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Spiriva® HandiHaler® (tiotropium bromide inhalation powder) and COPD Data to be Presented at the 2012 European Respiratory Society (ERS) Congress

Thursday, August 30, 2012 - 10:30pm

"We are committed to ongoing research which may help us understand the therapeutic potential of SPIRIVA and how to appropriately manage COPD,"

(BUSINESS WIRE)--Boehringer Ingelheim and Pfizer Inc (NYSE: PFE) announced today three scientific data presentations will take place at the 2012 European Respiratory Society (ERS) Congress in Vienna, Austria, Sept. 1-5, 2012.

SPIRIVA & Exercise Capacity Study (205.440)

Primary data from a new randomized, double-blind cross-over trial (205.440) comparing outcomes of treadmill exercise testing in patients with chronic obstructive pulmonary disease (COPD) treated with SPIRIVA or placebo will be presented during a poster session.[1] The study found that the mean difference in change of isotime inspiratory capacity (primary endpoint), or the total amount of air that can be drawn into the lungs after normal exhalation, from baseline to week six during rest and exercise between SPIRIVA and placebo was statistically significant (rest 125 mL, P<0.0001; exercise 65 mL, P=0.009) in patients with GOLD 1 and 2 COPD (mild-to-moderate, respectively), according to **G**lobal initiative for chronic **O**bstructive **L**ung **D**isease (GOLD) 2011, a global strategy for the diagnosis, management and prevention of COPD.[1,2] The difference in change from baseline to week six in exercise duration between SPIRIVA and placebo (secondary endpoint) was not statistically significant in the combined GOLD 1 and 2 groups (29.3 seconds, P=0.109) or the GOLD 1 patient subgroup (-26.5 seconds, P=0.4153). However, the difference in exercise duration was statistically significant in the GOLD 2 patient subgroup (63 seconds, P=0.007).[1]

The trial included 126 current or former smokers age 40 or older with a post-bronchodilator FEV_1/FVC less than 70 percent and a FEV_1 greater than or equal to 50 percent predicted airflow limitation who performed constant work rate exercise on a treadmill at 80 percent of peak incremental test work rate before and after treatment periods. FEV_1 is the maximal amount of air you can forcefully exhale (forced expiratory volume) in one second. FVC, or forced vital capacity, measures lung function by assessing the volume of air that is expelled following maximum inhalation.[1]

“We are committed to ongoing research which may help us understand the therapeutic potential of SPIRIVA and how to appropriately manage COPD,” said Dr. Tunde Otulana, vice president of clinical development and medical affairs at Boehringer Ingelheim.

Retrospective Analyses of UPLIFT® Study Presentations

UPLIFT was a landmark randomized double-blind placebo-controlled trial that assessed treatment with SPIRIVA HandiHaler (tiotropium bromide inhalation powder) in moderate-to-very severe COPD patients. The trial was conducted over four years in nearly 6,000 patients. The study found that, compared with placebo, treatment with SPIRIVA provided sustained improvement in lung function for up to four years and delayed the time to first exacerbation from a median of 12.5 months to 16.7 months. While SPIRIVA did not significantly reduce the yearly rate of decline in lung function, the study's primary endpoint, UPLIFT did reaffirm the well-established, long-term safety profile of SPIRIVA.[3]

Another poster will present a retrospective analysis of a subgroup of 2,012 low-risk patients from the UPLIFT study with COPD (GOLD A+B), according to the current GOLD guidelines. The analysis suggested that compared to placebo, SPIRIVA throughout four years reduced exacerbations in these patients (FEV_1 greater than or equal to 50 percent predicted airflow limitation and 0-1 exacerbations in the previous year). Compared to placebo, the St. George's Respiratory Questionnaire (SGRQ) score, after four years, was also significantly improved by SPIRIVA (-3.63, $P<0.0001$). The analysis also showed that SPIRIVA treatment resulted in a relative reduction in the incidence of exacerbations by 24 percent compared to placebo (HR=0.76, $P<0.0001$) and reduced the mean annual rate of exacerbations by 28 percent compared to placebo (rate ratio of 0.72, $P< 0.0001$).[4]

Also to be presented are the results of a separate retrospective analysis of the effect of a single first COPD exacerbation on the decline in lung function, as measured by the annual rate of decline in pre- and post-bronchodilator (BD) FEV_1 and FVC based on data from 462 patients with moderate-to-very severe COPD (mean age 64 years, 78 percent male, mean baseline FEV 1.19 L and FEV/FVC 0.44) in UPLIFT. The analysis suggested that a first exacerbation can lead to an increased rate of decline in lung function one to two years post exacerbation.[5]

"The damage that COPD causes often occurs gradually over time and patients are not always aware of the impact of the disease – not just in later stage disease, but in the earlier stages too," said Dr. Otulana. "These data generate an important hypothesis about COPD exacerbations and lung function that might prove useful in future COPD and SPIRIVA clinical studies."

Presentation Details

- ***The Effect of Tiotropium on Lung Dynamic Hyperinflation and Treadmill Exercise Capacity in Mild-to-Moderate COPD (205.440 Trial)***
  - Poster presentation: ID 8607
  - Monday, Sept. 3, 12:50-14:40 in Halle A-7
- ***Effectiveness of Tiotropium in Low-Risk Patients According to New GOLD Severity Grading***
  - Poster presentation: ID 9502/10287
  - Monday, Sept. 3, 12:50-14:40 in Halle A-11
- ***Impact of a Single Chronic Obstructive Pulmonary Disease (COPD) Exacerbation on Lung Function Decline: Analysis of UPLIFT®***
  - Oral presentation: ID 9500/10286
  - Sunday, Sept. 2, 8:30-10:30 in Lehar 1-2

About COPD and COPD Exacerbations

COPD is a chronic and progressive disease characterized by a restricted flow of air into and out of the lungs and loss of lung function over time. COPD is the second-leading cause of disability in the U.S.[6] and each year kills 120,000 Americans – that's one death every four minutes.

COPD primarily affects current and former smokers and symptoms include shortness of breath, coughing (sometimes with phlegm or mucus) and wheezing. When most severe, COPD may even limit a person's ability to perform simple tasks such as washing and dressing. The damage in the lungs caused by COPD is not reversible, but it is treatable.

Approximately one out of five (22 percent) moderate COPD patients experience at least two exacerbations per year.[7] COPD exacerbations are often the cause of COPD-related hospitalizations. Economic analyses suggest that hospitalization due to COPD exacerbations accounts for 40-70 percent of all medical expenses for patients with COPD.[8,9,10] The cost of hospitalization for COPD patients is estimated at more than $20 billion annually.[2]

About SPIRIVA® HandiHaler® (tiotropium bromide inhalation powder)

SPIRIVA HandiHaler is a prescription medicine used once every day (a maintenance medicine) to control symptoms of chronic obstructive pulmonary disease (COPD) by relaxing your airways and keeping them open. COPD includes chronic bronchitis, emphysema or both.

SPIRIVA HandiHaler also reduces the likelihood of flare-ups and worsening of COPD symptoms (COPD exacerbations). A COPD exacerbation is defined as an increase or new onset of more than one COPD symptom such as cough, mucus, shortness of breath and wheezing that requires medicine beyond your rescue medicine.

Important Safety Information for SPIRIVA HandiHaler

Do not use SPIRIVA HandiHaler if you are allergic to tiotropium or ipratropium (e.g., Atrovent®) or any of the ingredients in SPIRIVA. If your breathing suddenly worsens, your face, throat, lips or tongue swells, you get hives, itching or rash, stop taking SPIRIVA and seek immediate medical help.

SPIRIVA HandiHaler is not a rescue medicine and should not be used for treating sudden breathing problems.

Do not swallow SPIRIVA capsules. The contents of the capsule should only be inhaled through your mouth using the HandiHaler device.

If you have vision changes or eye pain or if you have difficulty passing urine or painful urination, stop taking SPIRIVA and call your doctor right away.

Tell your doctor if you have glaucoma, problems passing urine or an enlarged prostate, as these may worsen with SPIRIVA. Tell your doctor if you have kidney problems or are allergic to milk proteins. Ask your doctor if you are not sure. Also discuss with your doctor all the medicines you take, including eye drops.

The most common side effect with SPIRIVA is dry mouth. Others include constipation and trouble passing urine. For a complete list of reported side effects, ask your doctor or pharmacist.

Do not let the powder from the SPIRIVA capsule get into your eyes.

Dizziness and blurred vision may occur with SPIRIVA. Should you experience these symptoms, you should use caution when engaging in activities such as driving a car or operating appliances or other machines.

Read the Patient Information and the step-by-step Instructions for Use for SPIRIVA before you use your inhaler.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

For full prescribing information, please visit www.spiriva.com, or call 1-800-542-6257 option #4.

Boehringer Ingelheim: Leading respiratory forward

Through research, treatments and patient-centric support services, the Boehringer Ingelheim (BI) lung health portfolio is designed to help address the challenges people living with a lung disease face every day. Leveraging the company's cutting edge science and leadership in chronic obstructive pulmonary disease (COPD), BI is researching new treatment approaches where needs persist. It is the company's goal to make a difference in the lives of patients with COPD, asthma, lung cancer, idiopathic pulmonary fibrosis and other respiratory diseases.

About Boehringer Ingelheim Pharmaceuticals, Inc.

Boehringer Ingelheim Pharmaceuticals, Inc., based in Ridgefield, CT, is the largest U.S. Subsidiary of Boehringer Ingelheim Corporation (Ridgefield, CT) and a member of the Boehringer Ingelheim group of companies.

The Boehringer Ingelheim group is one of the world's 20 leading pharmaceutical companies. Headquartered in Ingelheim, Germany, it operates globally with 145 affiliates and more than 44,000 employees. Since it was founded in 1885, the family-owned company has been committed to researching, developing, manufacturing and marketing novel medications of high therapeutic value for human and veterinary medicine.

As a central element of its culture, Boehringer Ingelheim pledges to act in a socially responsible manner. Involvement in social projects, caring for employees and their families, and providing equal opportunities for all employees form the foundation of the global operations. Mutual cooperation and respect, as well as environmental protection and sustainability are intrinsic factors in all of Boehringer Ingelheim's endeavors.

In 2011, Boehringer Ingelheim achieved net sales of about $17.1 billion (13.2 billion euro). R&D expenditure in the business area Prescription Medicines corresponds to 23.5 percent of its net sales.

For more information, please visit http://us.boehringer-ingelheim.com and follow us on Twitter at http://twitter.com/boehringerus.

Pfizer Inc: Working together for a healthier world™

At Pfizer (NYSE: PFE), 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.

[1] Casaburi, R., et. al. The Effect of Tiotropium on Lung Dynamic Hyperinflation and Treadmill Exercise Capacity in Mild to Moderate COPD, European Respiratory Conference, Vienna; Vienna, 2012; P2110.

[2] Global Initiative for Chronic Obstructive Lung Disease, Inc. Global strategy for the diagnosis, management and prevention of chronic obstructive pulmonary disease. February 2011. Available at http://www.goldcopd.org/uploads/users/files/GOLD_Report_2011_Feb21.pdf. Accessibility verified June 8, 2012.

[3] Tashkin DP, Celli B, Senn S, et al, on behalf of the UPLIFT® (Understanding Potential Long-term Impacts on Function with Tiotropium) study investigators. A 4-year trial of tiotropium in chronic obstructive pulmonary disease. N Engl J Med. 2008;359:1543-1554.

[4] Halpin D, Decramer M, Celli B et al. Effectiveness of tiotropium in low-risk patients according to new GOLD severity grading, European Respiratory Society, Vienna; Vienna, 2012; 853288.

[5] Halpin D, Decramer M, Celli B et al. Impact of a single chronic obstructive pulmonary disease (COPD) exacerbation on lung -9-

function decline: analysis of UPLIFT, European Respiratory Society, Vienna; Vienna, 2012; 853426.

[6] National Heart, Lung, and Blood Institute. COPD Speaker's Guide Available at: http://www.nhlbi.nih.gov/health/public/lung/copd/campaign-materials/pub/speakers-guide-with-pp-inserted.pdf. Accessibility verified June 8, 2012

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[9] Rodriguez-Roisin R. Impacting patient-centred outcomes in COPD: exacerbations and hospitalizations. Eur Respir Rev 2006; 15: 99, 47–50.

[10] Chapman KR, Mannino DM, Soriano JB, et al. Epidemiology and costs of chronic obstructive pulmonary disease. Eur Respir J 2006;27:188–207.

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