SPIRIVA HandiHaler Prolonged Time To First COPD Exacerbation, New Study In NEJM Shows

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Long-term, Head-to-Head Study Showed SPIRIVA HandiHaler (tiotropium bromide inhalation powder) Significantly Prolonged Time to First Moderate or Severe COPD Exacerbation versus Salmeterol HFA-MDI

(BUSINESS WIRE)--A new study, published today in The New England Journal of Medicine (NEJM), showed that SPIRIVA® HandiHaler® (tiotropium bromide inhalation powder), a long-acting anticholinergic, was significantly more effective at preventing Chronic Obstructive Pulmonary Disease (COPD) exacerbations than salmeterol HFA-MDI (hydrofluoroalkane-metered dose inhaler). While salmeterol HFA-MDI, a beta-agonist is widely used as a COPD maintenance treatment worldwide, it is not approved in the U.S. for COPD or for reducing COPD exacerbations. The data are from The Prevention Of Exacerbations with Tiotropium (POET)-COPD® study, a randomized, double-blind, double-dummy, parallel-group trial involving 7,376 COPD male and female patients and conducted in 25 countries outside of the U.S. over one year. The objective of the study was to compare the effect of tiotropium HandiHaler and salmeterol HFA-MDI on moderate and severe COPD exacerbations.1

The POET-COPD study primary results demonstrated that SPIRIVA HandiHaler prolonged the time to first COPD exacerbation compared to salmeterol HFA-MDI with a 17 percent reduction in risk (hazard ratio 0.83; $p<0.001$). In the one-year study, the risk of moderate exacerbations was reduced by 14 percent ($p=0.001$) and the risk of severe exacerbations requiring hospitalization was reduced by 28 percent ($p<0.001$) with SPIRIVA HandiHaler, compared to salmeterol HFA-MDI. SPIRIVA HandiHaler also produced an 11 percent reduction per year in the number of exacerbations experienced by COPD patients ($p=0.002$), and reduced the risk of exacerbations treated with systemic steroids, antibiotics, or both by 23 percent, 15 percent and 24 percent, respectively ($p<0.001$),

compared to salmeterol HFA-MDI.

“This large exacerbation trial adds to the existing body of data regarding the efficacy and safety of SPIRIVA HandiHaler. It reinforces the evidence that, in addition to its use as a first-line maintenance bronchodilator for COPD, it also reduces COPD exacerbations,” said Christopher Corsico, M.D., M.P.H., U.S. medical director, Boehringer Ingelheim Pharmaceuticals, Inc.

The study included 7,376 COPD patients, of whom 2,691 patients experienced 4,411 exacerbations; 44 percent of the patients with an exacerbation were in GOLD2 Stage II (moderate COPD). The effects of SPIRIVA® HandiHaler® (tiotropium bromide inhalation powder) on time to first exacerbation and annual rate of exacerbations per patient were consistent over all pre-specified subgroup analyses for age, sex, smoking status, COPD severity (GOLD Stage), body mass index, and use of inhaled corticosteroids at baseline. Furthermore, the benefit of SPIRIVA HandiHaler compared with salmeterol HFA-MDI became apparent in this study as early as one month after commencement of treatment and was maintained over the one-year study period. _____ * Global Initiative for Chronic Obstructive Lung Disease

The safety profiles of SPIRIVA HandiHaler and salmeterol HFA-MDI have been well described.2,3,4,5 The POET-COPD safety analyses reaffirm the well-established safety profile of SPIRIVA HandiHaler in the treatment of COPD. The overall number of serious adverse events in the POET-COPD trial was comparable between the treatment groups (14.7 percent for SPIRIVA HandiHaler and 16.5 percent for salmeterol HFA-MDI).

About POET-COPD®

Prevention Of Exacerbations with Tiotropium (POET)-COPD® was a one-year, multicenter (725 sites), multinational (25 countries), randomized, double-blind, double-dummy, parallel-group trial, which included 7,376 male and female COPD patients. The primary objective of this study was to compare the effect of tiotropium (18 mcg once daily) inhalation capsule via HandiHaler and salmeterol (50 mcg twice daily) via HFA metered dose inhaler (MDI) on time to first COPD exacerbation. Salmeterol HFA-MDI is not available in the U.S. and is not approved for COPD or for reducing COPD exacerbations in the U.S.

Patients included in the trial had to be ≥40 years of age, have a smoking history of ≥10 pack-years and a diagnosis of moderate to very severe COPD with a history of at least one exacerbation within the previous year requiring treatment with systemic steroids and/or antibiotics or hospitalization.

About COPD and COPD Exacerbations

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.

Exacerbations, also known as flare-ups, are a worsening of COPD symptoms, and frequent exacerbations indicate a deterioration and progression of the disease.6,7,8 They are associated with a more rapid decline in lung function over time and severe exacerbations with an increased risk of mortality, and they can severely compromise patients’ health-related quality of life.6,7,8 Economic analyses suggest that hospitalization due to COPD exacerbations accounts for 40-70 percent of all medical expenses for patients with COPD.9,10,11,12. The cost of hospitalization for COPD patients is estimated at more than $20 billion annually.13

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

Do not use SPIRIVA® HandiHaler® (tiotropium bromide inhalation powder) if you are allergic to tiotropium or ipratropium (Atrovent®). Allergic reactions may include itching,

rash, or swelling of the lips, tongue or throat.

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 the mouth using the HandiHaler device.

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 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 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.

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.

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 142 affiliates in 50 countries and more than 41,500 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 2009, Boehringer Ingelheim posted net sales of 12.7 billion euro while spending 21% of net sales in its largest business segment Prescription Medicines on research and development.

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