



Lilly Receives Complete Response Letter From FDA for Liprotamase for the Treatment of Exocrine Pancreatic Insufficiency

INDIANAPOLIS, April 15, 2011 /PRNewswire/ -- Eli Lilly and Company (NYSE: LLY) has received a complete response letter from the U.S. Food and Drug Administration (FDA) for its New Drug Application (NDA) for liprotamase, a non-porcine pancreatic enzyme replacement therapy (PERT), under investigation for the treatment of exocrine pancreatic insufficiency (EPI).

The complete response letter communicated the need for Lilly to conduct an additional clinical trial prior to a re-submission.

"Lilly is looking forward to further discussion with the FDA to address the items outlined in the letter and provide the requested information as quickly as possible," said Eiry Roberts, M.D., Vice President, Autoimmune, Bone-Muscle-Joint, Liprotamase Product Development at Lilly. "We are committed to working with the Agency and the cystic fibrosis community to make this important treatment option available to patients."

People with EPI have very low levels or none of the key digestive enzymes made by the pancreas - lipase, amylase and protease - in their small intestine, resulting in improper digestion and absorption of fat, carbohydrates and proteins, often requiring treatment with PERTs. EPI occurs very frequently in patients with cystic fibrosis (a life-threatening genetic disorder) and in other diseases including chronic pancreatitis and pancreatectomy.

About Liprotamase

Liprotamase is an oral, non-porcine (not made from harvesting the pancreas of pigs), biotechnology-derived, pancreatic enzyme replacement therapy (PERT) developed to treat patients with EPI associated with cystic fibrosis, chronic pancreatitis and pancreatectomy.

About Eli Lilly and Company

Lilly, a leading innovation-driven corporation, is developing a growing portfolio of pharmaceutical products by applying the latest research from its own worldwide laboratories and from collaborations with eminent scientific organizations. Headquartered in Indianapolis, Ind., Lilly provides answers — through medicines and information — for some of the world's most urgent medical needs. Additional information about Lilly is available at www.lilly.com.

This press release contains forward-looking statements about liprotamase for the treatment of exocrine pancreatic insufficiency (EPI). It reflects Lilly's current beliefs; however, as with any such undertaking, there are substantial risks and uncertainties in the process of drug development and commercialization. There is no guarantee that liprotamase will be approved by the FDA on the anticipated timeline or at all, or that it will be commercially successful. For further discussion of these and other risks and uncertainties, please see Lilly's latest Forms 10-Q and 10-K filed with the U.S. Securities and Exchange Commission. The companies undertake no duty to update forward-looking statements.

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