

Inhaled Insulin Moves One Step Closer to FDA Approval

A needleless insulin delivery option may enhance compliance for many resistant patients.

The first inhaled form of insulin has moved closer to becoming a reality for millions of people with diabetes who are seeking an alternative to their daily routine of injections.

The Food and Drug Administration's (FDA) Endocrinologic and Metabolic Drugs Advisory Committee voted 7 to 2 to recommend approval of Exubera in adults with either type 1 or type 2 diabetes. The vote was despite questions from the panel regarding the the agent's use in patients with lung disease or those exposed to secondhand smoke.

Exubera was developed by Pfizer in a partnership with Sanofi-Aventis of France, and Nektar Therapeutics, a California biotechnology firm. The data Pfizer presented to the FDA showed Exubera was equivalent to injected insulin in controlling blood sugar.

The company's medical consultants argued that approval of this novel product would enhance public health by encouraging more people to use insulin, thus leading to better blood sugar control and fewer long-term complications in patients suffering with diabetes.

"Inhaled insulin would be more acceptable for some patients," said Eugene Barrett, MD, PhD, immediate past-president of the American Diabetes Association and director of the Diabetes Center at the University of Virginia Health System, in an interview earlier this year. Researchers have shown in studies that patients

who refuse to take injected insulin will take the inhaled form.

There is a resistance to use of insulin at least partly because people fear needles, said William T. Cefalu, MD,

a professor at Louisiana State University, who spoke in behalf of Pfizer. While fewer than one-third of diabetic patients use insulin, more could potentially benefit from an inhaled formulation. Two-thirds of diabetic patients have blood glucose levels that remain poorly controlled, he said.

Some patients who took the inhaled insulin in clinical trials complained of coughing and a small decrease in breathing capacity. Pfizer representa-

tives said that they recognize the need to assess the long-term effects on pulmonary function.

Inhaled insulin could be used to manage blood sugar levels in patients with either type 1 or type 2 diabetes who need insulin injections before meals. It would not replace longer-acting insulin injections that patients with type 1 diabetes take in the morning or before bed, according to FDA documents.

Exubera would be inhaled from a flashlight-sized device that creates a cloud of powdered insulin. It closely mimics the normal physiological insulin response to meals by quickly being absorbed into the bloodstream and reduced meal-related spikes in glucose levels in people with diabetes. ■



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