



Pfizer Announces FDA Acceptance For Review Of New Drug Application For Tofacitinib For Adult Patients With Moderately To Severely Active Rheumatoid Arthritis

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Application Also Filed with Regulatory Authorities in Japan

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(BUSINESS WIRE)--Pfizer Inc. (NYSE:PFE) announced today that the U.S. Food and Drug Administration (FDA) has accepted for review the New Drug Application (NDA) for tofacitinib (development code CP-690,550), an investigational novel, oral JAK inhibitor being studied for the treatment of adult patients with moderately to severely active rheumatoid arthritis (RA). The FDA has provided an anticipated Prescription Drug User Fee Act (PDUFA) action date in August 2012 for the NDA. Pfizer has also submitted an application for this indication for tofacitinib to regulatory authorities in Japan.

As disclosed in November, an application for tofacitinib for the treatment of adult patients with moderate-to-severe active RA is being reviewed by the European Medicines Agency.

"Pfizer is pleased to have achieved this regulatory milestone, which reflects our commitment to advancing treatments for inflammatory conditions, and constitutes a significant step toward bringing tofacitinib to RA patients who are in need of additional therapeutic options," said Geno Germano, president and general manager, Specialty Care

and Oncology, Pfizer Inc. “We are proud of the comprehensive Phase 3 clinical program that we have completed and believe that, if approved by the FDA, tofacitinib has the potential to improve the lives of people with RA.”

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 Americans and one percent of the population worldwide.ⁱⁱ

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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 December 20, 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 that involves substantial risks and uncertainties about a product in development, tofacitinib, including its potential benefits as a treatment for moderate-to-severe active RA, that is under review by regulatory authorities in the U.S., EU and Japan. Such risks and uncertainties include, among other things, the uncertainties inherent in research and development; decisions by those regulatory authorities regarding whether and when to approve drug applications that have been filed for tofacitinib for moderate-to-severe 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, 2010 and in its reports on Form 10-Q and Form 8-K.

i 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>.

ii Lee DM, Weinblatt ME. Rheumatoid arthritis. *Lancet*. 2001; 358:903-911.

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