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In First Phase 3 Trial, Tasocitinib (CP-690,550), an Oral JAK Inhibitor, Administered as Monotherapy, Reduces Signs and Symptoms of Active Rheumatoid Arthritis and Improves Physical Function

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Tasocitinib Demonstrates Sustained Efficacy at 24 Months in Phase 2/3 Open Label Extension Study

"We are encouraged by the statistically significant and clinically meaningful improvements we observed in a proportion of patients treated with tasocitinib monotherapy in ORAL Solo,"

NEW YORK--(BUSINESS WIRE)--Pfizer Inc. (NYSE: PFE) today announced results of ORAL Solo (1045), a Phase 3 study that showed tasocitinib (CP-690,550), an investigational, novel, oral JAK inhibitor, administered as monotherapy met two primary endpoints, demonstrating a statistically significant reduction in signs and symptoms of moderately to severely active rheumatoid arthritis (RA) and improvement in physical function as measured by ACR20 response rates and mean change in HAQ-DI, respectively, versus placebo at three months. For a third primary endpoint, the rate of DAS28-4(ESR) <2.6, a measure of disease remission, treatment with tasocitinib resulted in a numerically greater, but not statistically significant difference from placebo at three months.

In ORAL Solo, a similar frequency of adverse events was seen across all treatment groups. Serious adverse events were reported in 4.1 percent of patients. Additionally, decreases in neutrophil count and hemoglobin and an increase in cholesterol occurred by month three. These changes tended to stabilize thereafter. No new safety signals were detected.

"We are encouraged by the statistically significant and clinically meaningful improvements we observed in a proportion of patients treated with tasocitinib monotherapy in ORAL Solo," said Roy Fleischmann, MD, Clinical Professor in the Department of Internal Medicine at the University of Texas Southwestern Medical Center in Dallas. "Further research into additional treatment options for patients with moderately to severely active RA is important, and we look forward to seeing the results of the additional Phase 3 ORAL trials of tasocitinib."

ORAL Sequel (1024), an open label, follow-up Phase 2/3 study, had safety findings consistent with the global Phase 2 RA clinical program and showed sustained efficacy over 24 months when tasocitinib was administered as monotherapy or in combination with methotrexate.

Results of both studies will be presented at the American College of Rheumatology (ACR) Annual Meeting in Atlanta this week.

ORAL Solo (1045): Trial Design and Results

ORAL Solo was a six-month, double-blind, placebo-controlled study of 611 randomized patients. Patients with moderately to severely active RA who had an inadequate response to at least one disease- modifying antirheumatic drug (DMARD) received tasocitinib 5 mg or 10 mg monotherapy or placebo twice a day. After three months of treatment, patients randomized to the placebo group began receiving tasocitinib 5 mg or 10 mg in a blinded manner. Primary efficacy endpoints were ACR20 response rates (20 percent improvement from baseline in the American College of Rheumatology scale), mean change in HAQ-DI (Health Assessment Questionnaire Disability Index) and DAS (Disease Activity Score) 28-4(ESR) (DAS28) <2.6, all at month three. Secondary endpoints included ACR50/70 response rates and mean change in DAS28.

Efficacy Overview (all results were measured at three months):

Treatment Group	**ACR20 +/-**	**ACR50**	**ACR70**	**HAQ-DI +/-**	**DAS28 <2.6 +/-**	**DAS28**
	(%)	**(%)**	**(%)**	**mean change from baseline**	**(%)**	**mean change from baseline**
5 mg	59.8*	31.1*	15.4**	-0.50*	6.0	-2.04*
10 mg	65.7*	36.8*	20.3*	-0.57*	9.6	-2.26*
Placebo	26.7	12.5	5.8	-0.19	4.4	-1.17

+/- Primary efficacy endpoint; *p<0.0001; **p<0.05

ACR20/50/70, HAQ-DI and DAS28 measurements showed both a dose effect and improvement over time. ACR20 showed separation from placebo by week two, the first time point measured after baseline.

The safety findings in ORAL Solo were consistent with those observed in the global Phase 2 RA clinical program. In months 0-3 and months 3-6 of the study, respectively, 54.1 percent and 40.0 percent of patients had adverse events (AEs) and 2.1 percent and 1.0 percent discontinued due to these AEs, with similar frequency across groups. Twenty five patients (4.1 percent) had serious AEs and serious infections were reported in six patients during the total six months of the study. Among patients treated with tasocitinib, there were statistically significant decreases in neutrophil count, statistically significant increases in LDL and HDL cholesterol and not statistically significant changes in hemoglobin levels. These changes were seen at month three and were stable thereafter. During the course of the study, few patients had transaminase elevations distributed across all groups.

ORAL Sequel (1024): Trial Design and Results

ORAL Sequel is an ongoing Phase 2/3 study designed to evaluate the long-term safety and efficacy of tasocitinib 5 mg or 10 mg twice daily in the treatment of moderately to severely active RA in patients who have participated in a prior randomized study of tasocitinib and then rolled over to this open label extension study. The primary endpoints are laboratory safety data and AE reports. Secondary endpoints include ACR20/50/70 response rates and mean change in DAS28 and HAQ-DI.

Safety and efficacy were evaluated over 24 months in 1,070 patients, and compared between patients who received tasocitinib monotherapy and tasocitinib in combination with methotrexate.

ACR response rates showed a trend for improvement over time (month 1-24) with similar ACR20 response rates in tasocitinib monotherapy and tasocitinib on background methotrexate groups at month 24. The mean DAS28 and HAQ-DI scores also improved compared to baseline and remained consistent over time.

No new safety signals emerged in ORAL Sequel. For all patients, the most frequent AEs were bronchitis, upper respiratory infection and urinary tract infection. 6.3 percent of patients discontinued from the study due to AEs. The most frequently reported class of serious AEs was infections (n=34, 18.1 percent) with an incidence rate of 2.62/100 patient-years of tasocitinib treatment. There were two cases of TB; one disseminated TB, which occurred in the background methotrexate group, and one case that was reported two months after discontinuation of tasocitinib. The increases seen in mean total cholesterol, LDL, hemoglobin, serum creatinine and transaminases and the decrease seen in mean absolute neutrophil counts from baseline during the first 6-12 weeks in the prior randomized studies did not progress during the two years in ORAL Sequel.

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 1.3 million people in the U.S. and approximately one percent of the adult population worldwide.

About Tasocitinib

Tasocitinib is a novel, oral Janus kinase (JAK) inhibitor that is being investigated as a targeted immunomodulator and disease- modifying therapy for RA. Unlike current therapies for RA, which are directed at extracellular targets such as pro-inflammatory cytokines, tasocitinib takes a novel approach, targeting the intracellular signaling pathways that operate as hubs in the inflammatory cytokine network.

Pfizer is studying tasocitinib in one of the largest clinical programs of its kind, evaluating more than 4,000 RA patients. The Phase 3 ORAL Trials clinical program includes six studies with more than 350 locations in 35 countries worldwide (www.ORALtrials.com).

Pfizer is also studying orally administered tasocitinib in psoriasis, inflammatory bowel disease (Crohn's disease and ulcerative colitis) and organ transplant, and topical tasocitinib in both psoriasis and dry eye.

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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 November 7, 2010. 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, tasocitinib, 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 tasocitinib 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, 2009 and in its reports on Form 10-Q and Form 8-K.

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