Lilly Provides Its Perspective in Response to Amylin Lawsuit

INDIANAPOLIS, May 16, 2011 /PRNewswire/ -- Eli Lilly and Company (NYSE: LLY) has provided additional perspective in response to Amylin Pharmaceuticals, Inc.'s lawsuit filed in the United States District Court for the Southern District of California. The lawsuit alleges that Lilly is not using commercially reasonable efforts to support the success of BYETTA® (exenatide injection) and ultimately, BYDUREON™ (exenatide extended-release for injectable suspension).

"We emphatically reject the allegation that we did not meet our contractual obligations under the Lilly and Amylin alliance," said Enrique Conterno, president of Lilly Diabetes. "Lilly has been and remains fully committed to fulfilling its obligations under its exenatide collaboration agreement with Amylin as well as to complying with all laws and regulations."

More options for patients — Given that diabetes is a complex and chronic condition, patients and their health care providers need choices throughout the progression of the disease. Our strategy in Lilly Diabetes is to offer a broad range of treatment options.

Our pursuit of this strategy through collaborations with partners such as Amylin and Boehringer Ingelheim allows us to educate physicians more effectively and efficiently about a broad range of treatment options. Contrary to the suggestions in Amylin's complaint, Lilly's actions encourage competition and benefit diabetes patients for whom there is significant unmet need today.

Regarding BYETTA and Tradjenta™ (linagliptin) tablets, our broad market experience teaches us that injectables like BYETT generally compete with other injectable treatments in the class rather than with oral anti-diabetic agents.

No breach of contract — The Lilly and Amylin alliance contract specifically provides for Lilly's ability to develop and market a full range of diabetes treatment options for patients.

Since the alliance's inception in 2002, Lilly has upheld its obligations (including those related to confidentiality) under the various Amylin alliance agreements. Lilly has devoted significant talent, resources, and know-how to the alliance's efforts and has been instrumental in the success of the marketed medicine BYETTA and in the development of BYDUREON.

We greatly value our collaborative alliance with Amylin and are extremely proud of our work in bringing BYETTA to market and in developing BYDUREON. BYETTA is an important treatment option for health care professionals and their patients with type 2 diabetes.

Lilly's commitment — We are dedicated to patients, health care professionals and all our partners who help us achieve our mission of making medicines that help people live longer, healthier, more active lives.

About BYETTA® (exenatide) injection

BYETTA was the first glucagon-like peptide-1 (GLP-1) receptor agonist to be approved by the FDA for the treatment of type 2 diabetes. BYETTA exhibits many of the same effects as the human incretin hormone GLP-1. GLP-1 improves blood sugar after food intake through multiple effects that work in concert on the stomach, liver, pancreas and brain.

BYETTA is an injectable prescription medicine that may improve blood sugar (glucose) control in adults with type 2 diabetes mellitus, when used with a diet and exercise program. BYETTA is not insulin and should not be taken instead of insulin. BYETTA is not currently recommended to be taken with insulin. BYETTA is not for people with type 1 diabetes or people with diabetic ketoacidosis. BYETTA has not been studied in people who have pancreatitis.

BYETTA provides sustained A1C control and low incidence of hypoglycemia when used alone or in combination with metformin or a thiazolidinedione, with potential weight loss (BYETTA is not a weight-loss product). BYETTA was approved in the U.S. in April 2005 and in Europe in November 2006 and has been used by more than 1.8 million patients since its introduction. See important safety information below. Additional information about BYETTA is available at www.BYETTA.com.

Important Safety Information for BYETTA® (exenatide) injection

Based on postmarketing data BYETTA has been associated with acute pancreatitis, including fatal and non-fatal hemorrhagic or necrotizing pancreatitis. Patients should be observed for signs and symptoms of pancreatitis after initiation or dose

escalation of BYETTA. The risk for getting low blood sugar is higher if BYETTA is taken with another medicine that can cause low blood sugar, such as a sulfonylurea. BYETTA should not be used in people who have severe kidney problems and should be used with caution in people who have had a kidney transplant. Patients should talk with their healthcare provider if they have severe problems with their stomach, such as delayed emptying of the stomach (gastroparesis) or problems with digesting food. Antibodies may develop with use of BYETTA. Patients who develop high titers to exenatide could have worsening or failure to achieve adequate glycemic control. Consider alternative therapy if this occurs. Severe allergic reactions can happen with BYETTA. There have been no clinical studies establishing conclusive evidence of macrovascular risk reduction with BYETTA or any other antidiabetic drug.

The most common side effects with BYETTA include nausea, vomiting, diarrhea, dizziness, headache, feeling jittery, and acid stomach. Nausea most commonly happens when first starting BYETTA, but may become less over time.

These are not all the side effects from use of BYETTA. A healthcare provider should be consulted about any side effect that is bothersome or does not go away.

For additional important safety information about BYETTA, please see the full Prescribing Information (www.byetta.com/pi) and Medication Guide (www.byetta.com/mg).

What are TRADJENTA tablets?

TRADJENTA is a prescription medicine that is used along with diet and exercise to lower blood sugar in adults with type 2 diabetes.

TRADJENTA is not for people with type 1 diabetes or for people with diabetic ketoacidosis (increased ketones in the blood or urine).

It is not known if TRADJENTA is safe and effective when used with insulin.

Important Safety Information

Who should not take TRADJENTA?

Do not take TRADJENTA if you are allergic to linagliptin or any of the ingredients in TRADJENTA.

Symptoms of a serious allergic reaction to TRADJENTA are rash, raised red patches on your skin (hives), swelling of your face, lips, and throat that may cause difficulty breathing or swallowing. If you have any symptoms of a serious allergic reaction, stop taking TRADJENTA and call your doctor right away.

What should I tell my doctor before taking TRADJENTA?

Tell your doctor about all the medicines you take, including prescription and non-prescription medicines, vitamins, and herbal supplements.

Tell your doctor if you take other medicines that can lower your blood sugar, such as a sulfonylurea or insulin. If you take TRADJENTA with another medicine that can cause low blood sugar (hypoglycemia), such as a sulfonylurea or insulin, your risk of getting low blood sugar is higher. The dose of your sulfonylurea medicine or insulin may need to be lowered while you take TRADJENTA. Signs and symptoms of low blood sugar may include headache, drowsiness, weakness, dizziness, confusion, irritability, hunger, fast heart beat, sweating, or feeling jittery.

Also tell your doctor if you take rifampin (Rifadin®, Rimactane®, Rifater®, Rifamate®), an antibiotic that is used to treat tuberculosis.

TRADJENTA may affect the way other medicines work, and other medicines may affect how TRADJENTA works.

Tell your doctor if you are pregnant or planning to become pregnant or are breastfeeding or plan to breastfeed.

What are the possible side effects of TRADJENTA?

The most common side effects of TRADJENTA include stuffy or runny nose and sore throat.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

For more safety information, please see Patient Information and full Prescribing Information.

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 exenatide and our alliance with Amylin, and it reflects Lilly's current beliefs. There are substantial risks and uncertainties in the process of drug development and commercialization. There is no guarantee that future study results and patient experience will be consistent with study findings to date or that Bydureon will be approved. There is also no guarantee that Byetta will continue to be, or that Bydureon will prove to be, commercially successful. We cannot predict the outcome of any litigation with Amylin or its effect on our collaboration. For further discussion of risks and uncertainties, please see Lilly's latest Forms 10-Q and 10-K filed with the U.S. Securities and Exchange Commission. Lilly undertakes no duty to update forward-looking statements.

C-LLY

(Logo: http://photos.prnewswire.com/prnh/20031219/LLYLOGO)

SOURCE Eli Lilly and Company