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New Data Support Long-Term Efficacy and Safety in Patients Who Took Exubera for Eight Years

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A Second Exploratory Study Comparing Exubera and Lantus Assessed Daily Blood Sugar Levels in Patients with Type 2 Diabetes

(BUSINESS WIRE)--Two new studies presented today at the European Association for the Study of Diabetes (EASD) meeting reinforce the efficacy and safety of Exubera (insulin human [rDNA origin]) Inhalation Powder for adults with diabetes. An eight-year extension study showed that Exubera was well-tolerated and effective at maintaining blood sugar control. A second eight-day, exploratory study with Exubera and Lantus® (insulin glargine [rDNA origin] injection) in patients with type 2 diabetes not controlled with multiple diabetes pills showed that daily blood sugar levels were lower with Exubera at the end of treatment. These data add to the growing body of evidence that Exubera is a beneficial treatment option in the management of diabetes.

“It’s exciting that eight-year Exubera data are available so quickly after this medicine has become available to physicians and patients because it supports the safety and efficacy of Exubera,” said Dr. Mark Burge, from the University of New Mexico School of Medicine, Department of Medicine. “These data should reassure both patients and physicians that people with diabetes can use Exubera safely and effectively over an extended period. ”

Eight-Year Exubera Study

The first study assessed lung function and blood sugar control over eight years in adults with type 1 and type 2 diabetes. Patients, completing any of the three, three-month randomized phase 3 Exubera clinical trials, could enter the study and were treated with a diabetes treatment regimen (metformin and/or sulfonylurea and/or thiazolidinediones and/or injected insulin) that included Exubera (Exubera group) or that did not include Exubera (comparator group) for two years. One hundred seventy-three patients were enrolled in the Exubera group, and 44 patients were enrolled in the comparator group. When the study was extended for patients using Exubera, more than half remained in the study beyond two years, and 52 of the patients remained in the study for eight years. Lung function was measured using force expiratory volume (FEV_1) and yearly rates of decline were calculated and compared to the control group and to two databases which evaluated lung function over two and seven years in adults with diabetes.

The eight year study found that the average yearly reductions in lung function in patients using Exubera were similar to people with diabetes that were not treated with Exubera. From an initial lung function test (FEV_1) of 3,000 - 3,500 mL, yearly rates of decline were 49 mL for Exubera, 71 mL for the comparator group, and 57 mL and 71 mL for the 2 and 7 year database populations respectively. Other clinical studies for Exubera showed that average initial declines in lung function were small compared to the control group and did not progress. This study also showed that Exubera provided sustained blood sugar control throughout the eight year period. Blood sugar levels as measured by A1C were 8.5% at the beginning of the study, decreased after 3 months of therapy,

were maintained throughout the eight years ending with an A1C of 7.9%.

The most common adverse event was hypoglycaemia which decreased over time from 2.9 episodes/subject-month after 1 month of Exubera therapy to 1.7 episode/subject-month after 8 years of therapy. Over the eight years of the study, the three most common respiratory adverse events were respiratory tract infection, such as a common cold, (67.6%), cough (41.6%) and pharyngitis (sore throat) (38.2%). As can be expected in a long term trial, serious adverse events were reported. These occurred in 62 (35.8%) of patients over the eight-year period. Among the serious adverse events were coronary artery disease, degenerative joint disease, anemia, myocardial infarction and basal cell carcinoma. The study did not have a control group beyond two-years but no events occurred with consistency.

Exubera versus Lantus Exploratory Study

Because lack of mealtime, blood sugar control is the first defect in type 2 diabetes, a second exploratory study was designed to explore whether Exubera, mealtime insulin, could provide effective 24-hour blood sugar control.

In a single-site, two arm cross-over design, open label, exploratory in-patient study, 40 patients uncontrolled with multiple oral diabetes pills added either Exubera or Lantus as their first insulin. Patients' blood sugar levels were intensively monitored using an 8-pt glucose profile for five days of each treatment period and 24-hour blood sugar profiles were assessed using continuous glucose monitoring system (CGMS) technology for the final 3 days of each treatment period. Exubera and Lantus were titrated according to blood sugar levels based on prescribing information. At the end of the study period, the daily dose of Exubera was 15.1 mg (equivalent to approximately 40.1 IU) compared with 16.4 IU for Lantus.

In the final three days of the study, mealtime blood sugar levels with Exubera were lower with similar fasting blood sugar levels compared to Lantus which resulted in lower overall 24-hour blood sugar levels with Exubera. There were no differences in the blood sugar variability endpoints (SD, MAGE, MODD) between Exubera and Lantus. Additional large scale studies comparing Exubera and Lantus are on-going. No patients experienced severe adverse events with either treatment in the study. As with all forms of insulin, hypoglycemia (low blood sugar levels) was the most frequently observed adverse effect with both insulins, but was more frequent in the Exubera group than in the Lantus group (8.7 vs. 2.4 per-subject-month of exposure).

"The results of these two studies further support the role of Exubera as a first insulin option in the management of type 2 diabetes," said Dr. Rochelle Chaiken, Endocrinologist and Cardiovascular Medical Group Leader from Pfizer. "Given the progressive nature of diabetes and the challenges related to treating and managing the disease over time, we are committed to educating physicians and patients about the critical role that earlier insulin initiation may play in managing this disease."

About Diabetes

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.

Insulin is the most effective medication to control blood sugar for people with type 1 and type 2 diabetes. Because type 2 diabetes is a chronic disease which progresses over time, eventually many patients will need to administer insulin. However, many people with type 2 diabetes are reluctant to initiate insulin due to fear of injections. This delay may place them at risk for dangerous complications over the long-term.

About Exubera

Exubera is the first inhaled form of insulin and the first insulin option to be available in the U.S., United Kingdom, Germany, Ireland, Greece, Spain, Mexico, Brazil, Sweden and UAE 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 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.

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.

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

Lantus is a registered trademark of Sanofi-Aventis.

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, or 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.

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