Pfizer Receives CHMP Negative Opinion Regarding Marketing Authorization In Europe For Rheumatoid Arthritis Treatment XELJANZ® (tofacitinib citrate)

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Pfizer Intends to Appeal and Seek Re-Examination

(BUSINESS WIRE)--Pfizer Inc. (NYSE: PFE) announced today that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) has adopted a negative opinion for XELJANZ® (tofacitinib citrate) for the treatment of adult patients with moderate-to-severe active rheumatoid arthritis (RA). The CHMP is of the opinion that XELJANZ does not demonstrate a favorable risk:benefit profile at this time and recommended against marketing authorization. Pfizer intends to appeal this opinion and immediately seek a re-examination of the opinion by the CHMP.

The Committee considered that treatment with XELJANZ resulted in an improvement in the signs and symptoms of rheumatoid arthritis and the physical function of patients, but did not believe that a consistent reduction in disease activity and structural damage to joints had been sufficiently demonstrated. The CHMP also raised questions about the serious infections, gastrointestinal perforations and malignancies observed in XELJANZ trials.

The Marketing Authorization Application (MAA) included data from the comprehensive, global, multi-study clinical development program for XELJANZ, which included approximately 5,000 patients across Phase 2 and 3 trials in more than 40 countries,

resulting in 7,000 patient-years of exposure. The application was based on the same pivotal efficacy and safety data package that was provided to regulatory agencies around the world. XELJANZ is approved in the United States, Japan and Russia for the treatment of adults with moderate-to-severe active RA.

“We have confidence in XELJANZ and believe our application to the EMA demonstrates that XELJANZ has a favorable risk:benefit profile. XELJANZ’s safety profile is well-characterized, and the issues raised by the EMA, including serious infections, gastrointestinal perforations and malignancies, are familiar to rheumatologists who are experienced working with treatments for patients to manage this difficult disease,” said Dr. Yvonne Greenstreet, senior vice president and the head of the Medicines Development Group for Pfizer Specialty Care. “Each regulatory authority will review and interpret applications individually and different assessments are not uncommon. The re-examination process will enable us to seek to address the CHMP’s questions, and we will continue to work closely with the EMA with the goal of making this medicine available to appropriate patients in Europe.”

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 worldwide1 and 3 million in Europe.2 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.3,4,5,6,7,8 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.

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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 April 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 we will be able to address the CHMP’s concerns to its satisfaction regarding the Marketing Authorization Application (MAA) for XELJANZ for the treatment of adults with moderate-to-severe rheumatoid arthritis and receive a positive opinion from the CHMP for that indication for XELJANZ; whether the European Commission will approve the 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 for the fiscal year ended December 31, 2012, and in its reports on Form 10-Q and Form 8-K.

1 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.

2 Lundkvist J, Kastäng F, Kobelt G. The burden of rheumatoid arthritis and access to treatment: health burden and costs. Eur J Health Econ. 2008;8(Suppl 2):S49-60

3 Klareskog L, Van der Heijde D, de Jager J, et al. Therapeutic effect of the combination of etanercept and methotrexate compared with each treatment alone in patients with rheumatoid arthritis: double-blind randomized controlled trial. The Lancet 2004. 363: 675-681

4 Keystone, E, Kavanaugh A, Sharp J, et al. Radiographic, clinical and functional outcomes of treatment with adalimumab (a human anti-tumor necrosis factor monoclonal antibody)

in patients with active rheumatoid arthritis receiving concomitant methotrexate therapy. Arthritis & Rheumatism 2004. 50: 1400-1411

5 Lipsky, P, Van der Heijde, D, St. Clair, W. Infliximab and methotrexate in the treatment of rheumatoid arthritis. The New England Journal of Medicine 2000. 1594-1602.

6 Duclos M, Gossec L, Ruyssen-Witrand A, et al. Retention rates of tumor necrosis factor blockers in daily practice in 770 rheumatic patients. J Rheumatol 2006; 33:2433-8.

7 Maradit-Kremers H, Nicola PJ, Crowson CS, et al. Patient, disease, and therapy-related factors that influence discontinuation of disease-modifying antirheumatic drugs: a population-based incidence cohort of patients with rheumatoid arthritis. J Rheumatol 2006; 33(2):248-55.

8 Blum MA, Koo D, Doshi JA. Measurement and rates of persistence with and adherence to biologics for rheumatoid arthritis: a systematic review. Clin Ther 2011;33(7):901-913.

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