Pfizer Announces Positive Top-Line Results From The ORAL Start Phase 3 Study Of Tofacitinib In Rheumatoid Arthritis

Tuesday, July 31, 2012 - 12:42am

Pfizer Also Provides Update on Tofacitinib Filing in the U.S.

(BUSINESS WIRE)--Pfizer Inc. (NYSE:PFE) announced today top-line results from ORAL Start (A3921069), a Phase 3 study of the investigational agent tofacitinib, a novel, oral Janus kinase (JAK) inhibitor for the treatment of adults with moderate-to-severe active rheumatoid arthritis (RA).

ORAL Start, an ongoing two-year study in methotrexate (MTX)-naïve patients with moderate-to-severe active RA, randomized to receive tofacitinib 5 or 10 mg twice-daily (BID) as monotherapy or MTX, met its primary endpoints at both the 5 and 10 mg BID doses. Tofacitinib was found to be superior to MTX with statistically significant changes shown in inhibiting structural damage, as measured by change from baseline in modified Total Sharp Score (mTSS), and in reducing signs and symptoms of RA, as measured by ACR70 response rates. Both primary endpoints assessed tofacitinib versus MTX at six months. The data reported are from a planned analysis at one year.

No new safety signals emerged in the ORAL Start study, and the safety profile of tofacitinib remained consistent with that seen previously in the clinical development program. Safety findings observed in the overall tofacitinib RA program include serious and other important infections, including tuberculosis and herpes zoster; malignancies, including lymphoma; decreased neutrophil counts and neutropenia; and lipid elevations.

A detailed analysis of the ORAL Start findings will be submitted to a future scientific meeting.

Pfizer also noted today during its second quarter earnings call that the U.S. Food and Drug Administration (FDA) has recently requested additional analysis of the existing data in the tofacitinib New Drug Application (NDA). Pfizer is planning to provide FDA with this information in early August and, given this timing, it anticipates that FDA may require additional time beyond the August 21 Prescription Drug User Fee Act (PDUFA) date to review the information.

About ORAL Start

ORAL Start is an ongoing two-year study that randomized 958 patients with moderate-to-severe active RA who were naïve to MTX to receive tofacitinib monotherapy 5 or 10 mg BID or MTX. The primary objectives of ORAL Start are to compare preservation of joint structure, treatment of signs and symptoms and safety and tolerability with tofacitinib 5 or 10 mg BID versus MTX. Results are from a planned 12-month interim analysis.

About Rheumatoid Arthritis

Rheumatoid arthritis is a chronic inflammatory autoimmune disease that typically affects the hands and feet, although any joint lined by a synovial membrane may be affected. RA affects approximately 1.3 million Americans1 and 23.7 million people worldwide2. Although multiple treatments are available, many patients do not adequately respond, and there remains a need for additional options.

About Tofacitinib

Tofacitinib is a novel, oral JAK inhibitor that is being investigated as a targeted immunomodulator and disease-modifying therapy for RA. Unlike recent therapies for RA, which are directed at extracellular targets such as pro-inflammatory cytokines, tofacitinib takes a novel approach targeting the intracellular pathways that operate as hubs in the inflammatory cytokine network.

Tofacitinib was evaluated in the Phase 3 ORAL (Oral Rheumatoid Arthritis Phase 3 TriaLs) program, a comprehensive, multi-study, global clinical development program that included approximately 5,000 patients who represent a broad cross-section of the RA patient population. In these trials, tofacitinib was studied as monotherapy or in combination with non-biologic disease-modifying antirheumatic drugs (or DMARDs), mostly MTX, in patients who were MTX-naïve or who had a previous inadequate response

to DMARDs, including TNF inhibitors.

Tofacitinib is currently under review for the treatment of moderate–to-severe active RA by several regulatory agencies around the world, including in the United States, Europe and Japan. If approved, tofacitinib would be the first RA treatment in a new class of medicines known as JAK inhibitors.

Pfizer Inc.: Working together for a healthier world®

At Pfizer, we apply science and our global resources to improve health and well-being at every stage of life. We strive to set the standard for quality, safety and value in the discovery, development and manufacturing of medicines for people and animals. Our diversified global health care portfolio includes human and animal biologic and small molecule medicines and vaccines, as well as nutritional products and many of the world's best-known consumer 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 the world's leading biopharmaceutical company, we also 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 about our commitments, please visit us at www.pfizer.com.

DISCLOSURE NOTICE: The information contained in this release is as of July 31, 2012. 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 that involves substantial risks and uncertainties about a potential indication for a product in development, tofacitinib, as a treatment for moderate-to-severe active RA that is under review by regulatory authorities in various markets, including the United States, Europe and Japan. Such risks and uncertainties include, among other things, the uncertainties inherent in research and development; decisions by regulatory authorities regarding whether and when to approve drug applications that have been or may be filed for tofacitinib for moderate-to-severe active RA, 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, 2011 and in its reports on Form 10-Q and Form 8-K.

1 Helmick C, Felson D, Lawrence R, et al. Estimates of the prevalence of arthritis and other rheumatic conditions in the United States. Arthritis and Rheumatism. 2008: 58,1,15-25

2 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.

Pfizer Inc. Media Contact: Victoria Davis, 484-865-5194 Victoria.Davis@pfizer.com or Investor Contact: Chuck Triano, 212-733-3901 Charles.E.Triano@pfizer.com