



Pfizer Announces Top-Line Results Of The First Two Of Five Phase 3 Clinical Trials Of Tofacitinib In Adults With Moderate-To-Severe Chronic Plaque Psoriasis

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Pfizer Inc. (NYSE:PFE) announced today top-line results from two Phase 3 clinical trials of tofacitinib, a novel, oral Janus kinase (JAK) inhibitor that is being investigated for the treatment of adults with moderate-to-severe chronic plaque psoriasis: OPT Compare (A3921080) and OPT Retreatment (A3921111). These are the first two of five studies in the Phase 3 Oral Psoriasis Treatment (OPT) Program, one of the largest global clinical trial programs in moderate-to-severe chronic plaque psoriasis to date. Top-line results for the OPT Pivotal 1 and OPT Pivotal 2 trials (A3921078 and A3921079) are anticipated in the second quarter of 2014, and these four studies, in addition to a long-term extension study, will form the potential psoriasis submission package to regulatory authorities.

“We are excited to see progress in our development program in psoriasis,” said Dr. Steven Romano, senior vice president and the head of the Medicines Development Group for Pfizer Specialty Care. “The OPT Compare and OPT Retreatment studies provide information that is consistent with our expectations based on the Phase 2 data in psoriasis. We look forward to the results of our remaining Phase 3 trials in order to fully evaluate tofacitinib in psoriasis and how it may fit into clinical practice for patients and physicians.”

OPT Compare is a 12-week, non-inferiority study comparing the efficacy and safety of tofacitinib 5 and 10 mg twice-daily (BID) to high-dose ENBREL® (etanercept) 50 mg

twice-weekly (BIW), the approved starting dose for ENBREL for the first twelve weeks, and placebo for the treatment of adult patients with moderate-to-severe chronic plaque psoriasis. Top-line results from the OPT Compare study showed that tofacitinib met the primary endpoint of non-inferiority to high-dose ENBREL at the 10 mg BID dose. Tofacitinib did not meet the non-inferiority criteria to high-dose ENBREL at the 5 mg BID dose. The dose-response relationship observed for tofacitinib in this trial is consistent with the findings from the Phase 2 trial. Additionally, rates of important safety events were similar across the active treatment arms.

OPT Retreatment is a 56-week study comparing the efficacy and safety of withdrawal and retreatment with tofacitinib 5 and 10 mg BID to placebo for the treatment of adult patients with moderate-to-severe chronic plaque psoriasis. The OPT Retreatment study met its primary efficacy endpoints at the 5 and 10 mg BID doses by demonstrating that a greater proportion of patients continuing tofacitinib treatment maintained their response during the treatment withdrawal phase compared to patients who switched to placebo. Additionally, among patients who lost an adequate response, many were able to recapture their response upon retreatment with tofacitinib. The results of OPT Retreatment will provide relevant information to physicians in clinical practice, as it is common for patients with psoriasis to stop and restart therapy.

No new safety signals for tofacitinib were observed in these studies, and the efficacy and safety profile of tofacitinib in psoriasis remains consistent with that seen in the Phase 2 clinical trial. Full analyses of the OPT Compare and OPT Retreatment data, including additional efficacy and safety data, will be submitted for presentation at a future scientific meeting.

About OPT Compare (A3921080)

OPT Compare was a Phase 3 randomized, double-blind, placebo-controlled 12-week non-inferiority study comparing the efficacy and safety of tofacitinib 5 and 10 mg BID to ENBREL (etanercept) 50 mg BIW and placebo for the treatment of adult patients with moderate-to-severe chronic plaque psoriasis who had an inadequate response to, intolerance to, or contraindication to systemic therapy. There were 1106 patients enrolled in this study. The primary objectives of the study were to compare the efficacy of tofacitinib to ENBREL and placebo for the reduction in severity of plaque psoriasis as measured by the proportion of patients achieving a Physician's Global Assessment (PGA) response of "clear" or "almost clear," and the proportion of patients achieving at least a 75 percent reduction in Psoriasis Area and Severity Index (PASI75) relative to baseline, two commonly used measures of efficacy in psoriasis.

About OPT Retreatment (A3921111)

OPT Retreatment was a Phase 3 randomized, mixed-blind, three-period, parallel group, placebo-controlled study evaluating the efficacy and safety of the withdrawal and retreatment with tofacitinib 5 and 10 mg BID to placebo in adult patients with moderate-to-severe chronic plaque psoriasis. There were 674 patients enrolled in the study. During period A (24 weeks), patients were treated with tofacitinib at a dose of 5 or 10 mg BID in a blinded manner. To qualify for period B, patients had to achieve both a PASI75 and a PGA response of “clear” or “almost clear”. In period B, patients were randomized to either continue tofacitinib or switch to placebo for 16 weeks or until they lost half of their original PASI response to treatment from Period A, whichever occurred first. In period C, all patients resumed their original tofacitinib dose until week 56. One of the primary objectives of the study was to compare the maintenance of response (period B, withdrawal) with tofacitinib relative to placebo at various time points during the 16 week double-blind active or placebo treatment period. The second primary objective of the study, evaluated in period C (retreatment), was to assess the percentage of patients who regained responses with tofacitinib retreatment after having lost adequate responses during period B. The data announced today are from the planned final analysis at 56 weeks.

About the OPT Clinical Trial Program

The Phase 3 OPT clinical trial program consists of five studies, including one open-label, long-term extension study evaluating oral tofacitinib 5 and 10 mg BID in adults with moderate-to-severe chronic plaque psoriasis. It is a global, multi-study, comprehensive clinical development program that includes 3,600 patients in 39 countries. The OPT Program is designed to specifically evaluate tofacitinib in moderate-to-severe chronic plaque psoriasis, and to support an independent assessment of the benefit:risk profile of tofacitinib in psoriasis patients.

In addition to OPT Compare and OPT Retreatment, the OPT Program includes the following Phase 3 studies of tofacitinib in psoriasis:

- OPT Pivotal #1 (A3921078) and OPT Pivotal #2 (A3921079): Two Phase 3, 52-week, multi-site, randomized, double-blind, placebo-controlled, parallel-group studies evaluating the safety and efficacy of tofacitinib 5 and 10 mg BID. The primary objectives of the studies are to compare the efficacy of tofacitinib to placebo for the reduction in severity of plaque psoriasis as measured by the proportion of patients achieving a Physician’s Global Assessment (PGA) response of “clear” or “almost clear,” at week 16, and the

proportion of patients achieving at least a 75 percent reduction in Psoriasis Area and Severity Index (PASI75) relative to baseline at week 16, as well as to evaluate the safety and tolerability of tofacitinib over 52 weeks. Key secondary objectives are to evaluate the onset of efficacy and durability of efficacy of tofacitinib 5 and 10 mg BID for the reduction in severity of plaque psoriasis at various time points during 52 weeks of treatment. · OPT Extend (A3921061): A long-term (5-year) open-label, extension study evaluating the safety and tolerability of tofacitinib. Patients who have completed any of the other Phase 3 studies have the option, if eligible, to enroll in this study.

About Plaque Psoriasis

Psoriasis is a chronic, systemic, inflammatory disease affecting the skin and other organs, such as nails and joints. It affects approximately 125 million people worldwide and 7.5 million in the U.S.[1],[2],[3] Due to inconsistent response to treatment, adverse effects, and the limited persistence of therapeutic effects of some systemic therapies, a need for additional therapies for patients with moderate-to-severe chronic plaque psoriasis still remains.[4],[5],[6] Even though guidelines typically state that moderate-to-severe patients are candidates for systemic therapy, 30 percent of moderate patients and 22 percent of severe patients appear to be undertreated, and many (moderate 24 percent, severe 9 percent) receive no treatment at all, according to a published study. Furthermore, while various treatment modalities are available for psoriasis, widespread treatment dissatisfaction exists, with more than 50 percent of moderate and more than 40 percent of severe patients saying they are dissatisfied with the treatment they have received for their psoriasis.[7]

About Tofacitinib

Tofacitinib is a novel oral Janus kinase (JAK) inhibitor that is being investigated for the treatment of adults with moderate-to-severe chronic plaque psoriasis.

Discovered and developed by Pfizer scientists, tofacitinib has a novel mechanism of action specifically designed to inhibit the JAK pathways, which are signaling pathways inside the cell that are thought to play a role in the chronic inflammatory responses involved in psoriasis. By inhibiting these JAK pathways, tofacitinib reduces cytokine signaling, cytokine-induced gene expression and activation of cells, which when over activated, results in the immune and inflammatory response, which characterizes psoriasis.

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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 October 9, 2013. 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, 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 ability to meet anticipated clinical trial completion dates as well as the possibility of unfavorable clinical trial results; whether and when any applications may be filed with regulatory authorities in various jurisdictions for tofacitinib for the treatment of moderate-to-severe chronic plaque psoriasis and whether and when regulatory authorities may approve 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/A for the fiscal year ended December 31, 2012 and in its reports on Form 10-Q and Form 8-K.

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