Pfizer Logo

Pfizer Announces Top-Line Results from the Oral Strategy Trial of XELJANZ® (tofacitinib citrate) Compared to Humira® (adalimumab)

Thursday, February 16, 2017 - 03:00am

Pfizer Inc. (NYSE:PFE) announced today top-line results from ORAL Strategy, a Phase 3B/4 study of XELJANZ® (tofacitinib citrate) 5mg twice daily (BID) in the treatment of moderate to severe rheumatoid arthritis (RA). ORAL Strategy is the first trial to compare a JAK inhibitor as monotherapy or in combination with methotrexate (MTX) versus adalimumab (Humira) plus MTX in MTX inadequate responders using ACR50 at Month 6 as the primary endpoint. There were three comparisons,which found:

• XELJANZ 5mg plus MTX met its primary endpoint in demonstrating non-inferiority versus Humira plus MTX

• XELJANZ 5mg monotherapy did not meet its primary endpoint of non-inferiority versus Humira plus MTX or versus XELJANZ plus MTX

“ORAL Strategy is representative of the type of innovative and clinically meaningful trials that Pfizer Inflammation & Immunology believes are important to help advance patient care and the science of JAK inhibition,” said Michael Corbo, Chief Development Officer, Inflammation & Immunology, Global Product Development. “We are pleased that we demonstrated non-inferiority of XELJANZ plus MTX versus Humira plus MTX, reinforcing the efficacy of XELJANZ combination therapy. We will continue to analyze the monotherapy data from this study and look forward to sharing the full results of ORAL Strategy at an upcoming scientific forum.”

ORAL Strategy is a 12-month, double-blind, head-to-head study which included 1,152 patients randomized into one of three study arms that were independently compared against each other:

• XELJANZ 5 mg BID as monotherapy (n=386)

• XELJANZ 5 mg BID in combination with a weekly dose of MTX (15-25 mg) (n=378)

• Humira 40 mg every-other-week via subcutaneous injection in combination with a weekly dose of MTX (15-25 mg) (n=388)

The safety findings were consistent with the known adverse events and serious adverse events profile for XELJANZ.

The RA clinical development program has over 20 clinical trials and to-date represents more than 21,100 patient-years of drug exposure. The long-term extension program, spanning over eight years of safety experience, is one of the largest in the RA category with respect to number of patients and patient-years of

exposure.

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

XELJANZ®/XELJANZ XR® (tofacitinib citrate) is a prescription medicine called a JAK inhibitor. XELJANZ has been approved for use in more than 50 countries. Since XELJANZ was first approved in the U.S. in 2012, it has been prescribed to more than 90,000 patients worldwide. In the United States, Argentina, and Macau, XELJANZ XR is the first once-daily oral JAK inhibitor approved for the treatment of moderate to severe RA.

Pfizer is committed to advancing the science of JAK inhibition and enhancing the understanding of the efficacy and safety of XELJANZ through robust clinical development programs in the treatment of immune-mediated inflammatory conditions.

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 US Prescribing Information for XELJANZ/XELJANZ XR, 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 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 February 16, 2017. 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) 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; uncertainties regarding the commercial impact of the results of the ORAL Strategy trial; whether and when any other applications for XELJANZ or XELJANZ XR may be filed with regulatory authorities in any jurisdictions; whether and when regulatory authorities in any jurisdictions may approve any 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 moderate to severe active RA in adult patients who have responded inadequately to, or who are intolerant to one or more disease-modifying antirheumatic drugs. XELJANZ can be given as monotherapy in case of intolerance to MTX or when treatment with MTX is inappropriate) 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 Investors: Chuck Triano, 212-733-3901 Charles.E.Triano@pfizer.com