Pfizer Logo

Pfizer Builds Upon Robust Body Of Knowledge For XELJANZ® (tofacitinib citrate) With Clinical Trial And Real-World Use Data At The European League Against Rheumatism Annual Congress (EULAR 2015)

Wednesday, June 10, 2015 - 04:00am

New Research on XELJANZ Monotherapy and Once-Daily Formulation Among Abstracts Accepted

Pfizer Inc. announced today that more than 20 abstracts including new rheumatoid arthritis (RA) research for XELJANZ® (tofacitinib citrate) will be presented at the European League Against Rheumatism Annual Congress (EULAR 2015) June 10-15, Rome, Italy. Highlights include over six-years of safety and efficacy data from two long-term extension studies, real-world experience analyses, and clinical, patient-reported and radiographic efficacy outcomes with XELJANZ monotherapy, as well as health economics outcomes research that include patient-preference data for XELJANZ in patients with RA. Notably, new results from the XELJANZ 11 mg once daily clinical pharmacology program will be presented during the Congress, demonstrating equivalence in key pharmacokinetic parameters to XELJANZ 5 mg twice daily.

“As the developer of XELJANZ, the first oral Janus kinase inhibitor for the treatment of moderate to severe RA, Pfizer is a leader in the research of this new class of medications. Emerging real-world experience complements the clinical profile of XELJANZ as established through our extensive global development program,” said Rory O’Connor, MD, senior vice president and head of Global Medical Affairs, Global Innovative Pharmaceuticals Business, Pfizer Inc. “We continue to focus on further characterizing the overall clinical profile of XELJANZ that includes understanding the response of XELJANZ as monotherapy and by exploring a potential new once-daily formulation.”

These data — from clinical trials to real-world experience — further contextualize and expand the knowledge about the benefit:risk profile of XELJANZ in RA. XELJANZ is the first oral therapy in a new class of RA medicines, known as Janus kinase (JAK) inhibitors. Since the discovery of XELJANZ, the global clinical development program has accumulated efficacy and safety data with over six years of safety observations in long-term extension studies and more than 16,800 patient years of exposure across the program.

XELJANZ is approved in 40 countries for the treatment of moderate to severe RA as a second-line therapy after failure of one or more disease-modifying antirheumatic drugs (DMARDs). Pfizer is committed to making XELJANZ available to patients around the world, including working with the European Medicines Agency to plan to file a Marketing Authorization Application (MAA) in the European Union by the end of 2015 for the potential use of XELJANZ in treating moderate to severe RA. Pfizer is also committed to building on the science and understanding of JAK inhibition and XELJANZ with one of the largest clinical development programs in a

range of immune-mediated inflammatory conditions in the areas of rheumatology, dermatology and gastroenterology.

The following abstracts, focused on further characterizing the efficacy and safety profile of XELJANZ, have been accepted for presentation at the European League Against Rheumatism Annual Congress (EULAR 2015):

Real World Use Data for Tofacitinib from Registry and Claims Databases

- "Clinical characteristics of RA patients newly prescribed tofacitinib citrate (tofacitinib) in the United States after Food and Drug Administration approval: results from the CORRONA US rheumatoid arthritis registry" A. Kavanaugh, G. W. Reed, K. C. Saunders, A. S. Koenig, J. L. Geier, J. M. Kremer, J. D. Greenberg, C. O. Bingham III [AB0439]
- "Early experience with tofacitinib: treatment patterns in two US healthcare claims databases J. Harnett, J. Curtis, R. Gerber 3, D. Gruben, A. Koenig" [SAT0226; June 13, 2015 10:15 a.m. CET]

Long Term Safety and Efficacy Data

- "Tofacitinib, an oral Janus kinase inhibitor, for the treatment of rheumatoid arthritis: safety and efficacy in open-label, long-term extension over 6 years" J. Wollenhaupt, J. Silverfield, E. B. Lee, S. P. Wood, K. K. Terry, H. Nakamura, K. Kwok, A. Anisfeld, C. Nduaka, L. Wang [THU0179; June 11, 2015 12:05 p.m. CET]

Once-Daily Formulation

- "Evaluation of single-dose and steady-state pharmacokinetics, bioavailability and tolerability of the modified release formulation of tofacitinib vs the immediate release formulation of tofacitinib in healthy volunteers" M. Lamba, R. Wang, T. Fletcher, C. Alvey, J. Kushner, T. Stock [THU0188; June 11, 2015 12:00 p.m. CET]

Monotherapy Including Structure Data

- "Effects of tofacitinib on MRI endpoints in methotrexate-naive early rheumatoid arthritis: a Phase 2 MRI study with semi-quantitative and quantitative endpoints" P. G. Conaghan, M. Østergaard, M. A. Bowes, C. Wu, T. Fuerst, D. van der Heijde, P. Hrycaj, Z. Xie, R. Zhang, B. T. Wyman, J. Bradley, K. Soma, B. Wilkinson [SAT0222; June 13, 2015 11:30 a.m. CET]
- "Radiographic progression in modern RA trials is still a robust outcome: results of comprehensive sensitivity analysis in two Phase 3 trials with tofacitinib" D. Van der Heijde, C. Connell, J. Bradley, D. Gruben, S. Strengholt, R. B. Landewé [SAT0220; June 13, 2015 11:10 a.m. CET]
- "Relationship between different clinical measurements and patient-reported outcomes: results from a Phase 3 study of tofacitinib or methotrexate in methotrexate-naïve patients with rheumatoid arthritis" R. Fleischmann, V. Strand, B. Wilkinson, K. Kwok, E. Bananis [THU0180; June 11, 2015 12:05 p.m. CET]

Contextualization of Safety and Efficacy

- "Risk characterisation methodology enabling safety comparisons between tofacitinib and tumour necrosis factor inhibitors" J. R. Curtis, L. Klareskog, R. Zhang, S. Krishnaswami, A. Anisfeld, Y. Chen, J. Geier [SAT0346; June 13, 2015 10:15 a.m. CET]
- "Safety of tofacitinib compared to biological DMARDS in rheumatoid arthritis patients with an inadequate response to methotrexate: overview of systematic reviews" J.M. Reyes, A.E. Rodríguez [THU0186; June

11, 2015 12:00 p.m. CET]
- “Efficacy of tofacitinib in combination with methotrexate compared to biological DMARDS in combination with methotrexate in rheumatoid arthritis patients with an inadequate response to methotrexate: overview of systematic reviews” J.M. Reyes, A.E. Rodríguez [AB0439]

Safety

- “Analysis of non-melanoma skin cancer across the tofacitinib rheumatoid arthritis clinical programme” J. Curtis, E. B. Lee, G. Martin, X. Mariette, K. Terry, Y. Chen, J. Geier, J. Andrews, M. Kaur, H. Fan, C. Nduaka [THU0174; June 11, 2015 12:05 p.m. CET]
- “Relationship between NK cell count and important safety events in rheumatoid arthritis patients treated with tofacitinib” R. F. van Vollenhoven, Y. Tanaka, M. Lamba, M. Collinge, T. Hendrikx, T. Hirose, S. Toyoizumi, A. Hazra, S. Krishnaswami [THU0178; June 11, 2015 12:05 p.m. CET]
- “Pregnancy outcomes in the tofacitinib RA safety database through April 2014” A. Marren, Y. Chen, D. Frazier, J. Geier [THU0173; June 11, 2015 12:05 p.m. CET]
- “Herpes zoster and tofacitinib: the risk of concomitant nonbiologic therapy” K.L. Winthrop, S.M. Lindsey, H. Fan, L. Wang, D. Gelone, A. Mendelsohn, E. Bananis, J. Curtis [SAT0229; June 13, 2015 10:15 a.m. CET]

Health Economics Outcomes Research with Patient Preference Data

- “Patient preferences in the choice of disease modifying anti-rheumatic drugs” K. Krüger, R. Alten, J. Schiffner-Rohe, O. S. Behmer, G. Schiffhorst, J. Rellecke, H.D. Nolting [THU0350; June 11, 2015 12:00 p.m. CET]
- “Modelling the costs and outcomes associated with sequence of treatment with and without tofacitinib for the treatment of moderate to severe rheumatoid arthritis in the US” L. Claxton, M. Taylor, D. Moynagh, D. Gruben, G. Wallenstein, A. Singh [THU0343; June 11, 2015 12:00 p.m. CET]
- “The economic value of tofacitinib 5 mg BID in the treatment of moderate to severe rheumatoid arthritis: a Canadian analysis” J. C. Woolcott, G. Blackhouse, L. Claxton, G. Wallenstein, T. Tran, R. Goeree, M. Taylor, D. Moynagh, A.Singh [SAT0348; June 13, 2015 10:15 a.m. CET]
- “Real-world evaluation of TNF inhibitor utilisation in patients with rheumatoid arthritis in a US claims database” J. Harnett, D. Wiederkehr, R. Gerber, D. Gruben, A. Koenig, J. Bourret [THU0101; June 11, 2015 12:00 p.m. CET]
- “One-year treatment patterns and healthcare resource use among patients with rheumatoid arthritis newly initiating treatment with biologic DMARDS” J. Harnett, R. Gerber, D. Gruben, D. Wiederkehr, E. Y. Mahgoub, G. Wallenstein, A. Koenig [AB0275]
- “Treatment patterns and healthcare resource utilization among patients with psoriatic disease in a large national claims database” M.A. Hsu, J. Harnett, B. Emir, L. Mallbris, W. Ports, C. Mamolo [FRI0359; June 12, 2015 12:00 p.m. CET]

Subpopulations

- “Efficacy and safety of tofacitinib in Chinese patients with active rheumatoid arthritis: subgroup analysis from a Phase 3 study of tofacitinib in combination with nonbiologic disease-modifying antirheumatic drugs” Y. An, Z. Li, Q. Wu, K. Kwok, L. Wang [AB0514]

XELJANZ® (tofacitinib citrate) 5 mg Tablets RA 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.**
- **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.

- 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 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 approximately 23.7 million people worldwide.4 It can develop at any time during adulthood, but it usually occurs between 40 and 70 years of age.2

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 June 10, 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, a potential once daily formulation of XELJANZ, clinical trial data and the potential implications of such data and plans to file a marketing authorization application with the European Medicines Agency for XELJANZ for the treatment of moderate to severe rheumatoid arthritis, 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 -11- *ability to meet anticipated clinical trial commencement and completion dates and regulatory submission dates as well as the possibility of unfavorable clinical trial results, including unfavorable new clinical data and additional analyses of existing clinical data; whether and when Pfizer will file a marketing authorization application with the European Medicines Agency for XELJANZ for the treatment of moderate to severe rheumatoid arthritis; 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 World Health Organization, "The Global Burden of Disease, 2004 Update." Accessed 13 March 2012. Available at

http://www.who.int/healthinfo/global_burden_disease/GBD_report_2004update_full.pdf.

Media: Steven Danehy M: 978-273-3946 Steven.Danehy@pfizer.com or Investor: Chuck Triano O: 212-733-3901 Charles.E.Triano@pfizer.com