Alkermes to Expand Production Facility to Meet Projected Demand for Long-Acting Formulation of Risperdal; Signs New Agreement with Janssen Pharmaceutica

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CAMBRIDGE, Mass., Oct 30, 2001 (BUSINESS WIRE) -- Alkermes, Inc. (NASDAQ: ALKS) today announced the signing of an agreement with Janssen Pharmaceutica that provides for the expansion of Alkermes' manufacturing capacity for production of the new, long-acting injectable formulation of Risperdal(R) (risperidone). A new drug application (NDA) for the new formulation of Risperdal, currently the most widely prescribed antipsychotic medication in the United States, was submitted to the U.S. Food and Drug Administration on August 31, 2001. Risperdal is expected to be the first "atypical" antipsychotic to be available in a formulation that only requires administration every two weeks.

"Our current manufacturing facility is fully equipped to support launch quantities and to meet the early demand projected for long-acting Risperdal," stated David Broecker, Chief Operating Officer of Alkermes. "This expansion will include the construction of a separate, large-scale GMP facility on the same site and is designed to enable Alkermes to significantly expand our production capacity. Our agreement with Janssen eliminates the financial risk associated with the acceleration of this expansion."

Pursuant to the agreement announced today, Alkermes has committed to expand its production capacity prior to FDA approval of the new Risperdal formulation in exchange for certain guaranteed financial payments. In addition, Alkermes will receive, under earlier agreements, royalties and manufacturing payments from Janssen upon successful commercialization of the new, long-acting Risperdal.

The long-acting formulation of Risperdal uses Alkermes' proprietary, injectable sustained-release drug-delivery technology, Medisorb(R). The technology is based on the encapsulation of drug into small polymeric microspheres that degrade slowly and release the medication at a controlled rate following subcutaneous or intramuscular injection. Alkermes is developing Medisorb product candidates in collaboration with pharmaceutical and biotechnology companies and on its own.

Alkermes is a leader in the development of products based on sophisticated drug-delivery technologies. The company has several areas of focus, including (i) controlled, sustained-release of injectable drugs lasting several days to several weeks, using its ProLease(R) and Medisorb technologies and (ii) the development of pharmaceutical products based on its proprietary AIR(TM) pulmonary technology. In addition to its Cambridge, Massachusetts, headquarters, research and manufacturing facilities, Alkermes operates 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 Alkermes believes 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) long-acting Risperdal will be approved by regulatory authorities in the United States or abroad on a timely basis, if at all; (ii) if approved, this formulation of Risperdal will be commercialized successfully; or (iii) anticipated growth of sales will be achieved.

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