Alkermes and Lilly Announce Agreement for the Development and Commercialization of Inhaled Parathyroid Hormone for the Treatment of Osteoporosis

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CAMBRIDGE, Mass. and INDIANAPOLIS, Jan 09, 2006 (BUSINESS WIRE) -- Alkermes, Inc. (Nasdaq: ALKS) and Eli Lilly and Company (NYSE: LLY) announced today that they have signed an agreement to develop and commercialize inhaled formulations of parathyroid hormone (PTH). The development program will utilize the Alkermes AIR(R) pulmonary drug delivery system. Lilly's recombinant PTH, Forteo(R) (teriparatide (rDNA origin) injection), was approved in 2002 by the Food and Drug Administration (FDA) for the treatment of osteoporosis in postmenopausal women who are at high risk for bone fracture and to increase bone mass in men with primary or hypogonadal osteoporosis who are at high risk for fracture. The agreement was signed after completing extensive feasibility work.

Under the terms of the agreement, Alkermes will receive funding for product and process development activities and upfront and milestone payments. Lilly will have exclusive worldwide rights to products resulting from the collaboration and will pay Alkermes royalties based on product sales.

Alkermes and Lilly will form a joint development team and will share responsibility for executing the overall development strategy for inhaled PTH. Alkermes will have responsibility for nonclinical development activities, primarily formulation testing and device development. Lilly will have responsibility for all other nonclinical development activities as well as all clinical development and regulatory activities.

"Expanding our partnership with Lilly to include the development and commercialization of parathyroid hormone provides an opportunity to leverage the experience we have gained from our inhaled insulin and human growth hormone collaborations," stated Richard Pops, CEO of Alkermes. "In addition, we believe this partnership underscores the value of the Alkermes AIR technology system, which is designed to provide patients with a simple method of delivery across a variety of diseases that may enhance treatment outcomes."

"We look forward to expanding our collaboration with Alkermes to benefit patients with osteoporosis," said Patricia A. Martin, Executive Director of Osteoporosis Products for Lilly. "We believe that the Alkermes technology has the potential to increase compliance and ultimately improve clinical outcomes for patients with osteoporosis."

The partnership announced today to develop and commercialize PTH marks the third collaboration between Alkermes and Lilly to develop medicines based on Alkermes' AIR pulmonary drug delivery technology, which utilizes a small, easy-to-use inhaler designed to reliably deliver a broad range of doses. In 2000, the companies established an alliance for the development of an inhaled formulation of human growth hormone (hGH), currently in Phase I clinical development. In 2001, the companies entered an agreement to develop an inhaled insulin system that delivers human insulin inhalation powder (known as HIIP). Lilly and Alkermes began Phase III clinical studies with HIIP in July 2005.

About Alkermes, Inc.

Alkermes, Inc. is a pharmaceutical company that develops products based on sophisticated drug delivery technologies to enhance therapeutic outcomes in major diseases. The Company's lead commercial product is the first and only long-acting atypical antipsychotic medication approved for use in schizophrenia. The Company's lead proprietary product candidate, VIVITROL(TM) (naltrexone for extended-release injectable suspension), is being developed as a once-monthly injection for the treatment of alcohol dependence. The Company has a pipeline of extended-release injectable products and pulmonary drug products based on its proprietary technology and expertise. Alkermes' product development strategy is twofold: the Company partners its proprietary technology systems and drug delivery expertise with several of the world's finest pharmaceutical companies and it also develops novel, proprietary drug candidates for its own account. The Company's headquarters are in Cambridge, Massachusetts, and it operates research and manufacturing facilities in Massachusetts and Ohio.

About Lilly

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

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This press release contains forward-looking statements about the investigational inhaled formulation of recombinant PTH, Forteo(R) for the potential treatment of osteoporosis and the Alkermes AIR technology, and reflects Lilly's and Alkermes' current beliefs. However, as with any pharmaceutical product under development, there are substantial risks and uncertainties in the process of development and regulatory review. There is no guarantee that clinical trials for the product, if commenced, will be completed, that the product will receive regulatory approvals, or that the regulatory approval will be for the indication(s) anticipated by the companies. For further discussion of these and other risks and uncertainties, see Lilly's and Alkermes' filings with the United States Securities and Exchange Commission. Lilly and Alkermes undertake no duty to update forward-looking statements.

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