Oral Tasocitinib Demonstrates Statistically Significant Response by 12 Weeks in Phase 2 Study of People With Moderate to Severe Plaque Psoriasis

Wednesday, October 06, 2010 - 06:30pm

Results Presented at the Annual Meeting of the European Academy of Dermatology and Venereology in Gothenburg, Sweden

"We are encouraged by the results seen in the Phase 2 study and look forward to further studying tasocitinib in the recently initiated Phase 3 program called the OPT trials."

(BUSINESS WIRE)--Pfizer Inc. (NYSE: PFE) today announced that data from a Phase 2 efficacy and safety study of tasocitinib (proposed INN name for CP-690,550), the company's investigational oral JAK inhibitor, met its primary endpoint of a statistically significant greater proportion of patients achieving at least a 75 percent reduction from baseline in PASI (Psoriasis Area and Severity Index) at week 12 in individuals with chronic moderate to severe plaque psoriasis. At week 12, PASI 75 responses for tasocitinib 2, 5 and 15 mg twice daily groups were 25.0%, 40.8% and 66.7% respectively, versus placebo, 2.0% (all doses, $p<0.001$). As early as week 4, treatment with 5 and 15 mg twice daily of tasocitinib significantly improved patient reported health-related quality of life outcomes. These results were presented in two posters at the annual meeting of the European Academy of Dermatology and Venereology (EADV).

The double-blind, placebo-controlled, dose-ranging Phase 2 study was conducted in 197 adult patients with moderate to severe plaque psoriasis. Study participants were

randomized to receive 2, 5 or 15 mg tasocitinib or placebo twice daily. In the study, the most frequently reported treatment-emergent adverse events were upper respiratory tract infection and headache.

Three patients experienced a total of five serious adverse events during the study. Dose dependent decreases in mean neutrophil counts and hemoglobin values and increases in mean LDL, HDL and total cholesterol levels were observed.

About Plaque Psoriasis

Psoriasis is a chronic autoimmune skin disease that affects 125 million people worldwide.(1) Plaque psoriasis is the most common form of the disease, accounting for about 80 percent of cases.(2) It is characterized by raised, inflamed, red lesions covered by a silvery white scale that can be very itchy and painful.(2) Psoriasis is typically found on the elbows, knees, scalp and lower back.(2) For people who have moderate to severe psoriasis, quality of life can suffer significantly due to pain, itching and emotional impacts from the disease.(3) Patients also report dissatisfaction with traditional psoriasis therapies. According to published studies, 10–50% of people with psoriasis who used traditional therapies reported an inadequate response to treatment, and 42% said they were dissatisfied with their treatment options.(4)

Study Results

Efficacy was assessed at 12 weeks using the PASI scale (PASI 75 represents a 75 percent improvement from baseline in the psoriasis area and severity index), and Physician Global Assessment (PGA) which evaluated the percentage of patients scoring "clear" or "almost clear" in their psoriasis symptoms. The results are as follows:

Dose PASI 50 (% of patients) PASI 75 (% of patients) PASI 90 (% of patients) PGA "clear" or "almost clear" (% of patients) 2 mg 39.6* 25.0*** 14.6** 24.5* 5 mg 65.3* 40.8*** 18.4** 40.8* 15 mg 87.5* 66.7*** 33.3** 72.9* Placebo 20.0 2.0 0.0 10.0
*p less than or equal to 0.05 **p<0.01 *** p<0.001

Patient health-related quality of life was measured using the Dermatology Life Quality Index (DLQI); and the Physical (PCS) and Mental Component Scores (MCS) of the Short Form-36 questionnaire (SF-36 version 2, acute), a measure of individuals' physical and mental health and well-being.(5) Patient self-assessment of disease activity was measured using a 5-category Patient Global Assessment (PtGA) of psoriasis. These results

at week 12 are as follows:

Dose	DLQI (mean change in score from baseline)	PCS (mean change in score from baseline)	MCS (mean change in score from baseline)	PtGA "clear" or "almost clear" score (%)
2 mg	-7.74**	1.06	2.29*	35.1**
5 mg	-7.26**	3.44*	2.54*	38.5**
15 mg	-9.40**	3.31*	3.63*	74.4**
Placebo	-2.01	-1.17	-2.86	2.9

*p<0.05 ** p less than or equal to 0.0001

"Plaque psoriasis affects millions of people globally and can have a negative impact on a person's quality of life,"(6) said Saeed Fatenejad, M.D., VP, Clinical Development & Medical Affairs (CDMA), Disease Area Lead for Inflammation, Pfizer Specialty Care Business Unit. "We are encouraged by the results seen in the Phase 2 study and look forward to further studying tasocitinib in the recently initiated Phase 3 program called the OPT trials."

About Tasocitinib

Tasocitinib is a Janus Kinase (JAK) inhibitor. It is believed that the JAK pathways play an important role in the psoriasis disease cascade. Researchers are conducting clinical trials to test the hypothesis that inhibiting the JAK pathways modulates the immune and inflammatory responses involved in psoriasis, which may lead to clinically meaningful improvement for patients.

More than 4,000 people have participated in tasocitinib clinical trials to date. The most frequently reported adverse events include headaches, infections and gastrointestinal symptoms such as nausea, vomiting and diarrhea: most were mild to moderate in severity and were manageable with routine medical care.

Pfizer has initiated its study of tasocitinib in people with chronic moderate to severe plaque psoriasis in a Phase 3 program called the OPT (Oral Psoriasis Treatment) Trials to further characterize the efficacy and safety profile.

Tasocitinib is also being studied for the potential treatment of rheumatoid arthritis in a group of trials called the ORAL trials (www.ORALtrials.com). Additionally, tasocitinib is being studied in dry eye, Crohn's disease, ulcerative colitis and solid organ transplant.

Tasocitinib was discovered by Pfizer scientists in the company's Groton, Connecticut laboratories and is being developed solely by Pfizer.

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 October 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 psoriasis, 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.

(1) National Psoriasis Foundation. Statistics. http://www.psoriasis.org/netcommunity/learn_statistics. Accessed on July 1, 2010.

(2) National Psoriasis Foundation. Types of Psoriasis. http://www.psoriasis.org/netcommunity/learn_types. Accessed June 24, 2010.

(3) Rapp SR, Feldman SR, Exum ML, et al. Psoriasis causes as much disability as other major diseases. Journal of American Academy of Dermatology. 1999 Sep; 41:401-407.

(4) Christophers et al. The unmet treatment need for moderate to severe psoriasis: results of a survey and chart review. Journal of European Dermatology and Venereology. 2006 Sep;20(8):921-5.

(5) Quality Metric Incorporated.SF-36 Health Survey Update. http://www.sf-36.org/tools/sf36.shtml. Accessed on July 19, 2010.

(6) Kimball et al. National Foundation clinical consensus on psoriasis comorbidities and recommendations for screening. Journal of American Academy of Dermatology. 2008 Jun;58(6):1031-42.

Pfizer Inc. Media: Gwen Fisher, O: +1-484-865-5160, M: +1-215-407-1548, Gwen.Fisher@pfizer.com or Investor: Suzanne Harnett, O: +1-212-733-8009, M: +1-646-256-9250, Suzanne.Harnett@pfizer.com