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Pfizer to Present Additional Research For XELJANZ® (Tofacitinib Citrate) In Rheumatologic Diseases, Including Rheumatoid Arthritis and Psoriatic Arthritis

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Results of Phase 3 Studies for Investigational XELJANZ for Psoriatic Arthritis to be Presented at 2016 ACR/ARHP Annual Meeting Twenty Presentations at 2016 ACR/ARHP Annual Meeting Reinforce Pfizer's Leadership in Inflammation and Immunology

Pfizer Inc. (NYSE:PFE) announced today that 20 abstracts for XELJANZ® (tofacitinib citrate) will be presented at the upcoming 2016 ACR/ARHP Annual Meeting (November 11-16, Washington, DC). Notably, results from the two pivotal Phase 3 OPAL (**O**ral **P**soriatic **A**rthritis Tria**L**) studies of tofacitinib – the only Janus kinase (JAK) inhibitor under investigation for psoriatic arthritis (PsA) – will be presented for the first time. OPAL Broaden will be highlighted during a plenary session and OPAL Beyond will be presented during a late-breaking abstract poster session. In addition, new and updated research for XELJANZ in rheumatoid arthritis (RA) will be presented.

"As part of our commitment to inflammation and immunology, we continue to advance our leading science in the research of Janus kinase inhibition," said Michael Corbo, Chief Development Officer, Inflammation & Immunology, Pfizer Global Product Development. "The extensive data being presented at this year's ACR/AHRP annual meeting expands upon our knowledge about the role of XELJANZ for the treatment of moderate to severe rheumatoid arthritis and also highlights its potential, if approved, for the treatment of psoriatic arthritis."

The RA presentations at this year's meeting include new research on the benefit:risk profile of XELJANZ as monotherapy; efficacy and safety analyses of XELJANZ with or without concomitant use of glucocorticoids; investigation in the treatment of early RA; and information on time to response. Data being presented at ACR on the efficacy and safety of long-term XELJANZ therapy include real-world experience from an interim analysis of an RA registry and updated information from a long-term extension study up to eight years.

Pfizer-sponsored research at the 2016 ACR/ARHP Annual Meeting includes the following presentations:

XELJANZ RA

Oral Presentations

- Major Adverse Cardiovascular Events: Risk Factors in Patients with RA Treated with Tofacitinib [#3024, Session: Rheumatoid Arthritis – Small Molecules, Biologics and Gene Therapy III: Small Molecules and Early Intervention, Nov. 15, 2016, 2:30-4p.m.]

- Inflammation Detected with Modern Sensitive MRI Analysis Demonstrates that Therapeutic Response as Early as One Month Predicts 12-Month Radiographic Progression: Data from a Study Using Tofacitinib and Methotrexate in Early RA [#3090, Session: Rheumatoid Arthritis – Small Molecules, Biologics and Gene Therapy IV: Biomarkers, Nov. 15, 2016, 4:30-6p.m.]

Poster Presentations

- Magnitude and Duration of Early Response with Tofacitinib: Post-Hoc Analysis of Two Phase 3, Placebo-Controlled Studies [#1595, Session: Rheumatoid Arthritis – Small Molecules, Biologics and Gene Therapy - Poster II, Nov. 14, 2016, 9-11a.m.]
- Persistence of Tofacitinib in the Treatment of Rheumatoid Arthritis in Open-Label, Long-Term Extension Studies up to 8 Years [#1602, Session: Rheumatoid Arthritis – Small Molecules, Biologics and Gene Therapy - Poster II, Nov. 14, 2016, 9-11a.m.]
- Efficacy of Tofacitinib in Patients who are Inadequate Responders to Disease-Modifying Antirheumatic Drugs According to Early Versus Late Duration of Rheumatoid Arthritis: Post-Hoc Analysis of Data from Phase 3 trials [#1609, Session: Rheumatoid Arthritis – Small Molecules, Biologics and Gene Therapy - Poster II, Nov. 14, 2016, 9-11a.m.]
- Tofacitinib: Treatment Outcomes in Seropositive Versus Seronegative Patients in a Phase 3 RA Population [#1643, Session: Rheumatoid Arthritis – Small Molecules, Biologics and Gene Therapy - Poster II, Nov. 14, 2016, 9-11a.m.]
- Discontinuation of Methotrexate or Glucocorticoids in Patients with Rheumatoid Arthritis Treated with Tofacitinib: Clinical Efficacy Data from Long-Term Extension Studies [#1646, Session: Rheumatoid Arthritis – Small Molecules, Biologics and Gene Therapy - Poster II, Nov. 14, 2016, 9-11a.m.]
- Tofacitinib, an Oral Janus Kinase Inhibitor, in the Treatment of Rheumatoid Arthritis: Safety and Efficacy in Open-Label, Long-Term Extension Studies over 8 Years [#1647, Session: Rheumatoid Arthritis – Small Molecules, Biologics and Gene Therapy - Poster II, Nov. 14, 2016, 9-11a.m.]
- Long-Term Clinical, Radiographic and Patient-Reported Outcomes Based on RAPID3 Responses with Tofacitinib at 6 Months [#1648, Session: Rheumatoid Arthritis – Small Molecules, Biologics and Gene Therapy - Poster II, Nov. 14, 2016, 9-11a.m.]
- Evaluation of Disease Activity in Patients with Rheumatoid Arthritis Treated with Tofacitinib by RAPID3: An Analysis of Data from 6 Phase 3 Studies [#1600, Session: Rheumatoid Arthritis – Small Molecules, Biologics and Gene Therapy - Poster II, Nov. 14, 2016, 9-11a.m.]
- 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 [#1608, Session: Rheumatoid Arthritis – Small Molecules, Biologics and Gene Therapy - Poster II, Nov. 14, 2016, 9-11a.m.]
- Real World Results from a Post-Approval Safety Surveillance of Tofacitinib (Xeljanz): Over 3 Year Results from an Ongoing US-Based Rheumatoid Arthritis Registry [#2595, Session: Rheumatoid Arthritis – Small Molecules, Biologics and Gene Therapy - Poster III, Nov. 15, 2016, 9-11a.m.]
- Effect of Glucocorticoids on Clinical and Radiographic Efficacy Outcomes in Methotrexate-Naïve Patients with RA Receiving Tofacitinib or Methotrexate Monotherapy: Analysis of Data from a Phase 3 Trial [#2606, Session: Rheumatoid Arthritis – Small Molecules, Biologics and Gene Therapy - Poster III, Nov. 15, 2016, 9-11a.m.]
- The Effectiveness of Zoster Vaccine in RA Patients Subsequently Treated up to 19 Months with Tofacitinib [#2609, Session: Rheumatoid Arthritis – Small Molecules, Biologics and Gene Therapy - Poster III, Nov. 15, 2016, 9-11a.m.]

XELJANZ Investigational Research Areas

Oral Presentations

- Treatment with Tofacitinib is Associated with Clinically Meaningful Reductions in Axial MRI Inflammation in Patients with Ankylosing Spondylitis [#1044, Session: Spondylarthropathies and Psoriatic Arthritis – Clinical Aspects and Treatment II: Axial Spondyloarthritis – Treatment, Nov. 13, 2016, 4:30-6p.m.]
- Efficacy and Safety of Tofacitinib, an Oral Janus Kinase Inhibitor, or Adalimumab in Patients With Active Psoriatic Arthritis and An Inadequate Response to Conventional Synthetic DMARDs: A Randomized, Placebo controlled, Phase 3 Trial [#2983, Session: Plenary Session III: Discovery 2016, Nov. 15, 2016, 11a.m.-12:30p.m.]

Poster Presentations

- Efficacy and Safety of Tofacitinib, an Oral Janus Kinase Inhibitor, in Patients with Active Psoriatic Arthritis and an Inadequate Response to Tumor Necrosis Factor Inhibitors: OPAL Beyond, a Randomized, Double Blind, Placebo-Controlled, Phase 3 Trial [#10L, Late-breaking Abstract Poster Session, Nov. 13, 2016, 9-11a.m.]
- Pharmacokinetics, safety, and tolerability of tofacitinib in pediatric patients from two to less than eighteen years of age with juvenile idiopathic arthritis [#388, Session: Pediatric Rheumatology – Clinical and Therapeutic Aspects - Poster I: Juvenile Idiopathic Arthritis, Uveitis, Nov. 13, 2016, 9-11a.m.]

Additional Pfizer-Sponsored Abstracts

Poster Presentations

- Understanding the Importance of a Patient's Role in the Management of RA: Physician- and Patient-Based Survey [#81, Session: Health Services Research - Poster I, Nov. 13, 2016, 9-11a.m.]
- Treatment Patterns, Unmet Need, and Impact of Psoriatic Arthritis on Patient-Reported Outcomes in the United States [#2729, Session: Spondylarthropathies and Psoriatic Arthritis – Clinical Aspects and Treatment - Poster III, Nov. 15, 2016, 9-11a.m.]

About XELJANZ (tofacitinib citrate) and XELJANZ XR (tofacitinib citrate) extended-release

XELJANZ®/XELJANZ XR® (tofacitinib citrate) is a prescription medicine called a Janus kinase (JAK) inhibitor. In the United States, XELJANZ XR 11 mg QD is the first and only once-daily oral JAK inhibitor approved for the treatment of moderate to severe rheumatoid arthritis (RA) after intolerance or inadequate response to methotrexate.

As the developer of XELJANZ/XELJANZ XR, Pfizer is a leader in JAK innovation. XELJANZ is approved in 50 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).

Pfizer is committed to advancing the science of JAK inhibition and enhancing understanding of XELJANZ through a robust clinical development program. The efficacy and safety profile of XELJANZ has been studied in approximately 6,300 patients with moderate to severe RA, amounting to more than 21,000 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.

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, we have worked to make a difference for all who rely on us. We routinely post information that may be important to investors on our website at www.pfizer.com. In addition, to learn more, please visit us on www.pfizer.com and follow us on Twitter at @Pfizer and @PfizerNews, LinkedIn, YouTube and like us on Facebook at Facebook.com/Pfizer.

DISCLOSURE NOTICE: The information contained in this release is as of November 7, 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 XELJANZ (tofacitinib citrate)/XELJANZ XR (tofacitinib citrate) extended-release, including a potential new indication for XELJANZ for the treatment of psoriatic arthritis and 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, without limitation, the ability to meet anticipated 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; uncertainties regarding the commercial success of XELJANZ and XELJANZ XR; whether and when any applications for the potential new indication may be filed with regulatory authorities in any jurisdictions; whether and when regulatory authorities in any jurisdictions may approve such applications and/or any other applications that are pending (including the marketing authorization application

currently under review by the European Medicines Agency for the treatment of patients with moderate to severe RA who have had an inadequate response or intolerance to methotrexate) or may be filed for XELJANZ or XELJANZ XR, 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/XELJANZ XR; 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.

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