Statement From Lilly on FDA Advisory Committee Recommendation Regarding Liprotamase New Drug Application for Treatment of Exocrine Pancreatic Insufficiency

INDIANAPOLIS, Jan. 12, 2011 /PRNewswire/ -- Eli Lilly and Company (NYSE: LLY) announced the U.S. Food and Drug Administration (FDA) Gastrointestinal Drugs Advisory Committee voted today to recommend non-approval of liprotamase, a non-porcine pancreatic enzyme replacement therapy (PERT), currently under FDA review for the treatment of exocrine pancreatic insufficiency (EPI).

During the meeting, the committee had questions about the degree of efficacy of liprotamase and recommended that additional studies be conducted prior to considering approval of liprotamase for EPI.

"We appreciate the feedback the committee has provided, and we will continue to work with the FDA to address the questions raised in the meeting as the agency moves toward a final decision on the application," said Eiry Roberts, M.D., Vice President, Autoimmune, Bone-Muscle-Joint, Liprotamase Product Development at Lilly. "We remain confident in the clinical trial data package submitted to the FDA in support of the liprotamase application."

The FDA is not required to follow the recommendation of its advisory committees.

About Liprotamase & Pancreatic Enzyme Replacement Therapy

Liprotamase is an oral, non-porcine, pancreatic enzyme replacement therapy (PERT) under FDA review for the treatment of exocrine pancreatic insufficiency associated with cystic fibrosis and pancreatectomy. PERT is a treatment involving the oral administration of pancreatic enzyme replacements, which include protease, amylase and lipase.

Patients with EPI cannot properly digest and absorb nutrients including fat, protein and carbohydrates. Causes of EPI include cystic fibrosis (a life-threatening genetic disorder), chronic pancreatitis and pancreatectomy (surgical removal of the pancreas).

Cystic fibrosis affects approximately 30,000 children and adults in the United States and nearly 100,000 people worldwide. Approximately 90 percent of cystic fibrosis patients receive PERT.

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 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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