Pfizer Research Advances Body Of Evidence For Tofacitinib Citrate (XELJANZ®) Providing Clinicians With Additional Information For The Treatment Of Moderate to Severe RA

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More Than 20 Abstracts will be Featured at the European League Against Rheumatism Annual Congress (EULAR 2016)

“The research being presented at the Annual European Congress of Rheumatology (EULAR 2016) illustrates our continued commitment to improving care for patients living with chronic inflammatory conditions, like RA”

Pfizer Inc. (NYSE:PFE) announced today that 23 abstracts1, including research and analyses for tofacitinib citrate (XELJANZ®), will be featured at the upcoming European League Against Rheumatism (EULAR) Congress (June 8-11, London). The research being shared at the meeting provides new and additional information on the efficacy and safety profile of tofacitinib citrate, including its use as a single agent without methotrexate.

“The data being presented at the Annual European Congress of Rheumatology (EULAR 2016) provides important information to help guide physicians on treatment approaches for tofacitinib citrate in rheumatoid arthritis (RA),” said Dr. Roy Fleischmann, clinical professor in the Department of Internal Medicine at the University of Texas Southwestern Medical Center and Co-Medical Director, Metroplex Clinical Research Center. “For years, combination therapy has been the standard of care for treating RA. However, the monotherapy data reinforces the use of tofacitinib citrate as an oral option for patients to

manage their RA without the need for methotrexate.”

Tofacitinib citrate is approved in more than 45 countries around the world for the treatment of moderate to severe RA as a second-line therapy after failure of one or more disease-modifying antirheumatic drugs (DMARDs).

Tofacitinib citrate is not currently approved for use by the European Medicines Agency (EMA). A marketing authorization application for tofacitinib citrate 5 mg BID is currently under review by the EMA for the treatment of patients with moderate to severe RA who have had an inadequate response or intolerance to methotrexate.

Treatment Approaches

A number of analyses offer information to help guide physicians on treatment approaches for the use of tofacitinib citrate in moderate to severe RA. These include findings further contextualizing the safety profile of tofacitinib citrate as well as long-term data:

Tofacitinib, An Oral Janus Kinase Inhibitor, In The Treatment Of Rheumatoid Arthritis: Changes In Lymphocytes And Lymphocyte Subset Counts And Reversibility After Up To 8 Years Of Tofacitinib Treatment [THU0199, Thursday, June 9] Persistence Of Tofacitinib In The Treatment Of Rheumatoid Arthritis In Open-label, Long-term Extension Studies Up to 7 Years [THU0169, Thursday, June 9] Tofacitinib, An Oral JAK Inhibitor, In The Treatment Of Rheumatoid Arthritis: Safety And Clinical And Radiographic Efficacy In Open-label, Long-term Extension Studies Over 7 Years [THU0185, Thursday, June 9] Assessment of Immunogenicity of Live Zoster Vaccination in Rheumatoid Arthritis Patients on Background Methotrexate Before and After Initiating Tofacitinib or Placebo [FRI0110, Friday, June 10]
Providing Evidence for tofacitinib citrate as Monotherapy

Data supporting the use of tofacitinib citrate as monotherapy – without the need for methotrexate – include real-world efficacy results, as well as additional safety data:

Clinical Outcomes Of Rheumatoid Arthritis Patients Receiving Tofacitinib Monotherapy In The Open-label Long-term Extension [THU0202, Thursday, June 9] Lack Of Early Change In Disease Activity Score Predicts The Likelihood Of Achieving Low Disease Activity At Month 6: Tofacitinib Monotherapy Versus Methotrexate In Methotrexate-Naïve Patients With Rheumatoid Arthritis [THU0180, Thursday, June 9] Comparative Effectiveness Of TNFi And Tofacitinib Monotherapy In Clinical Practice: Results From Corrona Registry [THU0132, Thursday, June 9] A Safety Analysis Of Tofacitinib 5 Mg Twice Daily Administered As Monotherapy Or In Combination With Background Conventional Synthetic DMARDs In A Phase 3 Rheumatoid Arthritis Population [THU0174, Thursday,

June 9]
“The research being presented at the Annual European Congress of Rheumatology (EULAR 2016) illustrates our continued commitment to improving care for patients living with chronic inflammatory conditions, like RA,” said Michael Corbo, Chief Development Officer, Inflammation & Immunology, Pfizer Global Product Development. “Pfizer continues to advance the understanding of JAK science through the ongoing study of tofacitinib citrate, which has one of the largest RA clinical development programs with respect to the number of patients and patient years of exposure.”

Additional Pfizer Presentations at the Annual European Congress of Rheumatology (EULAR 2016):

Oral Presentations

Tofacitinib in patients with ankylosing spondylitis: a phase 2, 16-week, randomised, placebo-controlled, dose-ranging study [OP0002, Wednesday, June 8, 4:15 p.m. GMT, Hall D] Understanding the importance of a patient’s role in the management of RA: results from a patient-based survey developed by the RA NarRAtive global advisory panel [OP0248-PARE, June 10, 10:30 a.m. GMT, Room S19]
Guided Poster Tour and Poster Display

Long-term radiographic and patient-reported outcomes based on clinical disease activity index responses with tofacitinib at 6 months [THU0165, Thursday, June 9] Understanding the importance of a patient’s role in the management of RA: physician- and patient-based survey results developed by the RA NarRAtive advisory panel [SAT0640-HPR, Saturday, June 11]
Poster Presentations

Malignancy Data In Tofacitinib-Treated Japanese Patients With Rheumatoid Arthritis [THU0210, Thursday, June 9] Genome-Wide Trans-Ancestry Meta-Analysis Of Herpes Zoster In Rheumatoid Arthritis And Psoriasis Patients Treated With Tofacitinib [THU0196, Thursday, June 9] Effect Of Methotrexate Dose On The Efficacy Of Tofacitinib: Treatment Outcomes From A Phase 3 Clinical Trial Of Patients With Rheumatoid Arthritis [THU0200, Thursday, June 9] Safety Of Tofacitinib, An Oral Janus Kinase Inhibitor: Integrated Data Analysis From The Global Chronic Plaque Psoriasis Clinical Trials [THU0187, Thursday, June 9] Evaluating Pharmacokinetic Predictors Of Tofacitinib Clinical Response In Rheumatoid Arthritis [THU0192, Thursday, June 9] The Unmet Need In The Norwegian Disease-Modifying Antirheumatic Drug Registry [FRI0575, Friday, June 10] Tofacitinib Versus Biologic Treatments In Moderate To Severe Rheumatoid Arthritis Patients Who

Have Had An Inadequate Response To Nonbiologic DMARDs: Systematic Literature Review And Network Meta-Analysis [SAT0165, Saturday, June 11]

Publication Only

Safety Of Tofacitinib For The Treatment Of Rheumatoid Arthritis In Patients From Latin America And The Rest Of The World [AB0396] Efficacy Of Adalimumab And Tofacitinib In Rheumatoid Arthritis: Post-Hoc Analyses From A Phase 3 Study [AB0398] Real-World Experience With Tofacitinib Vs Adalimumab (ADA), Etanercept (ETN) And Abatacept (ABA) In Biologic-Experienced Patients With Rheumatoid Arthritis (RA): data from a us administrative claims database [AB0399] Pharmacokinetics, Safety, And Tolerability Of Tofacitinib In Paediatric Patients From Two To Less Than Eighteen Years Of Age With Juvenile Idiopathic Arthritis [AB0879]
About tofacitinib citrate and tofacitinib citrate extended-release

Tofacitinib citrate/tofacitinib citrate extended-release is a prescription medicine called a Janus kinase (JAK) inhibitor. In the United States, tofacitinib citrate extended-release 11 mg QD is the first and only once-daily oral JAK inhibitor approved for the treatment of moderate to severe rheumatoid arthritis (RA).

As the developer of tofacitinib citrate/tofacitinib citrate extended-release, Pfizer is a leader in JAK innovation.

Pfizer is committed to advancing the science of JAK inhibition and enhancing understanding of tofacitinib citrate through a robust clinical development program. The safety and efficacy profile of tofacitinib citrate has been studied in approximately 6,200 patients with moderate to severe RA, amounting to more than 19,400 patient-years of drug exposure in the global clinical development program.

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.

About Rheumatoid Arthritis

Rheumatoid arthritis (RA) is a chronic, inflammatory autoimmune disease that causes a range of symptoms, including pain and swelling in the joints,2,3 particularly those in the hands, feet and knees.2 Although the exact cause of RA is unknown,2 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.2 Some people are at increased risk of developing RA, including people with a family history of RA, smokers and women.4 Three times as many women are affected by RA compared to men.5 RA affects more than 17.6 million people worldwide6 and 1.6 million people in the United States.7,8 It can develop at any time during adulthood, but it usually occurs between 40 and 70 years of age.3

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 June 8, 2016. 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 tofacitinib citrate/tofacitinib citrate extended-release, including their 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 possibility of unfavorable clinical trial results, including unfavorable new clinical data and additional analyses of existing clinical data; uncertainties regarding the commercial success of tofacitinib citrate/tofacitinib citrate extended-release; whether and when any applications for tofacitinib citrate/tofacitinib citrate extended-release may be filed with regulatory authorities in any other jurisdictions; whether and when the EMA or regulatory authorities in other jurisdictions in which applications are pending or may be submitted may approve such applications, 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 tofacitinib citrate/tofacitinib citrate extended-release; 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, 2015 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.

1 Includes Pfizer-sponsored abstracts only.

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

3 Medline Plus, “Rheumatoid Arthritis” Accessed 11 October 2015. Available at http://www.nlm.nih.gov/medlineplus/ency/article/000431.htm.

4 Mayo Clinic, “Rheumatoid Arthritis.” Accessed 4 May 2016. Available at http://www.mayoclinic.org/diseases-conditions/rheumatoid-arthritis/symptoms-causes/dxc-20197390.

5 Centers for Disease Control and Prevention, “Rheumatoid Arthritis (RA).” Accessed 4 May 2016. Available at http://www.cdc.gov/arthritis/basics/rheumatoid.htm.

6 Annals of Rheumatic Diseases, “The global burden of rheumatoid arthritis: estimates from the Global Burden of Disease 2010 study.” Accessed 14 July 2015. Available at http://ard.bmj.com/content/early/2014/02/18/annrheumdis-2013-204627.

7 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.

8 Howden, L., Meyer, J., 2010 U.S. Census Bureau results --- U.S. Census Bureau, 2010 Census Summary File 1.

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