U.S. Food And Drug Administration Extends Action Date For Tofacitinib New Drug Application By Three Months

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BUSINESS WIRE)--Pfizer Inc. (NYSE: PFE) announced today that the U.S. Food and Drug Administration (FDA) has extended the action date by three months for the New Drug Application (NDA) for tofacitinib, an investigational oral treatment for adults with moderately to severely active rheumatoid arthritis (RA). If approved, tofacitinib would be the first RA treatment in a new class of medicines known as Janus kinase (JAK) inhibitors and the first new oral disease-modifying antirheumatic drug (or DMARD) for RA in more than 10 years.

The FDA determined that additional data analyses recently submitted by Pfizer constitute a major amendment to the application and will require additional time to review. The FDA has not asked that Pfizer complete any new studies. The FDA has provided an anticipated Prescription Drug User Fee Act (PDUFA) date of November 21, 2012.

“RA patients are in need of additional treatment options to help fight this serious chronic inflammatory autoimmune disease,” said Dr. Yvonne Greenstreet, senior vice president and head of the Medicines Development Group for Pfizer Specialty Care. “We believe that the results from the comprehensive multi-study clinical development program for tofacitinib have demonstrated a favorable benefit-risk profile, and we remain committed to working expeditiously with the FDA to make tofacitinib available to patients.”

Pfizer continues to progress the applications for tofacitinib for the treatment of moderately to severely active RA in markets outside the United States, including Europe and Japan.

Tofacitinib has one of the largest clinical databases of any RA drug ever submitted to the FDA for review. The medication has been evaluated in a comprehensive, multi-study, global clinical development program that included approximately 5,000 patients who represented a broad cross-section of the RA patient population in 44 countries.

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 1.6 million Americans1,2 and 23.7 million people worldwide.3 Although multiple treatments are available, many patients do not adequately respond. Specifically, up to one-third of patients do not adequately respond and about half stop responding to any particular DMARD within five years.4,5,6,7,8,9 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.

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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 August 21, 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, (i) the uncertainties inherent in research and development; (ii) 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 (iii) 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.--

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