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Pfizer Comments on ORAL Sync Tofacitinib Data in EULAR Abstract LB0005

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Detailed Results to be Presented at EULAR

(BUSINESS WIRE)--Pfizer Inc. commented on an abstract concerning the ORAL Sync Phase 3 study of tofacitinib in patients with rheumatoid arthritis (RA) which has been posted for the European League Against Rheumatism (EULAR) conference.

In this study, four deaths were reported in the tofacitinib arms, three of which were determined by the investigators not to be study drug related. The cases reported that were determined not to be study drug related involve one case of brain injury following trauma 22 days after discontinuation of study drug; one case of worsening of RA 42 days after discontinuation of study drug; and one case of acute heart failure. In addition, one case of respiratory failure was reported by the investigator as study drug related.

Because the initial randomization design of the study includes only one-fifth of the patients on placebo (2:2:1 randomization, n = 792), and because the placebo patients are converted to active arms beginning as early as 3 months into the study, the majority of adverse events would be expected to occur in patients on active treatment.

The mortality rate from all causes across the tofacitinib RA development program, including the ORAL Sync study, is within the range of rates reported for biologic therapies for RA.

Full results of ORAL Sync will be presented in a late-breaker oral session at EULAR on May 27, 2011, at 4:20 p.m. GMT in London.

About ORAL Sync

ORAL Sync evaluated the efficacy and safety of tofacitinib doses 5 mg and 10 mg given twice daily compared to placebo in patients with moderately to severely active RA who had a previous inadequate response to a DMARD and who continued to receive background traditional DMARD therapy throughout the study.

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DISCLOSURE NOTICE: The information contained in this release is as of April 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 about a product in development, tofacitinib, including its potential benefits, that involves substantial risks and uncertainties. Such risks and uncertainties include, among other things, the uncertainties inherent in research and development; decisions by regulatory authorities regarding whether and when to approve any drug applications that may be filed for tofacitinib 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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