Exenatide Once Weekly New Drug Application Review Extended by FDA Due to Weather-Related Closure

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SAN DIEGO & INDIANAPOLIS & WALTHAM, Mass., Feb 25, 2010 (BUSINESS WIRE) -- Amylin Pharmaceuticals, Inc. (Nasdaq: AMLN), Eli Lilly and Company (NYSE: LLY) and Alkermes, Inc. (Nasdaq: ALKS) today confirmed that the U.S. Food and Drug Administration (FDA) has set a new Prescription Drug User Fee Act (PDUFA) action date of March 12 for its review of the exenatide once weekly new drug application (NDA). The revised action date is the result of the FDA's decision to allow five additional days for its review of pending regulatory applications following the agency's recent five-day weather-related closure.

Exenatide once weekly is an investigational, extended-release medication for type 2 diabetes designed to deliver continuous therapeutic levels of exenatide in a single weekly dose. The NDA for exenatide once weekly was submitted in May 2009 and accepted by the FDA in July 2009.

Additional information about weather-related delays is available in a press release on the FDA's Web site: http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm200361.htm.

About Amylin, Lilly and Alkermes

Amylin, Lilly and Alkermes are working together to develop exenatide once weekly, a subcutaneous injection of exenatide for the treatment of type 2 diabetes based on Alkermes' proprietary Medisorb® technology for long-acting medications. Exenatide once weekly is not currently approved by any regulatory agencies.

Amylin Pharmaceuticals is a biopharmaceutical company dedicated to improving lives of patients through the discovery, development and commercialization of innovative medicines. Amylin's research and development activities leverage the Company's expertise in metabolism to develop potential therapies to treat diabetes and obesity. Amylin is headquartered in San Diego, California.

Through a long-standing commitment to diabetes care, Lilly provides patients with breakthrough treatments that enable them to live longer, healthier and fuller lives. Since 1923, Lilly has been the industry leader in pioneering therapies to help healthcare professionals improve the lives of people with diabetes, and research continues on innovative medicines to address the unmet needs of patients.

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, Indiana, Lilly provides answers - through medicines and information - for some of the world's most urgent medical needs.

Alkermes, Inc. is a fully integrated biotechnology company committed to developing innovative medicines to improve patients' lives. Alkermes' robust pipeline includes extended-release injectable, pulmonary and oral products for the treatment of prevalent, chronic diseases, such as central nervous system disorders, addiction and diabetes. Headquartered in Waltham, Massachusetts, Alkermes has a research facility in Massachusetts and a commercial manufacturing facility in Ohio.

SOURCE: Alkermes, Inc. and Amylin Pharmaceuticals, Inc. and Eli Lilly and Company

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