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European Commission Approves Exubera(R) (Inhaled Human Insulin) for Treatment of Type 1 and Type 2 Diabetes

SAN CARLOS, Calif., Jan 26, 2006 (BUSINESS WIRE) -- -- First Non-Injectable, Inhaleable Insulin Approved Since the Discovery of Insulin; Simple-to-Use, Hand-Held Inhaler and Easy Option for Those Failing Other Therapies

-- New Treatment Option for People with Diabetes Who are Not Adequately Controlled with Diabetes Pills or Insulin Injections

-- Diabetes is the Fourth Leading Cause of Death Worldwide and More than 48 Million People in Europe Suffer from Diabetes- - the Most Common Cause of Blindness, Amputations, Kidney Failure, Heart Attack and Nerve Damage

Nektar Therapeutics (Nasdaq:NKTR) today reported that Pfizer Inc said that the European Commission has approved Exubera (inhaled human insulin) for the treatment of adults with type 1 and type 2 diabetes. Exubera is the first non-injectable, inhaleable form of insulin to be approved since the discovery of insulin in the 1920s, and represents a major advance in diabetes treatment.

Nektar developed the inhalers and the powdered insulin formulation for Exubera in partnership with Pfizer. Pfizer is responsible for marketing, manufacturing and the clinical development of Exubera. Nektar provides support in the manufacturing process for Exubera insulin, and manufactures the inhalation devices. Under the agreement between Nektar and Pfizer, Nektar will receive royalties on all marketed products as well as revenue for the manufacture of the powders and the inhalation devices.

In the European Union, Exubera has been approved for the treatment of adults with type 2 diabetes (greater than 18 years of age) not adequately controlled with oral antidiabetic agents and requiring insulin therapy. Exubera is also indicated for the treatment of adult patients with type 1 diabetes mellitus, in addition to long or intermediate acting injectable insulin, for whom the potential benefits of adding inhaled insulin outweigh the potential safety concerns.

Exubera is pending approval in the U.S. In September 2005, the U.S. Food and Drug Administration (FDA) Advisory Committee recommended that Exubera should be approved for the treatment of adults with type 1 and type 2 diabetes.

"Today's EU approval of Exubera is an important landmark in the treatment of diabetes, a disease that is growing at epidemic proportions," said Dr. John Patton, co-founder and chief scientific officer, Nektar. "Approval of Exubera in the EU is the next step toward the realization of the dream we had when we founded Nektar and is a testament to all of our employees whose innovation and dedication resulted in this breakthrough product."

According to the World Health Organization (WHO), diabetes has reached epidemic proportions and affects approximately 48 million people in Europe alone. People with diabetes often suffer from debilitating complications due to uncontrolled blood sugar levels including heart disease, amputation, blindness and kidney failure. The direct healthcare costs associated with diabetes are estimated to be approximately $286 billion, with the majority of these costs linked to treating diabetes-related complications.

Since its discovery more than 80 years ago, insulin has been the gold standard treatment for diabetes. In order to achieve tight blood sugar control, insulin is often administered before meals to mimic the body's natural insulin response to food. Healthcare providers and patients have been reluctant to initiate or intensify insulin therapy due to the need for daily injections.

As quoted in Pfizer's announcement today: "Exubera is a major, first-of-its-kind, medical breakthrough that marks another critical step forward in the treatment of diabetes, a disease that has taken an enormous human and economic toll worldwide," said Hank McKinnell, Pfizer chairman and chief executive officer. "The global incidence of diabetes is currently at epidemic levels. Millions of patients are not achieving or maintaining acceptable blood sugar levels, despite the availability of current therapies. Exubera meets a critical medical need by offering a highly effective and needle-free alternative to diabetes pills and insulin injections to manage this complicated, debilitating disease."

Exubera is a fast-acting powder formulation of human insulin that is inhaled into the lungs via the mouth before meals using a simple-to-use, hand-held inhaler that does not require batteries or electricity. The inhaler, which weighs four ounces and is about the size of a carrying case for a pair of eye glasses, is designed to deliver an accurate and precise dose of insulin each

time it is used.

Exubera is the result of one of the most rigorous and innovative diabetes development programs ever and Pfizer's investment now stands at more than $1 billion. Pfizer invested in two state-of-the art manufacturing facilities -- the world's largest insulin plant in Frankfurt, Germany, and a high-tech facility in Terre Haute, Indiana, U.S. -- well ahead of regulatory actions, so that the product can reach patients as quickly as possible.

The efficacy and safety profile of Exubera was studied in more than 2,500 adults with type 1 and type 2 diabetes for an average duration of 20 months. In studies in adults with type 1 or type 2 diabetes, Exubera was shown to be as effective as injectable insulin in achieving glycemic control. In adults with type 2 diabetes who are not sufficiently controlled with commonly used oral therapies, Exubera has been shown to provide greater improvements in glycemic control. In addition, patients who took Exubera reported greater overall treatment satisfaction and acceptance compared to insulin injections or oral therapies.

As quoted in Pfizer's announcement today: "This is really good news for physicians and patients. It is truly a clinical and scientific milestone -- being able to give insulin without needles," said Chantal Mathieu, Professor of Endocrinology, University of Leuven, Belgium. "Physicians face many challenges with insulin therapy due to patients' reluctance to take injections, which up until now, was the only way to take insulin. With Exubera, patients now have another opportunity to take control of their blood sugar and take an active role in managing this complicated disease."

About Exubera

To further support the effective use of Exubera, Pfizer is investing in extensive educational programs to support healthcare professionals and patients.

Exubera is a product of a collaboration between Pfizer Inc and Nektar Therapeutics. Pfizer recently reached an agreement to acquire the sanofi-aventis worldwide rights to Exubera. The two companies were previously in a worldwide alliance to co-develop, co-promote and co-manufacture Exubera.

There are two major forms of diabetes -- type 1 and type 2. In type 1, which typically develops in childhood, the insulin-producing cells in the pancreas have been destroyed leading to a complete lack of insulin. In type 2 diabetes, the most common and progressive form of the disease, the body does not effectively use nor produce enough insulin to manage blood sugar levels, and eventually most people with type 2 diabetes will need insulin to achieve blood sugar control.

Important Safety Information about Exubera

The safety profile and tolerability of Exubera have been extensively studied in clinical trials. Adverse events throughout the clinical development program were generally mild to moderate, and discontinuation rates were low.

Patients should not take Exubera if they have poorly controlled or unstable lung disease, or if they smoke or have stopped smoking less than six months prior to starting Exubera treatment. If a patient starts smoking or resumes smoking, he or she must stop using Exubera and see a health care provider about a different treatment.

Before starting treatment with Exubera, a health care provider will carry out a simple test to check lung function. The test involves exhaling into a measuring device. This will help to find out if Exubera is the right treatment for individual patients. Once a patient starts treatment, it is recommended that a health care provider should check lung function again at six months (see full prescribing information).

A small decrease in lung function may occur during Exubera treatment although symptoms might not be noticeable. This change occurs within the first months of treatment and should not worsen as treatment is continued.

Like all medicines, Exubera can cause side effects. As with all forms of insulin, a possible side effect of Exubera is low blood sugar levels.

Some patients have reported a mild cough while taking Exubera, which occurred within seconds to minutes after Exubera inhalation. Coughing occurred less frequently as patients continued to use Exubera.

Consecutive inhalation of three 1mg unit dose blisters causes a significantly higher insulin exposure than inhalation of one 3mg unit dose blister. Therefore, three 1mg unit dose blisters should not be substituted for one 3mg unit dose blister.

About Nektar

Nektar Therapeutics enables high-value, differentiated therapeutics with its industry-leading drug delivery technologies,

expertise and manufacturing capabilities. The world's top biotechnology and pharmaceutical companies are developing new and better therapeutics using Nektar's advanced technologies and know-how. Nektar also develops its own products by applying its drug delivery technologies and its expertise to existing medicines to enhance performance, such as improving efficacy, safety and compliance.

This release contains forward-looking statements that reflect management's current views as to the impact of the approval of Exubera by the EU and the regulatory process for Exubera that is currently under review by the United States Food and Drug Administration. These forward-looking statements involve substantial risks and uncertainties including, among other things, the successful completion of the conditions to closing in the Pfizer and sanofi-aventis agreement, whether and when the U.S. regulatory authorities will approve Exubera, and regulatory decisions regarding labeling and other matters that could affect Exubera's commercial potential as well as competitive developments. A further description of other important risks and uncertainties related to these forward-looking statements are detailed in Nektar's reports and other filings with the SEC, including its Annual Report on Form 10-K, as amended, for the year ended December 31, 2004 and its Quarterly Report on 10-Q for the quarter ended September 30, 2005. Actual results could differ materially from these forward-looking statements. Nektar assumes no obligation to update any forward-looking statements contained in this release as the result of new information or future events or developments that may occur after the date of this release.

NOTE TO EDITORS: As of May 2004, there are 25 member states in the EU: Austria, Belgium, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Poland, Portugal, Slovakia, Slovenia, Spain, Sweden, and the United Kingdom

SOURCE: Nektar Therapeutics

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