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Pfizer's Oral JAK-3 Inhibitor Demonstrates Statistically Significant Response For Patients with Rheumatoid Arthritis, New Phase 2 Studies Show

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Global Phase 3 Clinical Program Enrolling Patients

(BUSINESS WIRE)--Pfizer announced today that data from two new mid-stage clinical studies of the company's oral JAK-3 inhibitor, CP-690,550, showed statistically significant response versus placebo for patients with rheumatoid arthritis (RA). Data from these two Phase 2 trials and one ongoing open-label safety study are being presented this week at the 10th Annual Congress of the European League Against Rheumatism (EULAR). These results confirm findings from two previously reported Phase 2 studies in RA and have been used to support dose selection for Phase 3.

Dose-Ranging with CP-690,550 Alone

Data presented from a 12-week interim analysis of a six-month, double-blind, placebo-controlled study (Study A3921035), which evaluated 384 patients with active RA who had not responded to a disease-modifying anti-rheumatic drug (DMARD), such as methotrexate, showed that patients treated with 5, 10 and 15 mg twice-daily doses of CP-690,550 experienced statistically significantly superior outcomes compared to placebo.

"This compound could represent a promising advance in rheumatoid arthritis treatment for patients who need an alternative to currently available therapies," said Michael Berelowitz, MD, Senior Vice President Clinical Development and Medical Affairs for Pfizer Specialty Care. "The size of our comprehensive Phase 2 program enabled us to identify doses for advancement into late-stage clinical trials."

The primary endpoint of the study was ACR 20 response rate, which signifies a 20 percent improvement in tender and swollen joint counts as well as other criteria, at Week 12. ACR 20 responses for the 3, 5, 10 and 15 mg twice-daily doses were statistically significantly superior (49.0 percent, 63.3 percent, 75.4 percent, 75.4 percent) versus patients treated with placebo (28.8 percent), and these differences were seen as early as week two. In addition, statistically significantly superior responses were also seen in ACR 50 response rates for the 5, 10 and 15 mg twice daily doses and in the ACR 70 response rates for the 10 and 15 mg twice-daily doses. The study included adalimumab as an active control.

In this study, most commonly-reported treatment-emergent adverse events were urinary tract infections, diarrhea, bronchitis, and headache. All of these adverse events were mild or moderate in severity. Serious adverse events and adverse events leading to discontinuation were infrequent. Significant, dose-dependent decreases in mean neutrophil counts and increases in mean LDL, HDL, total cholesterol and mean serum creatinine were consistent with what had been observed in previous studies of CP-690,550 in RA.

CP-690,550 with Methotrexate in Japanese Patients

In addition, data from a three-month, double-blind, placebo-controlled study (Study A3921039) evaluating 136 Japanese patients whose RA was active despite ongoing treatment with methotrexate demonstrated that patients treated with 1, 3, 5 and 10 mg doses of CP-690,550 in addition to stable background methotrexate experienced statistically significantly superior ACR 20 response rates compared to methotrexate plus placebo. The primary endpoint was ACR 20 response rate at week 12.

All doses (1, 3, 5 and 10 mg) were statistically significantly superior by week 12 (64.3 percent, 77.8 percent, 96.3 percent and 80.8 percent) compared to methotrexate plus placebo (14.3 percent) and these differences were seen as early as week two. In addition, secondary endpoints for the ACR 70 response rates with the 5 mg and 10 mg doses (33.3 percent, 34.6 percent) at week 12 were statistically significantly superior compared to methotrexate plus placebo (3.6 percent).

In this study, most commonly-reported treatment-emergent adverse events were nasopharyngitis, increased liver transaminases, increased blood cholesterol, and stomach discomfort. All of these adverse events were mild or moderate in severity. Serious adverse events and adverse events leading to discontinuation were infrequent. Significant, dose-dependent decreases in mean neutrophil counts and increases in mean LDL, HDL, total cholesterol and mean serum creatinine were consistent with what had been observed in previous studies of CP-690,550 in RA.

Ongoing, Long-term, Open Label Safety Study

Data from an ongoing, long-term, open label safety study (Study A3921024) were also presented. In this interim analysis, CP-690,550 showed a safety profile similar to that observed in previous randomized trials. Most adverse events were mild or moderate. Most frequently reported adverse events (greater than or equal to 1.5 percent) were urinary tract infection, diarrhea, anemia, nausea and sinusitis.

All studies were sponsored by Pfizer Inc.

Phase 3 Program in RA Currently Enrolling Patients

Pfizer's Specialty Care Business Unit initiated a large, global Phase 3 clinical program with CP-690,550 in RA in February 2009 and is exploring the compound as a potential treatment for other autoimmune diseases, including psoriasis and inflammatory bowel disease and for solid organ transplant.

About CP-690,550

CP-690,550 is an oral, selective, potent inhibitor of the JAK family of enzymes, which are involved in numerous inflammatory and autoimmune diseases, including RA. By inhibiting these enzymes, which affect the signaling of multiple cytokines (proteins released by cells to communicate with other cells) that are involved in a broad spectrum of inflammatory and autoimmune diseases, treatment with CP-690,550 may lead to clinically meaningful improvement for patients.

CP-690,550 was invented at Groton labs.

Pfizer Invites Public to View and Listen to Webcast

Pfizer will webcast a conference call with investment analysts at 1:00 p.m. EDT on Friday, June 12, 2009 to review Phase 2 data for CP-690,550. This webcast is open to the public. To view and listen to the webcast, visit our web site homepage at www.pfizer.com and click on the "Pfizer Conference Call with Analysts at EULAR"

link in the Investor Presentations tab. Participants are advised to pre-register in advance of the conference call.

You can also listen to the conference call by dialing either (877) 888-4913 in the United States or (513) 618-5002 outside of the United States. The password is “EULAR Webcast”.

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Founded in 1849, Pfizer is the world's premier biopharmaceutical company taking new approaches to better health. We discover, develop, manufacture and deliver quality, safe and effective prescription medicines to treat and help prevent disease for both people and animals. We also partner with healthcare providers, governments and local communities around the world to expand access to our medicines and to provide better quality health care and health system support. At Pfizer, more than 80,000 colleagues in more than 90 countries work every day to help people stay happier and healthier longer and to reduce the human and economic burden of disease worldwide.

DISCLOSURE NOTICE: The information contained in this release is as of June 11, 2009. Pfizer assumes no obligation to update any 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, CP-690,550, including its potential benefits as a treatment for rheumatoid arthritis, certain other diseases and solid organ transplant, 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 CP-690,550 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, 2008 and in its reports on Form 10-Q and Form 8-K.

Pfizer Inc Media: Jack Cox, 212-733-5017 or Investors: Jennifer Davis, 212-733-0717