FDA Advisory Committee Finds Data Support the Claim That SPIRIVA® HandiHaler® Reduces COPD Exacerbations

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Advisory Committee Also Reaffirms the Product's Safety Profile

(BUSINESS WIRE)--The U.S. Food and Drug Administration (FDA) Pulmonary-Allergy Drugs Advisory Committee voted 11 to 1 that clinical data included in a supplemental new drug application (sNDA) provide substantial and convincing evidence to support the claim that SPIRIVA® HandiHaler® (tiotropium bromide inhalation powder) reduces exacerbations (worsening of symptoms) in patients with chronic obstructive pulmonary disease (COPD).

The advisory committee also voted affirmatively that data from the UPLIFT (Understanding Potential Long-term Impacts on Function with Tiotropium) trial adequately addressed the potential safety concern for an increased risk of stroke (11 yes to 1 no) or adverse cardiovascular events (11 yes with 1 abstention). This is consistent with the current product label. The advisory committee makes recommendations to the FDA, which the agency considers in its final decision.

"We are pleased with the advisory committee's vote today supporting the claim that SPIRIVA HandiHaler reduces COPD exacerbations," said Christopher Corsico, M.D., MPH, Vice President, Drug Regulatory Affairs, Boehringer Ingelheim Pharmaceuticals, Inc. "Exacerbations in COPD patients may lead to disability, premature death and increased healthcare costs. We look forward to working with the FDA during the final stages of its review of our sNDA."

The advisory committee reviewed pivotal data from a six-month trial (Veterans Affairs Study, 205.266) of 1,829 COPD patients and secondary endpoints from a four-year trial

(UPLIFT Study, 205.235) of approximately 6,000 COPD patients. Although UPLIFT did not meet its primary endpoint, the study supports data from the VA trial showing that SPIRIVA HandiHaler consistently reduced the risk of exacerbations in COPD patients. COPD exacerbations were defined as patients having a new onset or worsening of symptoms (including cough, sputum, wheezing, or difficulty breathing) lasting for at least three days and which require a change in treatment (antibiotics or steroids), which could include hospitalization.

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 U.S. 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. COPD makes it difficult to breathe and, over time, interferes with a person’s ability to perform daily physical activities. 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). COPD includes chronic bronchitis, emphysema, or both. SPIRIVA relaxes airways and helps keep them open, to help make it easier to breathe when used every day.

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

Do not swallow SPIRIVA capsules. Only use SPIRIVA capsules with the HandiHaler device. The contents of the capsule should only be inhaled by mouth using the HandiHaler device.

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

Tell your doctor if you have glaucoma, problems passing urine or an enlarged prostate, as these may worsen with SPIRIVA. 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 get SPIRIVA powder in your eyes.

Do not use SPIRIVA if you are allergic to any of the ingredients in SPIRIVA capsules (tiotropium, lactose monohydrate) and if you have had any allergic reaction to atropine or any medicines like it, such as ipratropium (Atrovent).

For full prescribing information, please visit www.spiriva.com.

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.

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