# Alkermes Announces Receipt by Johnson & Johnson Pharmaceutical Research & Development of Non-Approvable Letter for Risperdal Consta

July 1, 2002

CAMBRIDGE, Mass., Jul 1, 2002 (BW HealthWire) -- Alkermes, Inc. (Nasdaq: ALKS) today announced that Johnson & Johnson Pharmaceutical Research & Development, LLC has received a non-approvable letter from the U.S. Food and Drug Administration (FDA) related to its New Drug Application (NDA) for Risperdal Consta(TM) (risperidone) long-acting injection.

"One of the strengths of our business model is the quality of the pharmaceutical companies with whom we collaborate," said Richard Pops, Chief Executive Officer of Alkermes. "Johnson & Johnson is one of the world's leading health care companies. We have great confidence in relying on their ability and judgment in dealing with regulatory authorities around the world."

Risperdal Consta is a long-acting injectable formulation of Risperdal(R) that uses Alkermes' Medisorb(R) drug-delivery technology. If approved, Risperdal Consta will be manufactured by Alkermes and the product will be marketed by Janssen Pharmaceutica Products, L.P. in the United States, Janssen-Ortho in Canada and Janssen-Cilag elsewhere.

"Alkermes' business is based on multiple drug delivery technologies and multiple product candidates with independent opportunities for commercial success," said Richard Pops. "We are very committed to the success of Risperdal Consta. The ultimate success of our business, however, is not dependent solely upon it. We have a unique combination of personnel, technologies, financial resources and an operating plan that enables us to develop a broad pipeline of product candidates."

Alkermes' Business

Alkermes has more than ten product candidates in various stages of development, in collaboration with pharmaceutical companies and for our own account. Each of these product candidates is based on the application of one of Alkermes' three proprietary drug delivery technologies.

In addition to Risperdal Consta, the five most advanced product candidates in Alkermes' disclosed pipeline are:

Nutropin Depot(TM). Nutropin Depot is an injectable, extended-release formulation of recombinant human growth hormone developed in collaboration with Genentech, Inc. Nutropin Depot was launched in the U.S. by Genentech in June 2000 for pediatric growth hormone deficiency. A Phase III clinical trial of Nutropin Depot in growth hormone deficient adults is currently underway.

Vivitrex(TM). Vivitrex is an injectable, extended-release formulation of naltrexone, an FDA-approved drug used for the treatment of alcohol and opioid dependence that is currently available in daily oral dosage form. Vivitrex, a proprietary product candidate of Alkermes based on its Medisorb drug delivery technology, is designed to provide once-a-month dosing to enhance patient adherence by removing the need for daily dosing. A Phase III clinical trial of Vivitrex in alcohol-dependent patients is currently underway.

r-hFSH (recombinant human follicle stimulating hormone). Alkermes and Serono S.A. are collaborating on the development of an injectable, extended-release formulation of r-hFSH based on Alkermes' ProLease drug delivery technology for the treatment of infertility. This product candidate has completed a Phase I study and further clinical studies are planned.

AC2993 LAR (synthetic Exendin-4). Alkermes and Amylin Pharmaceuticals, Inc. are collaborating on the development of an injectable, extended-release formulation of AC2993 based on Alkermes' Medisorb drug delivery technology for use in the treatment of diabetes. A Phase I clinical trial has been completed and a Phase II clinical trial is currently underway.

Inhaled Insulin. Alkermes and Eli Lilly and Company are collaborating on the development of inhaled formulations of insulin for the treatment of diabetes. These product candidates are based on Alkermes' proprietary pulmonary drug delivery technology, AIR. Multiple early stage clinical trials have been completed and additional clinical development is ongoing.

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

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, various factors may cause our actual results to differ materially for our expectations. These include: whether regulatory approvals will be received for Risperdal Consta; actions by our partners with regard to marketing and regulatory filings; the outcome of clinical and preclinical work we are pursuing; decisions by the FDA or foreign regulatory authorities regarding our product candidates; potential changes in cost, scope and duration of clinical trials; and decisions we make about the timing and scope of proprietary product development. For further information with respect to factors that could cause actual results to differ from expectations, reference is made to the reports filed by us with the Securities and Exchange Commission under the Securities Exchange Act of 1934, as amended.

CONTACT: Alkermes, Inc. Rebecca Peterson Director, Corporate Communications (617) 583-6378