Pfizer Announces Positive Top-Line Results From Two Phase 3 Trials Of Tofacitinib In Adults With Moderate-to-Severe Chronic Plaque Psoriasis

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OPT Pivotal #1 and OPT Pivotal #2 Studies, Together with Three Other Phase 3 Trials, to Form Basis for Planned Psoriasis Indication Submission to Regulatory Authorities

Pfizer Inc. (NYSE:PFE) announced today top-line results from two pivotal Phase 3 trials from the Oral treatment Psoriasis Trials (OPT) Program, OPT Pivotal #1 (A3921078) and OPT Pivotal #2 (A3921079), evaluating the efficacy and safety of tofacitinib, an oral Janus kinase (JAK) inhibitor, the first in a new class of medicines being investigated for the treatment of moderate-to-severe plaque psoriasis. The OPT Pivotal #1 and OPT Pivotal #2 studies showed that tofacitinib, as a 5 mg or a 10 mg dose taken as a pill twice-daily, met the primary efficacy endpoints of statistically significant superiority over placebo at Week 16 in the proportion of subjects achieving a Physician's Global Assessment response of "clear" or "almost clear," and the proportion of subjects achieving at least a 75% reduction in Psoriasis Area and Severity Index, two commonly used measures of efficacy in psoriasis.

No new safety signals for tofacitinib were observed in the OPT Pivotal #1 or OPT Pivotal #2 studies. Detailed analyses of these studies, including additional efficacy and safety data, will be submitted for presentation at a future scientific meeting.

“Psoriasis is a long-term disease with no cure that can have a significant impact on patients. Although it is one of the most common chronic inflammatory diseases, many psoriasis patients remain untreated, undertreated or dissatisfied with their treatment, according to recently published surveys,” said Dr. Steven Romano, Global Medicines Development Lead for the Pfizer Global Innovative Pharmaceutical business. “Tofacitinib is the first in a new class of investigational psoriasis treatments, and I am encouraged by our Phase 3 results to-date that demonstrate the potential of tofacitinib to be an important new treatment option for adults with moderate-to-severe chronic plaque psoriasis.”

Top-line results from the first two studies from the OPT Program, OPT Compare and OPT Retreatment, were previously announced in October 2013, and these four studies, in addition to a long-term extension study, will form the planned psoriasis submission package to regulatory authorities in various markets. Pfizer currently intends to submit a supplemental New Drug Application (sNDA) to the U.S. Food and Drug Administration (FDA) for the approval of tofacitinib 5 mg and 10 mg twice-daily for the treatment of adults with moderate-to-severe chronic plaque psoriasis by early 2015.

About OPT Pivotal #1 (A3921078) and OPT Pivotal #2 (A3921079)

OPT Pivotal #1 and OPT Pivotal #2 were Phase 3, 52-week, multi-site, randomized, double-blind, placebo-controlled, parallel-group studies evaluating the safety and efficacy of tofacitinib 5 mg and 10 mg twice-daily in patients with moderate-to-severe chronic plaque psoriasis who are candidates for systemic therapy or phototherapy. There were over 900 patients randomized into each of the studies.

About the OPT Clinical Trial Program

The Phase 3 OPT clinical trial program consists of five studies (including one long-term extension study) evaluating oral tofacitinib 5 mg and 10 mg twice-daily in adults with moderate-to-severe chronic plaque psoriasis. It is a global, comprehensive clinical development program that includes over 3,600 patients in 36 countries, and is one of the largest global clinical trial programs in moderate-to-severe chronic plaque psoriasis to date. In addition to the OPT Pivotal #1 and OPT Pivotal #2 studies, the OPT Program includes the following Phase 3 studies of tofacitinib in adults with moderate-to-severe chronic plaque psoriasis:

OPT Compare (A3921080): A 12-week, Phase 3 study comparing the efficacy and safety of tofacitinib 5 mg and 10 mg twice-daily to high-dose ENBREL (etanercept) 50 mg twice-weekly as well as to placebo. OPT Retreatment (A3921111): A Phase 3 study evaluating

the efficacy and safety of the withdrawal from, and then the retreatment with, tofacitinib 5 mg and 10 mg twice-daily compared to placebo. OPT Extend (A3921061): A long-term extension study evaluating the safety and tolerability of tofacitinib. Patients who participated in the Phase 2 trial or any of the other Phase 3 studies had the option, if eligible, to enroll in this study.

About Plaque Psoriasis

Psoriasis is a chronic, immune-mediated disease, affecting the skin and other organs, such as nails and joints. It affects approximately two-to-three percent of people worldwide and 7.4 million people in the United States.1,2,3,4,5,6,7 Due to inconsistent response to treatment, adverse effects, and the limited persistence of therapeutic effects of some therapies, a need for additional therapies for patients with moderate-to-severe chronic plaque psoriasis still remains.8,9,10 According to recently published surveys, approximately 50% of patients with psoriasis are dissatisfied with their treatment, and under-treatment represents a significant problem. Even though guidelines typically state that moderate-to-severe patients are candidates for systemic therapy – e.g., medicines given by mouth or an injection - many treated adult plaque psoriasis patients appear to be undertreated, with approximately 30% of treated moderate patients and 22% of treated severe patients receiving only topical therapies, like ointments and creams, in the U.S.11

XELJANZ® (tofacitinib citrate) RA U.S. Label Information

Tofacitinib is approved in more than 20 countries around the world for the treatment of moderate-to-severe rheumatoid arthritis. In the U.S., the brand name for tofacitinib is XELJANZ® (ZEL’ JANS’) 5 mg tablets, and it is approved for the treatment of adults with moderately to severely active rheumatoid arthritis who have had an inadequate response or intolerance to methotrexate.

XELJANZ is a prescription medicine called a Janus kinase (JAK) inhibitor. XELJANZ is used to treat adults with moderately to severely active rheumatoid arthritis in which methotrexate did not work well.

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 prescribing information for XELJANZ, including boxed warning and Medication Guide: http://labeling.pfizer.com/ShowLabeling.aspx?id=959.

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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 April 22, 2014. 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, including its potential benefits and the anticipated submission of applications with regulatory authorities, that involves substantial risks and uncertainties. Such risks and uncertainties include, among other things, the uncertainties inherent in research and development, including, without limitation, the possibility of unfavorable clinical trial results; whether an sNDA will be filed in the U.S. in early 2015, and whether and when any applications may be filed with regulatory authorities in various other jurisdictions, for tofacitinib for the treatment of moderate-to-severe chronic plaque psoriasis; whether and when the FDA and regulatory authorities in other jurisdictions mayapprove any such applications, as well as their decisions regarding labeling and other matters that could affect its availability or

commercial potential; 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, 2013 and in its subsequent reports on Form 10-Q and Form 8-K.

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