Alkermes Announces Launch of Risperdal Consta in the United States by Its Partner, Janssen Pharmaceutica Products, L.P.; First New Approach to Schizophrenia Treatment in 14 Years

December 3, 2003

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Dec. 3, 2003--Alkermes, Inc. (Nasdaq: ALKS) today announced that its partner, Janssen Pharmaceutica Products, L.P., has launched RISPERDAL(R) CONSTA(R) ((risperidone) long-acting injection) in the United States as a treatment for schizophrenia. Risperdal Consta will be covered under the federal Medicare program and under most state Medicaid programs. To date, Risperdal Consta has been approved in more than 45 countries around the world and was approved by the U.S. Food and Drug Administration on October 29, 2003. The drug is manufactured by Alkermes, Inc. and marketed by Janssen Pharmaceutica Products, L.P. in the United States.

"We are pleased to see the U.S. launch of Risperdal Consta and are committed to its success," commented Richard Pops, Chief Executive Officer of Alkermes. "Risperdal Consta, the only long-acting atypical antipsychotic on the market, uses Alkermes' Medisorb(R) technology to produce a unique and novel therapeutic alternative that may improve quality of life in the many U.S. patients suffering from this devastating disease."

Risperdal Consta is a long-acting injectable form of risperidone that was developed utilizing Alkermes' proprietary Medisorb(R) drug-delivery technology. Risperdal Consta is administered once every two weeks, rather than daily, for the management of schizophrenia. Until now, long-acting injection formulations of antipsychotics have been available only for older, conventional treatments.

Schizophrenia is a brain disorder that impairs a person's ability to think clearly, relate to others and distinguish between reality and imagination. It is estimated that more than 2 million Americans suffer from the condition.(1) One of the biggest challenges in treating people with schizophrenia is ensuring that medication is taken routinely. As many, as 75 percent of patients with schizophrenia have difficulty taking their oral medication on a regular basis.(2)

In clinical trials, Risperdal Consta was generally well tolerated. The most common treatment-emergent adverse events with an incidence of 5 percent or greater in at least one of the Risperdal Consta groups (25 mg or 50 mg) and at least twice that of placebo were: somnolence, akathisia, parkinsonism, dyspepsia, constipation, dry mouth, fatigue, weight increase. As with all antipsychotic medications, prescribing should be consistent with the need to minimize the risk of tardive dyskinesia, a neurological side effect that can include repetitive twitching; if its signs and symptoms appear, discontinuation of Risperdal Consta should be considered. In the integrated database of multiple-dose studies, the incidence of tardive dyskinesia was 0.6 percent (9/1499 patients).

For more information about Risperdal Consta and schizophrenia, visit www.risperdalconsta.com. For more information about schizophrenia, visit www.mentalwellness.com.

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 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.

This press release may contain forward-looking statements within the meaning of the Private Securities Litigation Reform Act about the launch of Risperdal Consta and anticipated demand in the U.S. These statements reflect Alkermes' current beliefs; however, as with any pharmaceutical product, there remain substantial risks and uncertainties related to market acceptance. There are no guarantees regarding what the demand for the product may be in the U.S., whether Alkermes can manufacture Risperdal Consta on a commercial scale or economically, whether our partner will market the product effectively, whether our partner will effectively secure reimbursement, or whether, in commercial use, Risperdal Consta would have unintended side effects, adverse reactions or incidents of misuse. For additional information about the factors that affect Alkermes' business, products and product candidates, please see Alkermes' filings with the Securities and Exchange Commission under the Securities Exchange Act of 1934.

(1)NIH Publication No. 02-3517.

(2)Weiden, PJ, Zygmunt, A. J. Prac Psych Behavior Health. 1997, March: 106-110.

CONTACT: Alkermes, Inc.
Rebecca Peterson, 617-583-6378

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