CHMP Confirms Prior Opinion Regarding Marketing Authorization In Europe For Pfizer's XELJANZ® (tofacitinib citrate)

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Pfizer Plans to Work with the European Medicines Agency (EMA) to Resubmit Marketing Authorization Application (MAA)

NEW YORK, N.Y., July 25 - Pfizer Inc. (NYSE: PFE) announced today that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) has confirmed its April 25, 2013, opinion to recommend against approval of XELJANZ® (tofacitinib citrate) for the treatment of adult patients with moderate-to-severe active rheumatoid arthritis (RA). After re-examination of the application as requested by Pfizer, the CHMP is of the opinion that XELJANZ does not demonstrate a favorable benefit:risk profile.

While the CHMP considered that treatment with XELJANZ resulted in reduction in the signs and symptoms of RA and improvement in the physical function of patients, it has outstanding concerns on safety, including serious infections.

The Company is currently evaluating the feedback from the CHMP and will determine next steps to resubmit a MAA to the EMA.

"We are disappointed in the outcome of the re-examination process. A narrow majority of the CHMP felt there is too limited experience in the patient population to fully characterize the profile of XELJANZ and the Committee did not recommend approval at this time," said Dr. Steven Romano, senior vice president and the head of the Medicines Development Group for Pfizer Specialty Care. "The clinical experience with XELJANZ to

date, which includes data from approximately 5,000 patients treated for RA, demonstrates a consistent efficacy and safety profile across a range of patient types and a risk profile that is familiar to rheumatologists who have experience utilizing the range of treatments available to treat this disease. We believe that the benefit:risk profile of XELJANZ is favorable, and we remain committed to working with the EMA to make XELJANZ available to appropriate patients in Europe."

About the Marketing Authorization Application

The MAA included data from the comprehensive, global, multi-study clinical development program for XELJANZ, which included approximately 5,000 patients across Phase 2 and Phase 3 trials in more than 40 countries, resulting in 7,000 patient-years of exposure at the time of regulatory submission. The application was based on the same pivotal efficacy and safety data package that was provided to regulatory agencies around the world.

About Rheumatoid Arthritis

RA 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 23.7 million people worldwide and 6.2 million in Europe.[1] 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 non-biologic disease-modifying antirheumatic drug (DMARD) within five years.[2],[3],[4],[5],[6],[7] There remains a need for additional therapeutic options.

About XELJANZ

XELJANZ is a novel, oral Janus kinase (JAK) inhibitor for the treatment of RA. Unlike recent therapies for RA, which are directed at extracellular targets such as pro-inflammatory cytokines, XELJANZ takes a novel approach targeting the intracellular pathways that operate as hubs in the inflammatory cytokine network.

XELJANZ is approved in the United States, Japan, Argentina, Kuwait, Russia, Switzerland and the United Arab Emirates for the treatment of adults with moderate-to-severe active RA.

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At Pfizer, we apply science and our global resources to bring therapies to people that extend and significantly improve their lives. We strive to set the standard for quality, safety and value in the discovery, development and manufacture of health care products. Our global portfolio includes medicines and vaccines as well as many of the world's best-known consumer health care 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 one of the world's premier innovative biopharmaceutical companies, we 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, please visit us at www.pfizer.com.

DISCLOSURE NOTICE: The information contained in this release is as of July 25, 2013. 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 XELJANZ (tofacitinib citrate), including its potential benefits, that involves substantial risks and uncertainties. Such risks and uncertainties include, among other things, whether and when we will resubmit a Marketing Authorization Application (MAA) in Europe for XELJANZ for the treatment of adults with moderate-to-severe rheumatoid arthritis and, if so, whether we will be able to address the CHMP's concerns to its satisfaction and receive a positive opinion from the CHMP for that indication for XELJANZ; whether and when the European Commission will approve any such MAA for that indication for XELJANZ; and competitive developments.

A further description of risks and uncertainties can be found in Pfizer's Annual Report on Form 10-K/A for the fiscal year ended December 31, 2012, and in its reports on Form 10-Q and Form 8-K.

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