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FDA Arthritis Advisory Committee Recommends Approval of Tofacitinib for Adult Patients with Moderately to Severely Active Rheumatoid Arthritis

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(BUSINESS WIRE)--Pfizer Inc. (NYSE:PFE) announced today that the Arthritis Advisory Committee to the U.S. Food and Drug Administration (FDA) voted 8-2 to recommend approval of the investigational agent tofacitinib for the treatment of adult patients with moderately to severely active rheumatoid arthritis (RA). The Committee's recommendation will be considered by the FDA in its review of the New Drug Application (NDA) for tofacitinib. The FDA has provided an anticipated Prescription Drug User Fee Act (PDUFA) action date in August 2012. If approved by the FDA, tofacitinib would be the first new oral disease-modifying antirheumatic drug (or DMARD) for RA in more than 10 years and the first RA treatment in a new class of medicines known as Janus kinase (JAK) inhibitors.

"We are pleased with the Committee's positive evaluation of the tofacitinib data and its decision to recommend approval," said Dr. Yvonne Greenstreet, senior vice president and the head of Medicines Development Group for Pfizer Specialty Care. "The RA patient population needs additional treatment options, and Pfizer looks forward to working with the FDA on next steps as it completes its review of the tofacitinib application."

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 Americans[1] and 23.7 million people worldwide[2]. 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 more 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 has been evaluated in approximately 4,800 patients yielding 7,000 patient-years of exposure in a comprehensive, global clinical development program that included five pivotal Phase 3 trials and two ongoing long-term extension studies in 45 countries.

Tofacitinib is currently under review for the treatment of moderately to severely active RA by several regulatory agencies around the world, including the United States, Europe and Japan.

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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 May 9, 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 moderately to severely 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 moderately to severely 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.

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