Pfizer Announces Top-Line Results Of Third Phase 3 Clinical Trial Of Tofacitinib (CP-690,550) In Patients With Active Rheumatoid Arthritis

Thursday, April 14, 2011 - 10:36pm

Detailed Results to be Submitted to Future Scientific Meeting

(BUSINESS WIRE)--Pfizer Inc. announced today top-line results from the ORAL Scan Phase 3 study (A3921044) of tofacitinib (development code: CP-690,550), formerly known as tasocitinib, an investigational, novel, oral JAK inhibitor. ORAL Scan is an ongoing two-year study in patients with moderate-to-severe active rheumatoid arthritis (RA) who had an inadequate response to methotrexate (MTX) and were randomized to receive tofacitinib 5 or 10 mg BID or placebo added to background MTX. The data reported are from a planned analysis at one year.

The ORAL Scan study met all primary endpoints at the 10 mg BID dose, showing statistically significant changes versus placebo in reducing signs and symptoms of RA, as measured by ACR20 response rates at six months; in reducing the progression of structural damage, as measured by change from baseline in modified Total Sharp Score (mTSS) at six months; in improving physical function, as measured by mean change in HAQ DI at three months; and in reaching DAS28-4(ESR) <2.6 at six months.

For the 5 mg BID dose, the study demonstrated statistically significant improvements versus placebo in ACR20 response rates at six months, but the difference from placebo in mTSS did not reach statistical significance at six months. Due to the pre-specified step-

down statistical procedure, no further testing was performed on HAQ DI and DAS28-4(ESR) <2.6 for the 5 mg BID dose.

No new safety signals emerged in the ORAL Scan study. The efficacy and safety profile of tofacitinib in this study remains consistent with that seen previously in the clinical program. A full analysis of the ORAL Scan efficacy and safety data will be submitted to a future scientific meeting.

About ORAL Scan

ORAL Scan is an ongoing two-year study that randomized 800 patients with moderate-to-severe active RA who had an inadequate response to MTX to receive tofacitinib 5 or 10 mg BID or placebo added to background MTX. At the three month visit, non-responding placebo-assigned patients were advanced in a blinded fashion to a predetermined treatment of tofacitinib, 5 or 10 mg BID, for the remainder of the study. At the end of six months, all placebo-assigned patients were advanced to their predetermined tofacitinib treatment assignment in a blinded fashion for the remainder of the study. The two year data from this study are expected in 2012.

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 people in the U.S. 1 and one percent of the adult population worldwide.2

About Tofacitinib

Tofacitinib is a novel, oral Janus kinase (JAK) inhibitor that is being investigated as a targeted immunomodulator and disease-modifying therapy for RA. More than 4,000 RA patients have been treated with tofacitinib in clinical trials to date. Unlike current therapies for RA, which are directed at extracellular targets such as pro-inflammatory cytokines, tofacitinib takes a novel approach, targeting the intracellular signaling pathways that operate as hubs in the inflammatory cytokine network.

In addition to ORAL Scan (A3921044), the ORAL Trials clinical program includes the following pivotal Phase 3 studies of tofacitinib in RA:

ORAL Solo (A3921045): 6-month study in inadequate responders to a disease modifying anti-rheumatic drug (DMARD), traditional or biologic, receiving tofacitinib monotherapy, evaluating signs and symptoms and physical function. ORAL Sync (A3921046): 12-month

study in inadequate responders to a DMARD (traditional or biologic) receiving tofacitinib and background traditional DMARD(s), evaluating signs and symptoms and physical function. ORAL Standard (A3921064): 12-month study in inadequate responders to MTX receiving tofacitinib and background MTX, with active comparator of adalimumab and background MTX, evaluating signs and symptoms and physical function. ORAL Step (A3921032): 6-month study in inadequate responders to TNF-inhibiting therapy receiving tofacitinib and background MTX, evaluating signs and symptoms and physical function.

In addition, there is an ongoing Phase 3 study that will not be a part of the initial registration:

ORAL Start (A3921069): 24-month study in MTX-naïve patients receiving tofacitinib monotherapy or MTX, including a structural endpoint in addition to evaluating signs and symptoms and physical function.
For more information about the ORAL trials clinical program, visit www.ORALtrials.com.

Pfizer is also studying orally administered tofacitinib in psoriasis, inflammatory bowel disease (Crohn’s disease and ulcerative colitis) and renal transplant, and topical tofacitinib in both psoriasis and dry eye disease.

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 April 15, 2011. 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 a product in development, tofacitinib, including its potential benefits as a treatment for rheumatoid arthritis, certain other diseases and renal transplant that involves substantial risks and uncertainties. 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 any drug applications that may be filed for tofacitinib 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, 2010 and in its reports on Form 10-Q and Form 8-K.

1 Arthritis Today. "What is Rheumatoid Arthritis." Accessed 24 February 2011. Available at: http://www.arthritistoday.org/conditions/rheumatoid-arthritis/all-about-ra/what-is-ra.php.

2 Rubbert-Roth A, Finckh A. Treatment options in patients with rheumatoid arthritis failing initial TNF inhibitor therapy: a critical review. Arthritis Res Ther. 2009; 11(Suppl 1): S1.Published online 2009 April 6. doi: 10.1186/ar2662.

Pfizer Inc. Media: Victoria Davis (484) 865-5194 (347) 558-3455 Victoria.Davis@pfizer.com or Investor: Jennifer Davis (212) 733-0717 Jennifer.M.Davis@pfizer.com