Exubera Demonstrated Pulmonary Safety with Blood Sugar Control in Three-Year Interim Analyses

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(BUSINESS WIRE)--Results from three-year interim analyses of two ongoing long-term clinical trials showed that small mean declines in lung function in diabetes patients who took Exubera® (insulin human [rDNA origin]) Inhalation Powder reversed when Exubera was discontinued. Upon re-initiation of Exubera, lung function changes similar to first time users of Exubera were observed. The studies also showed that patients on an Exubera regimen maintained blood sugar control and generally gained less weight over the three-year period than those on an injected insulin regimen. These data were presented today at the 67th Annual Scientific Sessions of the American Diabetes Association.

In the first two years of these studies, Exubera patients had small and non-progressive mean declines in lung function that reversed one month after discontinuing treatment. Upon re-initiation of Exubera, small changes in lung function re-appeared and were consistent with those shown in previous Exubera studies. These studies are part of the largest database of pulmonary function in patients with diabetes.

“These data further our understanding of the pulmonary profile of Exubera. This highly effective treatment option will help patients control their blood sugar levels, which is critical given the progressive nature of diabetes and the challenges related to treating and managing the disease over time,” said Dr. William Cefalu, lead investigator and Chief of the division of nutrition and chronic diseases at the Pennington Biomedical Research Center, a campus of the Louisiana State University System, in Baton Rouge.

The rates of diabetes are high and growing in almost all areas of the globe. By 2030, the World Health Organization predicts that 366 million people worldwide will have diabetes.

The ADA recognizes insulin as the most effective medication to control blood sugar, and despite this, studies have shown that people – even those poorly controlled – delay the initiation of insulin for 5 years or longer. Injection fear and anxiety are often cited as some of the key reasons to delay.

“Patients have stated that Exubera has had a positive impact on their diabetes and some of these patients have been taking Exubera for up to eight years,” said Rochelle Chaiken, M.D., vice president cardiovascular medical group leader at Pfizer. “We are committed to educating physicians and patients about the critical role that earlier insulin initiation may play in managing this disease.”

Cefalu et al Study: Type 2 Diabetes

-- The primary endpoint was to evaluate pulmonary safety in patients without underlying lung disease upon discontinuation and re-initiation of Exubera. -- 627 adults with type 2 diabetes who had stable injected insulin therapy (basal insulin, plus two or three injections of short-acting insulin) at baseline were randomized to receive either Exubera or continued injected insulin therapy for two years, followed by a six month wash-our period during which all patients received injected insulin, and subsequent re-administration of their original randomized therapy for six-months. -- Exubera was well-tolerated and this study confirmed that mean decreases in lung function as measured by FEV1 and DLco relative to comparator treatments were small, occurred early, did not progress and showed resolution one month after discontinuation of therapy. -- The study also showed the following: -- Baseline blood sugar levels (A1C) were 7.7 percent in both groups. After three years, patients in both groups had similar improvement or maintained their blood sugar levels (A1C levels of approximately 7.4 percent after 3 years). -- Patients using Exubera achieved lower fasting blood sugar levels throughout the study versus comparator. -- Patients using Exubera gained less weight (3.5 kg, 7.7 pounds) than those using injected insulin (4.1 kg, 9.1 pounds) over the three-year study period despite comparable blood sugar control. -- Adverse events were similar in both groups with the exception of cough and shortness of breath (dyspnea), which were more frequent in the Exubera group. The cough was predominantly mild, occurring shortly after dosing, decreasing over time and rarely resulted in discontinuation of treatment. -- In addition, the overall hypoglycemic and severe hypoglycemic event rates in the two studies were similar between treatment groups. Hollander et al Study: Type 1 Diabetes -- This study, with 580 adults with type 1 diabetes, had the same endpoints and methodology as the type 2 diabetes study. -- Exubera was well-tolerated, with comparable lung function

changes, and this study confirmed that mean decreases in lung function relative to comparator treatments were small, occurred early, did not progress and showed resolution one month after discontinuation of therapy. -- The study also showed the following: -- Baseline blood sugar levels (A1C) were 7.4 percent (Exubera) and 7.5 percent (injected insulin). Over three years, blood sugar control was generally well maintained (A1C levels of 7.6 percent on Exubera and 7.2 percent on injected insulin). -- Patients using Exubera gained less weight (1.6 kg, 3.5 pounds) than those using injected insulin (2.9 kg, 6.4 pounds) over the three-year study period. -- Adverse events were similar in both groups with the exception of cough, which was more frequent in the Exubera group. The cough was predominantly mild, occurring shortly after dosing and rarely resulted in discontinued treatment. In addition, the overall hypoglycemic and severe hypoglycemic event rates in the two studies were similar between treatment groups.

About Exubera

Exubera is the first inhaled form of insulin and the first insulin option in the U.S., European Union, Mexico and Brazil in 85 years that does not need to be administered by injection.

It is a rapid-acting insulin that is inhaled through the mouth prior to eating, using the handheld Exubera Inhaler. The unique Exubera® Inhaler produces a standing cloud of insulin powder, which is designed to pass rapidly into the bloodstream to regulate the body’s blood sugar levels.

In the U.S., Exubera is a prescription medicine approved for the treatment of adults with type 1 or type 2 diabetes for the control of high blood sugar levels. Patients with type 1 diabetes will still have to take some injected insulin in addition to Exubera. Some, but not all, patients with type 2 diabetes will also need to take some injected insulin in addition to Exubera.

In the European Union, Exubera is approved for the treatment of adult patients with type 2 diabetes who require insulin therapy and are not adequately controlled with diabetes pills. In patients with type 1 diabetes, Exubera should be used in combination with long or intermediate acting insulin.

Exubera is currently available in the United States, United Kingdom, Germany, Ireland, Greece, Mexico, Spain and Brazil.

Exubera is marketed by Pfizer and is a product of a developmental collaboration between Pfizer and Nektar Therapeutics.

Important Safety Information about Exubera

Exubera may lower your lung function, so you will need to take a breathing test before you start treatment and, from time to time, as you keep taking Exubera.

You should not take Exubera if you have an unstable or poorly controlled lung disease (such as unstable or poorly controlled asthma, chronic obstructive pulmonary disease) or if you smoke, start smoking, or quit smoking less than 6 months ago.

You should not take Exubera if you are under 18 years of age or if you are allergic to insulin or any of the inactive ingredients in Exubera.

Tell your health care provider about all your health and medical conditions, including if you have any lung disease or breathing problems, if you are pregnant, or plan to become pregnant.

As with all forms of insulin, a possible side effect of Exubera is low blood sugar (hypoglycemia), which can be mild to severe. It is important to check your blood sugar as your health care provider has advised you. Other common side effects are cough, dry mouth and chest discomfort.

Patients and health care providers in the U.S. can call 1-800-EXUBERA (800-398-2372) or visit www.EXUBERA.com and register to receive more information about Exubera, including the Medication Guide and the full prescribing information.

Pfizer Inc Vanessa Aristide, 212-733-3784 or 917-697-0481 or Jennifer Brendel, 212-733-9690 or 917-837-3867