Amylin, Lilly and Alkermes Announce Preliminary Phase 2 Results and Submission Of IND for Exenatide LAR (Sustained Release) Program in Type 2 Diabetes

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SAN DIEGO, INDIANAPOLIS and CAMBRIDGE, Mass., Mar 19, 2003 /PRNewswire via COMTEX/ -- Amylin Pharmaceuticals, Inc., (Nasdaq: AMLN), Eli Lilly and Company (NYSE: LLY) and Alkermes, Inc. (Nasdaq: ALKS) today announced preliminary pharmacokinetic results from the first Phase 2 study of exenatide LAR, formerly referred to as AC2993 LAR. The results from this study verify that sustained levels of exenatide are possible and support the continuation of the Phase 2 program. Based on these data and previous clinical results, an Investigational New Drug application (IND) has been submitted to the FDA to support an independent development program for exenatide LAR. Previous clinical work has been performed under the existing IND for the twice-daily formulation of exenatide.

The goal of the exenatide LAR program is to develop a sustained release, subcutaneous injection of exenatide (synthetic exendin-4) for the treatment of type 2 diabetes. Exenatide LAR is based on Alkermes' proprietary Medisorb(R) injectable sustained release drug delivery technology.

"We continue to make progress with sustained release formulations of exenatide," said Alain D. Baron, MD, Senior Vice President, Clinical Research at Amylin Pharmaceuticals, Inc. "Additional activities are now underway to optimize the formulation and manufacturing process in preparation for additional Phase 2 work planned for later this year."

"The exenatide LAR program utilizing Alkermes' technology could offer people with type 2 diabetes an alternative to frequent injections," said Elizabeth Klimes, President of Diabetes and Growth Disorders at Lilly.

Exenatide, formerly referred to as AC2993, is being studied for its potential to address important unmet medical needs of people with type 2 diabetes. Clinical trials suggest that exenatide decreases blood glucose toward normal levels. This control of blood glucose is likely due to some of the actions of exenatide that are similar to those of the native incretin hormone GLP-1. These actions include glucose-dependent stimulation of insulin secretion, suppression of glucagon secretion and slowing of gastric emptying.

In September 2002, Amylin and Eli Lilly and Company announced a global agreement to collaborate on the development and commercialization of exenatide.

Amylin Pharmaceuticals, headquartered in San Diego, California, is a biopharmaceutical company dedicated to developing innovative medicines to improve the lives of people with metabolic diseases. The Company's two late-stage, first-in-class diabetes product candidates -- SYMLIN(R) (pramlintide acetate) and exenatide (synthetic exendin-4) -- are being developed to address the global epidemic of diabetes. Amylin has a strategic alliance with Eli Lilly and Company for the co-development and global commercialization of exenatide and an extended release formulation, exenatide LAR. Building on its experience in the diabetes field, Amylin is developing candidates for cardiovascular disease and obesity by utilizing its research experience in the metabolic components common to the three areas. Further information on Amylin and its pipeline in metabolism is available at www.amylin.com .

Lilly, a leading innovation-driven corporation, is developing a growing portfolio of best-in-class 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 .

Alkermes, Inc. is an emerging pharmaceutical company developing products based on its sophisticated drug delivery technologies to enhance therapeutic outcomes. Alkermes' areas of focus include: controlled, extended-release of injectable drugs utilizing its ProLease(R) and Medisorb(R) delivery systems and the development of inhaled pharmaceutical products based on its proprietary Advanced Inhalation Research, Inc. ("AIR(R)") pulmonary delivery system. Alkermes' business strategy is twofold. Alkermes partners its proprietary technology systems and drug delivery expertise with many of the world's finest pharmaceutical companies and also develops novel, proprietary drug candidates for its own account. In addition to Alkermes' Cambridge, Massachusetts headquarters, research and manufacturing facilities, it operates research and manufacturing facilities in Ohio.

This press release contains forward-looking statements, which involve risks and uncertainties. Actual results could differ materially from those forward-looking statements discussed in this press release. There can be no assurance that future clinical trials will confirm the preliminary results referred to in this release or that exenatide or exenatide LAR will receive regulatory approvals or prove to be commercially successful. There can also be no assurance that the regulatory filings will proceed on the current timetable. Additional risks and uncertainties are described more fully in Amylin's most recently filed SEC documents, such as its Annual Report on Form 10-K for the fiscal year ended December 31, 2001 under the heading "Risk Factors," its Quarterly Reports on Form 10-Q, and the "Risk Factors" in its recently filed registration statement on Form S-3.

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

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