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## Pfizer Inc.

### Exubera Effective in Diabetes Patients who Have Respiratory Infections or are Exposed to Passive Cigarette Smoke, New Analyses Show

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Copenhagen, Denmark (ots/PRNewswire) -

@@start.tl@@ - Twice as Many People With Uncontrolled Type 2 Diabetes Would Accept Insulin if Offered Exubera, Even in Countries Where Pens are Commonly Used, Additional Study Shows

- Patients With Diabetes Gained Less Weight With Exubera Than With Injectable Insulin, According to Five Clinical Studies
- Investigator: 'Patients Taking Exubera are No More Likely to Develop a Respiratory Infection Than Patients Using Injectable Insulin.'@@end@@

Adult patients with diabetes who took Exubera(R) (insulin human [rDNA origin]) were able to safely maintain good blood sugar control even if they developed a respiratory infection or were exposed to passive (second-hand) cigarette smoke. These analyses were presented today at the 42nd European Association for the Study of Diabetes.

In addition, according to a retrospective analyses of 14 Exubera phase 2 and 3 clinical studies, Exubera was well tolerated and efficacious, even during respiratory illness in adults with type 1 or type 2 diabetes.

Another new study found that while passive smoke exposure could result in decreased absorption, Exubera could be used by patients who were exposed to a smoky environment.

"This information is important for healthcare providers who have prescribed or are considering prescribing Exubera to their patients," said Professor Philippe Camus, lead investigator from the University Medical Center, Dijon, France. "It shows that the efficacy and tolerability of Exubera remain unchanged even if patients develop a cold or the flu. Also, studies showed patients taking Exubera are no more likely to develop a respiratory infection than patients using injectable insulin."

Exubera should not be used by people who smoke or have smoked in the past six months, or by people who have underlying lung diseases such as asthma or chronic obstructive pulmonary disease.

An analysis of a previously reported study showed that Exubera has the potential to encourage twice as many people with uncontrolled Type 2 diabetes to try insulin (44 percent choosing insulin with Exubera availability versus 17 percent choosing insulin without Exubera availability). This held true even in countries where insulin pens are commonly used to administer insulin. Past studies have shown that people avoid or delay starting insulin therapy, for example due to the fear and pain of injection, even when suffering from devastating complications brought about by uncontrolled blood sugar levels.

"This finding contradicts the perception that insulin pens can overcome peoples' resistance to using insulin. If Exubera can get more people to accept insulin at all and to accept it earlier than they ordinarily might, we would expect that more people could get their blood sugars under control," said Professor Nick Freemantle, professor of clinical epidemiology and biostatistics from the University of Birmingham, U.K. "This is incredibly important in helping people to reduce their chances of suffering from the serious complications of uncontrolled diabetes such as blindness and amputations as well as for healthcare systems responsible for reducing diabetes related morbidity and mortality."

In addition, an analysis of five clinical trials showed that people with either Type 1 or Type 2 diabetes who used Exubera gained less weight than those using injectable insulin. Type 2 patients

gained less than half with Exubera (0.7 kg vs. 1.6 kg), while the difference was even greater for Type 1 patients (0.2 kg with Exubera vs. 1.1 kg with injected insulin).

"Many of my patients worry about weight gain with insulin," said Dr. Priscilla Hollander, lead investigator from Baylor University Medical Center, Dallas, U.S. "This analysis reassures me that people who need insulin will not gain as much weight if they use Exubera. This may be another reason for physicians and their patients to consider Exubera to control blood sugar levels."

#### About Exubera

Exubera is the first inhaled form of insulin and the first insulin option in the European Union, U.S., Brazil, and Mexico in more than 80 years that does not need to be administered by injection. Exubera is currently available in the U.S., United Kingdom, Ireland, and Germany.

It is a fast-acting powdered insulin that is inhaled through the mouth prior to eating, using the handheld Exubera(R) Inhaler. The unique Exubera Inhaler produces a visible 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, for whom the potential benefits of adding inhaled insulin outweigh the potential safety concerns.

In the U.S., Exubera is approved for the treatment of adults with type 1 or type 2 diabetes for the control of high blood sugar levels. In patients with type 2 diabetes, Exubera can be used alone or in combination with diabetes pills or longer-acting insulin. In patients with type 1 diabetes, Exubera should be used in combination with a longer-acting insulin.

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

#### Important Safety Information about Exubera

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.

In clinical trials, mean treatment group differences between Exubera and comparator showed that Exubera was associated with small, nonprogressive declines in lung function relative to comparator treatments.

Before starting treatment with Exubera, a healthcare professional will carry out a simple test to check lung function. 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 check lung function again at six months and yearly thereafter.

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 tended to occur within seconds to minutes after Exubera inhalation. Coughing occurred less frequently as patients continued to use Exubera.

For more information about Exubera visit <http://www.Exubera.com>

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