Pfizer Announces European Medicines Agency Acceptance Of Regulatory Submission For Tofacitinib For The Treatment Of Rheumatoid Arthritis

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(BUSINESS WIRE)--Pfizer Inc. (NYSE:PFE) announced today that its Market Authorisation Application for tofacitinib (development code CP-690,550), a novel, oral JAK inhibitor being studied for the treatment of moderate-to-severe active rheumatoid arthritis (RA), has been validated by the European Medicines Agency (EMA). Validation means that the EMA has confirmed that the application is complete and the agency is beginning its review procedure.

Pfizer studied tofacitinib for moderate-to-severe active RA in the Phase 3 ORAL (Oral Rheumatoid Arthritis Phase 3 TriaLs) program. The ORAL Trials program consists of five studies for which data needed for registration are complete and one ongoing Phase 3 clinical trial. In addition, tofacitinib is being investigated in two ongoing long-term open-label extension studies. Close to 5,000 RA patients at more than 350 sites in 35 countries worldwide have been treated with tofacitinib in clinical trials.

Pfizer Inc.: Working together for a healthier world™

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 November 21, 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 RA that is under review by the EMA. Such risks and uncertainties include, among other things, the uncertainties inherent in research and development; whether and when the EMA and regulatory authorities in other jurisdictions in which applications may be filed for tofacitinib for RA will approve applications for that indication, 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.

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