Pfizer Logo

FDA Approves SPIRIVA® HandiHaler® for the Reduction of COPD Exacerbations

Thursday, December 17, 2009 - 07:33am

(BUSINESS WIRE)--Boehringer Ingelheim Pharmaceuticals, Inc. and Pfizer Inc. announced today that the U.S. Food and Drug Administration (FDA) has approved SPIRIVA® HandiHaler® (tiotropium bromide inhalation powder) for the reduction of exacerbations in patients with chronic obstructive pulmonary disease (COPD). SPIRIVA HandiHaler is already FDA-approved as a once-daily maintenance treatment for breathing problems associated with COPD, which includes chronic bronchitis, emphysema, or both.

Reducing exacerbations is a key goal of COPD disease management, according to treatment guidelines. In the clinical trials that served as the basis for this approval, COPD exacerbations were defined as a new onset or increase of symptoms (including cough, sputum, wheezing or difficulty breathing) lasting for at least three days and which required a change in treatment (antibiotics or steroids), which could include hospitalization. COPD exacerbations may be caused by viral or bacterial infections, as well as environmental irritants.

“Exacerbations of COPD are serious events that can negatively impact the lives of patients,” said Dr. Donald P. Tashkin, emeritus professor of medicine, David Geffen School of Medicine at UCLA, Los Angeles. “People with COPD now have a once-daily treatment option that not only helps them manage the debilitating symptoms of COPD, but also can help them reduce the chance of an exacerbation.”

The new indication is supported by data from two clinical trials: the landmark UPLIFT (Understanding the Potential Long-term Impacts on Function with Tiotropium) study and a six-month study conducted in the Veterans Affairs setting, which together involved nearly 8,000 people with COPD. While the UPLIFT trial did not meet its primary endpoint (slowing the rate of decline in lung function versus placebo), it provided relevant and important clinical information regarding the effect of SPIRIVA HandiHaler on COPD exacerbations.

“With today’s approval, SPIRIVA HandiHaler is now the first steroid-free maintenance treatment that has been shown to reduce COPD exacerbations,” said Dr. Christopher Corsico, vice president, drug regulatory affairs, Boehringer Ingelheim Pharmaceuticals, Inc. “We also are pleased that the product label will now include data from the landmark UPLIFT trial, which provides important information for physicians to consider when making treatment decisions.”

Along with the new indication, the SPIRIVA HandiHaler product label now includes clinical trial data from the UPLIFT study. In this trial, COPD patients in both treatment groups were allowed to use all of their respiratory medications with the exception of inhaled anticholinergics in order to simulate a real-world environment. The clinical data demonstrated that SPIRIVA HandiHaler sustained improved lung function over four years when compared with placebo and reduced COPD exacerbations, even with the use of these medications. Additionally, the inclusion of the safety data reaffirmed the established safety profile of SPIRIVA HandiHaler.

The safety profile of SPIRIVA HandiHaler has been well-established in clinical studies involving more than 17,000 COPD patients, 11,000 of whom were treated with SPIRIVA HandiHaler, and in post-marketing experience involving more than 16 million patient-years of exposure since its European approval in 2002. SPIRIVA HandiHaler was approved in the United States in 2004.

About COPD

COPD is a progressive, but preventable and treatable lung condition that is characterized by a restricted flow of air into and out of the lungs and loss of lung function over time. It includes chronic bronchitis, emphysema, or both.

COPD is the fourth-leading cause of death and the second-leading cause of disability in the United States, and is projected to become the third-leading fatal illness by 2020. Each year, COPD kills 120,000 Americans – that's one death every four minutes.

The disease 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.

About SPIRIVA® HandiHaler®

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.

Do not use SPIRIVA HandiHaler if you are allergic to tiotropium or if you have had an allergic reaction to ipratropium.

Allergic reactions may include itching, rash, or swelling of the lips, tongue or throat (trouble swallowing).

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

Do not swallow SPIRIVA capsules. SPIRIVA capsules should only be used with the HandiHaler device. SPIRIVA HandiHaler should only be inhaled by mouth (oral inhalation).

Stop taking SPIRIVA and get medical help right away if your breathing suddenly worsens, your throat, lips, or tongue swells, you get hives, you have vision changes or eye pain, or you have difficulty passing urine or painful urination.

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 are allergic to milk proteins. Ask your doctor if you are not sure. Tell your doctor if you have kidney problems. Also discuss with your doctor all the medicines you take, including eye drops.

The most common side effects with SPIRIVA include upper respiratory tract infection, dry mouth, sinus infection, and sore throat. For a complete list of reported side effects, ask your doctor or pharmacist.

Do not get SPIRIVA powder in your eyes.

Read the Patient Information and the step-by-step Patient's Instructions for Use for SPIRIVA before you take your medicine.

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

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 138 affiliates in 47 countries and approximately 41,300 employees. Since it was founded in 1885, the family-owned company has been committed to researching, developing, manufacturing and marketing novel products of high therapeutic value for human and veterinary medicine.

In 2008, Boehringer Ingelheim posted net sales of US $17 billion (11.6 billion euro) while spending approximately one-fifth of net sales in its largest business segment, Prescription Medicines, on research and development.

For more information, please visit http://us.boehringer-ingelheim.com.

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.

Boehringer Ingelheim Pharmaceuticals, Inc.External CommunicationsEmily Baier, 203-791-5997emily.baier@boehringer-ingelheim.comorPfizer Inc.Worldwide Media RelationsMacKay Jimeson, 212-733-2324mackay.jimeson@pfizer.comorInvestor RelationsJennifer Davis, 212-733-0717jennifer.m.davis@pfizer.com