Alkermes and Lilly Announce Successful Completion of Early-Phase Clinical Trial for Inhaled Form of Human Growth Hormone

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CAMBRIDGE, Mass., Jan 8, 2002 (BW HealthWire) -- Alkermes, Inc., (NASDAQ: ALKS) and Eli Lilly and Company (NYSE: LLY) announced today the decision to move forward with multiple-dose Phase I studies for inhaled human growth hormone following the successful completion of a single dose Phase I clinical trial. The study was based on Alkermes' AIR(TM) pulmonary drug delivery system and was conducted with Lilly, the company's partner in the development of an inhaled formulation of human growth hormone.

The study was conducted in healthy volunteers and was designed to test safety, tolerability and pharmacokinetics. The findings demonstrated encouraging pulmonary bioavailability and the formulation was well tolerated.

Specific results from the trial are planned for scientific release at a later date.

"We believe these clinical results provide evidence that Alkermes' AIR pulmonary drug delivery system can deliver high molecular weight proteins for systemic delivery," said James Wright, Ph.D., Senior Vice President, Research and Development at Alkermes. "It is particularly noteworthy that we reached relevant blood levels of human growth hormone."

In February 2000, Alkermes and Lilly signed a broad, mutually exclusive agreement to develop an inhaled formulation of human growth hormone based on Alkermes' AIR pulmonary drug delivery system.

About Alkermes

Alkermes' AIR drug delivery system is based on a novel concept, published in Science magazine in 1997, that relatively large, low-density drug particles can be inhaled into the lungs with high efficiency from simple inhalers. These particles have distinct physical characteristics with several potential advantages over other inhalation delivery systems. The AIR system utilizes a small, convenient delivery device, can deliver a wide range of drug doses, and has the potential to provide sustained-release drug delivery.

Alkermes is a leader in the development of products based on sophisticated drug delivery technologies. We have several areas of focus, including (i) controlled, sustained-release of injectable drugs lasting several days to several weeks, using our ProLease(R) and Medisorb(R) technologies and (ii) the development of pharmaceutical products based on our proprietary AIR pulmonary technology. In addition to our Cambridge, Massachusetts, headquarters, research and manufacturing facilities, Alkermes operates research and manufacturing facilities in Ohio and a medical affairs office in Cambridge, England. Additional information about Alkermes is available at www.alkermes.com.

About Eli Lilly and Company

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, IN, 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.

Certain statements set forth above may constitute forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Although we believe that such statements are based on reasonable assumptions within the bounds of our knowledge of our business and operations, there can be no assurance that: (i) clinical trials of our product candidates will be permitted by regulatory authorities, be successful and completed on a timely basis, if at all, (ii) our partners will continue development of any product candidate to the point of receiving marketing approval from regulatory authorities, or (iii) our product candidates, if approved, will be commercialized successfully.

Alkermes' business is subject to significant risks and there can be no assurance that actual results of its development activities and its results of operations will not differ materially from its expectations. For information with respect to other factors that could cause actual results to differ from expectations, reference is made to the reports filed by Alkermes with the Securities and Exchange Commission under the Securities Exchange Act of 1934, as amended.

CONTACT:	Alkermes, Inc.	Eli Lilly and Company
	Rebecca Peterson	Greg Kueterman
	(617) 583-6378	(317) 433-6067