New Data Continue to Characterize the Safety and Efficacy of XELJANZ® (tofacitinib citrate) in the Treatment of Rheumatoid Arthritis

Monday, November 02, 2015 - 03:06am

Twenty-six Pfizer scientific abstracts will be presented for the first time at the ACR/ARHP 2015 Annual Meeting

Pfizer Inc. announced today that 26 new scientific abstracts, including 20 presentations for XELJANZ® (tofacitinib citrate) in rheumatoid arthritis (RA) will be presented on behalf of Pfizer at the American College of Rheumatology (ACR)/Association of Rheumatology Health Professionals (ARHP) 2015 Annual Meeting (November 7-11, San Francisco, CA).

“Ongoing clinical trials and long term extension studies provide important information about the safety and efficacy of XELJANZ in RA,” said Rory O’Connor, MD, senior vice president and head of Global Medical Affairs, Global Innovative Pharmaceuticals Business, Pfizer Inc. “We continue to build on our knowledge of the clinical application of XELJANZ in real-world settings.”

The full list of scientific abstracts to be presented at ACR/ARHP 2015 is as follows:

Safety of XELJANZ in RA:

1. Herpes Zoster during the Tofacitinib Clinical Development Program for RA: Characterization of Herpes Zoster Incidence and Evaluation of Whether Herpes Zoster Predicts Subsequent Serious Infections or Malignancy (Winthrop K, Tanaka Y,Yamaoka K, et al., Abstract #2050 Monday, November 9, 2015 2:30PM-4:00PM)

2. A Safety Analysis of Tofacitinib 5mg Twice Daily Administered As Monotherapy or in Combination with Background Conventional Synthetic DMARDs in a Phase 3 Rheumatoid Arthritis Population (Kivitz AJ, Haroui B, Kaine J, et al., Abstract #2143, Monday, November 9, 2015 4:30PM-6:00PM)

3. Herpes Zoster and Tofacitinib: The Risk of Concomitant Nonbiologic Therapy (Winthrop K, Curtis J, Lindsey S, et al., Abstract #559 Sunday, November 8, 2015 9:00AM-11:00AM)

4. Genome-Wide Trans-Ancestry Meta-Analysis of Herpes Zoster in RA and Pso Patients Treated with Tofacitinib (Nan B, Zhou HY, Zhang B, et al., Abstract #566 Sunday, November 8, 2015, 9:00AM-11:00AM)

5. Malignancy Data in Tofacitinib-Treated Japanese Patients with Rheumatoid Arthritis (Tanaka Y, Takeuchi T, Yamanaka H, et al., Abstract #571 Sunday, November 8, 2015 9:00AM-11:00AM)

6. Assessment of Immunogenicity of Live Zoster Vaccination (Zostavax®) in Rheumatoid Arthritis Patients on Background Methotrexate before and after Initiating Tofacitinib or Placebo (Winthrop K, Wouters A, Choy E,et al., Abstract 12L Tuesday, November 10, 2015 9:00AM-11:00AM)

XELJANZ RA Long Term Extension Studies:

7. Tofacitinib, an Oral Janus Kinase Inhibitor, in the Treatment of Rheumatoid Arthritis: Safety and Clinical and Radiographic Efficacy in Open-Label, Long-Term Extension Studies over 7 Years (Wollenhaupt J, Silverfield J, Lee EN, et al., Abstract #1645 Monday, November 9, 2015 9:00AM-11:00AM)

8. Clinical Outcomes for Rheumatoid Arthritis Patients Receiving Tofacitinib Monotherapy in the Open-Label Long-Term Extension over 6 Years (Fleischmann R, Yazici Y, Wollenhaupt J, et al., Abstract #1639 Monday, November 9, 2015 9:00AM-11:00AM)

Post-hoc Analyses of XELJANZ in RA:

9. Long-Term Radiographic and Patient-Reported Outcomes Based on Clinical Disease Activity Index Responses with Tofacitinib at 6 Months (Strand V, Kavanaugh A, Kivitz A, et al., Abstract #1633 Monday, November 9, 2015 9:00AM-11:00AM)

10. The Effects of Glucocorticoids on the Efficacy of Tofacitinib As Monotherapy and in Combination Therapy with Nonbiologic DMARDs: An Analysis of Data from Six Phase 3 Studies (Fleischmann R, Charles-Schoeman C, Burmester G, et al., Abstract

#1634 Monday, November 9, 2015 9:00AM-11:00AM)

11. Effect of Methotrexate Dose on the Efficacy of Tofacitinib: Treatment Outcomes from a Phase 3 Clinical Trial of Patients with Rheumatoid Arthritis (Fleischmann R, Mease P, Schwartzman S, et al., Abstract #1640Monday, November 9, 2015 9:00AM-11:00AM)

12. Consistency of Treatment Effects Across Different High-Risk Clinical Phenotypes in the Tofacitinib Clinical Program (Winthrop K, Curtis, J, Lindsey S, et al., Abstract #2737 Tuesday, November 10, 2015 9:00AM-11:00AM)

13. Efficacy and Safety of Tofacitinib Monotherapy Versus Combination Therapy in a Latin American Subpopulation of Patients with Rheumatoid Arthritis: A Pooled Phase 3 Analysis (Zerbini CAF, Radominski SC, Cardiel MH, et al., Abstract #2742 Tuesday, November 10, 2015 9:00AM-11:00AM)

14. An Analysis of the Efficacy of Tofacitinib Monotherapy in MTX-Naïve Patients with Early RA Compared with Patients with Established RA (Fleischmann R, Huizinga TWJ, Kavanaugh A, et al., Abract #2741 Tuesday, November 10, 2015 9:00AM-11:00AM)

15. 3D Location of Erosions in an Early Rheumatoid Arthritis Population: An MRI Study Using Statistical Shape Models with Implications for Pathogenesis (Bowes MA, Guillard G, Xie Z, et al., Abstract #2706 Tuesday, November 10, 2015 9:00AM-11:00AM)

Once-daily Formulation of XELJANZ in RA:

16. Modified-Release Formulation of Tofacitinib: Evaluation of Pharmacokinetics Compared with Immediate-Release Tofacitinib and Impact of Food (Lamba M, Wang R, Fletcher T, et al., Abstract #1643 Monday, November 9, 2015 9:00AM-11:00AM)

17. Evaluating Pharmacokinetic Predictors of Tofacitinib Clinical Response in Rheumatoid Arthritis (Lamba M, Furst D, Dikranian A, et al., Abstract #2755 Tuesday, November 10, 2015 9:00AM-11:00AM)

Real-World Data for XELJANZ in RA:

18. An Economic Evaluation of Tofacitinib (XELJANZ) Treatment in Rheumatoid Arthritis: Modeling the Cost of Treatment Strategies in the US (Claxton L, Taylor M, Jenks M, et al., Abstract #123 Sunday, November 8, 2015 9:00AM-11:00AM)

19. Real World Evaluation of Patients with Rheumatoid Arthritis Initiating Tofacitinib Vs. Adalimumab and Etanercept (Chastek B, Harnett J, Curtis J, et al., Abstract #2745

Tuesday, November 10, 2015 9:00AM-11:00AM)

XELJANZ in Juvenile Idiopathic Arthritis:

20. Pharmacokinetics, Safety, and Tolerability of Tofacitinib in Pediatric Patients from Six to Less Than Eighteen Years of Age with Juvenile Idiopathic Arthritis (Brunner H, Ruperto N, Tzaribachev T, et al., Abstract #2416 Tuesday, November 10, 2015 9:00AM-11:00AM)

XELJANZ in Ankylosing Spondylitis

21. Tofacitinib in Patients with Ankylosing Spondylitis: A Phase 2, 16-Week, Randomized, Placebo-Controlled, Dose-Ranging Study (van der Heijde D, Abstract 5L , Tuesday, November 10, 2015; 4:30PM-6:00PM)

Health Economics Outcomes Research:

22. Understanding the Importance of a Patient's Role in the Management of RA: Results from a Patient-Based Survey (Dikranian A, Galloway J, Kekow J, et al., Abstract #2324 Tuesday, November 10, 2015 9:00AM-11:00AM)

23. Adoption of Treat to Target Management in the Context of Achievable Goals and Satisfaction in RA (Taylor P, Gomez-Reino JJ, Alten R, et al., Abstract #430 Sunday, November 8, 2015 9:00AM-11:00AM)

24. Clinical Characteristics and Health Outcomes of RA Patients Not Adequately Controlled By Current Treatment (Taylor P, Alten R, Bertin P, et al., Abstract #2667 Tuesday, November 10, 2015 9:00AM-11:00AM)

25. Factors Influencing Treatment Adjustments in RA Patients - Biologic DMARD Treatment Start and Options(Taylor P, Sullivan E, Wood R, et al., Abstract #2640 Tuesday, November 10, 2015 9:00AM-11:00AM)

26. Correlation of Rheumatologists' Perceptions of RA Severity with Observed Disease Activity, Patient Impact and Treatment Patterns (Taylor P, Gomez-Reino JJ, Caporali R, et al., Abstract #2641 Tuesday, November 10, 2015 9:00AM-11:00AM)

About XELJANZ

XELJANZ (tofacitinib citrate) is a prescription medicine called a Janus kinase (JAK) Inhibitor.

XELJANZ is the first and only JAK inhibitor approved in over 40 countries around the world for the treatment of moderate to severe rheumatoid arthritis (RA) as a second-line therapy after failure of one or more disease-modifying antirheumatic drugs (DMARDs). The benefit:risk profile of XELJANZ in RA has been studied in approximately 6,200 patients with more than 19,000 patient-years of drug exposure in the global clinical development program for XELJANZ in moderate to severe RA. A new drug application (NDA) for XELJANZ 11 mg once-daily modified release for the treatment of moderate to severe RA is under review with the U.S. Food & Drug Administration (FDA). In the United States, XELJANZ has a boxed warning for serious infections and malignancies.

Pfizer is committed to advancing the science of JAK inhibition and enhancing understanding of XELJANZ through a robust clinical development program in a range of immune-mediated inflammatory conditions.

About Rheumatoid Arthritis

Rheumatoid arthritis (RA) is a chronic, inflammatory autoimmune disease that causes a range of symptoms, including stiffness and swelling in the joints,1,2 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 as 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 an estimated 17.5 million people worldwide.4 It can develop at any time during adulthood, but it usually occurs between 40 and 70 years of age.2

XELJANZ U.S. Label Information

XELJANZ is a prescription medicine called a Janus kinase (JAK) inhibitor. The recommended dose is 5 mg twice-daily (BID). 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.

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.

People may be at a higher risk of developing shingles.

XELJANZ may increase the risk of certain cancers by changing the way the immune system works. Lymphoma and other cancers, including skin cancers, have happened in patients taking 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. 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 prescribing information for XELJANZ, 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, 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 November 2, 2015. 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, 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 and non-clinical trial results, including unfavorable new data and additional analyses of existing data; uncertainties regarding the company's ability to address the comments in the complete response letter received with respect to the company's supplemental NDA for XELJANZ for the treatment of adult patients with moderate to severe chronic plaque psoriasis to the satisfaction of the FDA; whether and when any applications for XELJANZ may be filed with regulatory authorities in other jurisdictions; whether and when regulatory authorities in jurisdictions in which applications for XELJANZ are pending or will be submitted will 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 XELJANZ; 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, 2014 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 SEC and available at www.sec.gov and www.pfizer.com.

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 Cross M, Smith E, Hoy D, et al. Ann Rheum Dis 2014;73:1316–1322.

Media:Steven DanehyM: 978-273-3946E: Steven.Danehy@pfizer.comorInvestor:Chuck TrianoO: 212-733-3901E: Charles.E.Triano@pfizer.com