CP-690,550, Pfizer’s Oral JAK Inhibitor, Demonstrates Response Both Alone And In Combination With Methotrexate At 24 Weeks In Patients With Active Rheumatoid Arthritis

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Final Phase 2 Analyses Presented at the American College of Rheumatology/ Association of Rheumatology Health Professionals (ACR/ARHP) Annual Scientific Meeting

(BUSINESS WIRE)--Pfizer Inc announced today that 24-week data from two clinical studies of the oral JAK inhibitor, CP-690,550, confirmed statistically significant ACR20 response and DAS28 remission rates for several doses versus placebo when given alone or in combination with methotrexate for patients with active rheumatoid arthritis (RA). The findings, which were presented this week at the 2009 ACR/ARHP Annual Scientific Meeting in Philadelphia, represent the final analyses from two Phase 2 trials evaluating the effect of CP-690,550 over 24 weeks.

“These data suggest that CP-690,550 could represent a promising advance for patients with rheumatoid arthritis,” said Michael Berelowitz, MD, senior vice president Clinical Development and Medical Affairs for Pfizer Specialty Care. “Our Phase 3 program is currently underway with enrollment progressing as planned, and we are hopeful that data from these trials will validate the Phase 2 results.”

Efficacy as Monotherapy at 24 weeks

Data presented from a six-month, double-blind, placebo-controlled Phase 2B study (Study A3921035), which evaluated 384 patients with active RA who had not responded to

disease-modifying anti-rheumatic drugs (DMARDs), showed that patients treated with 5, 10 and 15 mg twice-daily doses of CP-690,550 dosed without background methotrexate experienced statistically significant ACR response rates and DAS28 remission rates at week 24 as compared to placebo. These results were consistent with the previously reported primary analysis of ACR response at week 12.

24-Week efficacy results are as follows:

Treatment ACR20(%) ACR50(%) ACR70(%) DAS28 Remission(%)

1 mg 24.1 7.4 5.6 5.8 3 mg 37.3 27.5* 13.7 13.7* 5 mg 51.0* 34.7* 20.4* 14.6* 10 mg 65.6*** 44.3*** 37.7*** 21.3** 15 mg 66.7*** 54.4*** 33.3** 21.1** Placebo 25.4 10.2 6.8 1.8
*p≤0.05 **p≤0.01 *** p≤0.0001

All patients were randomized to either placebo or one of the studied doses of CP-690,550. This study also included adalimumab (40 mg subcutaneously every other week) as an active control in the first 12 weeks of the study.

Efficacy in Combination with Methotrexate at 24 weeks

Data from a second six-month, double-blind, placebo-controlled Phase 2b study (Study A3921025) evaluating 507 patients whose RA was active despite ongoing treatment with methotrexate demonstrated that patients treated with 3, 10 and 15 mg twice-daily and 20 mg once-daily doses of CP-690,550 in addition to stable background methotrexate experienced statistically significant ACR response rates and DAS28 remission rates at week 24 as compared to placebo. These results were consistent with previously reported primary analysis of ACR response at week 12.

24 week efficacy results are as follows:

Treatment ACR20(%) ACR50(%) ACR70(%) DAS28 Remission(%)

1 mg 41.4 31.4 20.0* 13.2 3 mg 52.9* 27.9 19.1* 23.9* 5 mg 47.9 33.8 19.7* 28.6* 10 mg 55.4* 35.1 17.6 29.6* 15 mg 58.7* 44.0* 30.7** 29.7* 20 mg 52.5* 38.8* 23.8* 22.8* Placebo 34.8 23.2 7.3 10.5
*p≤0.05 **p≤0.01

This study evaluated CP-690,550 doses of 1, 3, 5, 10 and 15 mg twice daily and 20 mg once daily. All patients were maintained on their stable background of methotrexate and randomized to either addition of placebo or one of the studied doses of CP-690,550.

In both studies, the most commonly-reported treatment-emergent adverse events were urinary tract infections, headache, and diarrhea. Most adverse events were mild or moderate in severity. Serious adverse events and adverse events leading to discontinuation were infrequent. Dose-dependent decreases in mean neutrophil counts and increases in mean LDL, HDL, and total cholesterol were consistent with what has been observed in previous studies of CP-690,550 in RA. For patients dosed on background methotrexate, transaminase increases were also consistent with what had been reported in interim analyses in previous studies of CP-690,550 in RA.

All studies were sponsored by Pfizer Inc.

ORAL Trials: Advancing Clinical Research for RA

The Phase 3 program, which is known as the ORAL (Oral CP-690,550 Rheumatoid Arthritis Phase 3 TriaLs) Program, consists of six Phase 3 studies at more than 350 locations in 35 countries worldwide (www.ORALtrials.com.)

About CP-690,550

CP-690,550 is an oral, selective, potent inhibitor of the JAK family of enzymes. In cell-based assays, CP-690,550 has been shown to inhibit JAK-3 and JAK-1 with functional selectivity over JAK-2. 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 is also being evaluated as a potential treatment for psoriasis, Crohn’s disease, ulcerative colitis and solid organ transplant.

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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 October, 17, 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.

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