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Pfizer Statement on Exubera Labeling Update in the United States

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<(BUSINESS WIRE)--Pfizer Inc said today that it updated the US product labeling for EXUBERA® (insulin human [rDNA original]) Inhalation Powder to include a warning with safety information about lung cancer cases observed in patients who used Exubera.

This update is based on an ongoing review of the data from the Exubera clinical trial program and post-marketing experience by Pfizer and the Food and Drug Administration (FDA). Since the inception of the program, Pfizer has continuously monitored respiratory safety. Over the course of the clinical trial program, 6 of the 4,740 Exubera-treated patients versus 1 of the 4,292 patients not treated with Exubera developed lung cancer. In addition there was a post-marketing report of lung cancer in one Exubera-treated patient. The update to the labeling states that all patients who developed lung cancer had a prior history of cigarette smoking, and that there were too few cases to determine whether the development of lung cancer is related to the use of Exubera.

“Pfizer is vigilant in monitoring adverse drug reports for all its products, including Exubera, which has shown in clinical trials to be a safe and effective medicine in the treatment of adults with type 1 or type 2 diabetes,” said Joe Feczko, MD Pfizer’s Chief Medical Officer.

Pfizer announced in October 2007 that it would stop marketing Exubera because it did not meet customers’ needs or the company's financial expectations. Nektar Therapeutics announced today that it has stopped its search for a new marketing partner. Pfizer will be discussing the timing of marketing authorization withdrawals with regulatory agencies.

“Some patients continue to take Exubera, including those enrolled in extended transition programs or clinical trials. We are working closely with patients and their physicians to ensure the continued orderly transition from Exubera to alternative therapies. Physicians should seek alternate treatment options to maintain patients’ glycemic control,” said Dr. Feczko.

Pfizer remains committed to helping diabetes patients and their doctors manage the many conditions that are associated with diabetes, including heart disease and DPN (diabetic peripheral neuropathy). Pfizer is developing new treatments for diabetes, an area of huge unmet medical need. Our R&D portfolio spans the width of the diabetes continuum, from genetic susceptibility at birth to the onset of devastating complications.

Diabetes currently affects an estimated 230 million people worldwide and nearly 21 million in the U.S. Despite the existence of available therapies for diabetes, millions of patients do not achieve or maintain acceptable blood sugar levels which can leave them at increased risk for the complications of diabetes.

Exubera is a prescription medicine that you breathe in through your mouth using the Exubera® Inhaler. It is a short-acting insulin that helps to control high blood sugar in adults with diabetes. If you have Type 1 diabetes, Exubera should be taken with longer-acting insulin. If you have Type 2 diabetes, Exubera may be used by itself

or with diabetes pills. Some patients with Type 2 diabetes will need to take some longer-acting insulin in addition to Exubera.

For additional information about Exubera, please see Exubera.com

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