Once Daily Formulation in Healthy Volunteers

“Pharmacokinetics, Bioavailability And Safety Of A Modified Release Once Daily Formulation Of Tofacitinib In Healthy Volunteers.” Lamba M, Wang R, Fletcher T et. al. [THU0143; June 12, 2014 11:45 a.m.; Poster Session]
Health Economics and Outcomes Research

“Estimated Medical Expenditures Among Patients With Rheumatoid Arthritis Undergoing Treatment With Tofacitinib, An Oral Janus Kinase Inhibitor.” Rendas-Baum R, Kosinski M, Singh A et. al.[FRI0178; June 13, 2014 11:45 a.m.; Poster Session]
Safety findings observed in the overall rheumatoid arthritis program for XELJANZ include serious and other important infections, including tuberculosis and herpes zoster; malignancies, including lymphoma; gastrointestinal perforations; decreased neutrophil and lymphocyte counts; 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.

XELJANZ® (tofacitinib citrate) 5 mg Tablets RA U.S. Label Information

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. 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. The recommended dose is 5 mg twice-daily (BID).

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. Malignancies were observed in clinical studies of 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. [BEGIN TEXT BOX]
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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 U.S. 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 typically affects the hands and feet, although any joint lined by the synovial membrane can be affected.1 RA causes a range of symptoms, including stiffness and swelling in the joints,2 particularly those in the hands, feet and knees.1 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.1 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 June 11, 2014. 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 that involves substantial risks and uncertainties about XELJANZ, including its potential benefits and risks as well as clinical trial data relating to XELJANZ and the potential implications of such data. Such 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 Pfizer will re-file an application with the European Medicines Agency for XELJANZ for the treatment of moderately to severely active rheumatoid arthritis, whether and when regulatory authorities in jurisdictions in which applications for XELJANZ for the treatment of moderately to severely active rheumatoid arthritis are pending or will be submitted will approve such applications as well as their decisions regarding labeling and other matters that could affect its availability or commercial potential; 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, 2013and in its subsequent reports on Form 10-Q and Form 8-K.

References:

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

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

3 Mayo Clinic, "Rheumatoid Arthritis." Accessed 14 September 2011. Available at http://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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