Alkermes Announces Additional Data and Analyses Submitted to FDA for Risperdal Consta; Response Package Sets in Motion New FDA Action on NDA

April 29, 2003

CAMBRIDGE, Mass.--(BUSINESS WIRE)--April 29, 2003--Alkermes, Inc. (Nasdaq: ALKS) today announced that its partner, Johnson & Johnson Pharmaceutical Research & Development (J&JPRD), has submitted additional data and analyses to the U.S. Food and Drug Administration (FDA) to fulfill a complete response to the 'non-approvable' letter issued by the FDA regarding the New Drug Application (NDA) for Risperdal Consta(TM) long-acting injection. The specific data and analyses provided were generated following discussions with the FDA, particularly related to the agency's questions pertaining to aspects of the preclinical data presented in the NDA for the long-acting injection form of the atypical antipsychotic, risperidone.

It is anticipated, based on criteria set forth in the Prescription Drug User Fee Act (PDUFA), that the FDA will issue a formal response to the submission in the fourth quarter of calendar year 2003.

"This submission represents an important step towards our goal of bringing the first long-acting atypical antipsychotic drug to patients with schizophrenia in the U.S.," commented Richard Pops, Chief Executive Officer of Alkermes. "We are producing commercial quantities of Risperdal Consta for currently approved markets outside the U.S., and are ramping-up our manufacturing capabilities significantly in anticipation of continuing approvals."

J&JPRD, which is responsible for obtaining regulatory approval of Risperdal Consta, submitted an NDA for Risperdal Consta in August 2001, and received a non-approvable letter in June 2002.

Risperdal Consta has been submitted to regulatory agencies for review around the world. Risperdal Consta is now approved for sale in 23 countries. Janssen-Cilag, a wholly owned subsidiary of Johnson & Johnson, is currently marketing Risperdal Consta in Austria, Denmark, Germany, Ireland, Mexico, Switzerland and the United Kingdom. The product also is approved, but has not yet been launched, in Argentina, Australia, Columbia, the Czech Republic, Estonia, Finland, Hungary, Iceland, Israel, Korea, Latvia, Lithuania, The Netherlands, New Zealand, Norway, and Spain.

Risperdal Consta is a long-acting injectable form of risperidone that was developed utilizing Alkermes' proprietary Medisorb(R) drug-delivery technology. Using this technology, risperidone is encapsulated in microspheres made of a biodegradable polymer, which are suspended in a water-based solution and administered to patients by intra-muscular injection. Under agreements between Janssen-Cilag and Alkermes for Risperdal Consta, Janssen-Cilag is responsible for worldwide sales and marketing of the product. Alkermes is responsible for worldwide manufacturing and receives manufacturing fees and royalties on product sales.

Risperdal Consta is administered once every two weeks for the management of schizophrenia -- a brain disorder affecting 1-2% of the world's population. Until now, long-acting injection formulations have been available only for older, first-generation antipsychotics.

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(R)") 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.

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 from our expectations. These include whether regulatory approvals will be received for Risperdal Consta, particularly in the United States; actions by our partners with regard to marketing and regulatory filings; the outcome of clinical and preclinical work we are pursuing; whether the FDA will interpret clinical and preclinical data, if and when such data is submitted, in a manner consistent with our interpretations of such data; 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.

Editor's Note:

Alkermes will host a conference call at 8:30am EDT today, April 29, 2003, as part of the company's effort to ensure full disclosure to all parties. The dial in number is 888-792-1079 for domestic callers and 703-871-3092 for international callers, following which participants can enter the code number of 121548 #. A replay of the conference call will be available for 48 hours and may be accessed by dialing 888-266-2081 for domestic callers and 703-925-2505 for international callers. The replay access code is 121548.

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