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Pfizer Announces Primary Endpoints Met In Second Phase 3 Clinical Trial Of Tofacitinib (CP-690,550) In Patients With Active Rheumatoid Arthritis

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Detailed Results to be Submitted to Future Scientific Meeting

(BUSINESS WIRE)--Pfizer Inc. (NYSE:PFE) today announced that the ORAL Sync Phase 3 study (A3921046) of tofacitinib (development code: CP-690,550), formerly known as tasocitinib, an investigational, novel, oral JAK inhibitor, being studied in moderate-to-severe rheumatoid arthritis (RA), met its primary endpoints by showing statistically significant changes versus placebo in reducing signs and symptoms of RA, as measured by ACR20 response rates 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. The safety profile of tofacitinib was consistent with that seen previously in the clinical program, and no new safety signal was detected. A full analysis of efficacy and safety data will be submitted to a future scientific meeting.

About ORAL Sync

ORAL Sync evaluated the efficacy and safety of tofacitinib doses 5 mg and 10 mg given twice daily compared to placebo in patients with moderately to severely active RA who had a previous inadequate response to a DMARD and who continued to receive background traditional DMARD therapy throughout the study.

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 1 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.

The Phase 3 ORAL Trials clinical program includes six studies with more than 350 locations in 35 countries worldwide. For more information, 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.

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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 March 4, 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.

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