# Alkermes Announces Approval in Germany for Risperdal Consta; First Atypical Antipsychotic to be Available as Long-Acting Injection

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CAMBRIDGE, Mass., Aug 1, 2002 (BW HealthWire) -- Alkermes, Inc. (Nasdaq: ALKS) today announced that its partner, Johnson & Johnson Pharmaceutical Research & Development (J&JPRD), has received approval to market Risperdal Consta(TM) (risperidone) in Germany. The first launch of Risperdal Consta, the only approved long-acting injection developed for a newer-generation, atypical antipsychotic, will occur in Germany following yesterday's approval by the national regulatory agency. The launch of Risperdal Consta in Germany by Janssen-Cilag GmbH is planned for August 15. In a number of other countries, Risperdal Consta is in late-stage regulatory review.

Risperdal Consta is administered once every two weeks, rather than daily, for the management of schizophrenia -- a brain disorder affecting 1-2% of the world's population. Until now, long-acting injectable formulations of antipsychotics have been available only for older, conventional treatments. However, these conventional antipsychotics are more likely to cause serious movement disorders and are not considered by most experts to be as effective in treating "negative" symptoms (such as social withdrawal and apathy), as they are in alleviating "positive" symptoms (including hallucinations and delusions).

"We are very pleased Risperdal Consta has been approved in this significant market," commented Richard Pops, Chief Executive Officer of Alkermes. "The approval represents an important milestone in our goal of developing Medisorb technology into innovative products that offer major therapeutic benefits for patients."

Risperdal Consta is a long-acting injectable formulation of Risperdal(R) that uses Alkermes' Medisorb(R) drug-delivery technology. Risperdal Consta will be manufactured by Alkermes and the product will be marketed by Janssen-Cilag in Germany.

Risperdal Consta was developed by J&JPRD to combine the advantages of long-acting delivery with the established benefits of oral risperidone. Risperdal has been marketed in tablet form in the United States by Janssen Pharmaceutica Products, L.P., since 1994, and is the most widely prescribed atypical antipsychotic in the world. In a study published in a January issue of The New England Journal of Medicine, Risperdal was found to be significantly more effective in reducing the risk of relapse than haloperidol, a conventional antipsychotic long considered the "gold standard" in treatment of psychosis.

Using proprietary Medisorb technology developed by Alkermes, the new formulation encapsulates risperidone in microspheres made of a biodegradable polymer, which are suspended in a water-based solution and injected into the muscle. Laboratory and clinical research has shown that the microspheres gradually degrade at a set rate to provide therapeutic blood levels of the drug in the bloodstream for an extended period. The polymer from which the microspheres are made breaks down into two naturally occurring compounds that are then eliminated by the body.

Risperdal Consta has been submitted for review around the world. In the United States, discussions are ongoing with the Food and Drug Administration (FDA), which has issued a non-approvable letter based on questions related to certain aspects of the pre-clinical data. J&JPRD, which is responsible for obtaining regulatory approval of Risperdal Consta, is currently in discussions with the FDA and is working to answer the agency's questions.** If approved in the US, Canada and elsewhere, 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.

In the United States, Risperdal is indicated for the treatment of schizophrenia and is currently available in 0.25, 0.5, 1, 2, 3 and 4 mg tablets as well as a 1mg/mL oral solution. In clinical trials, Risperdal was generally well tolerated. However, as with all other antipsychotics, Risperdal can cause some adverse events. In two controlled trials, adverse events with an incidence of 5% or greater in at least one of the Risperdal groups and that occurred at a rate at least twice that of placebo were anxiety, drowsiness, extrapyramidal symptoms (uncontrolled tremors and muscle stiffness), dizziness, constipation, nausea, dyspepsia (upset stomach), rhinitis (inflammation of nasal membranes), rash and tachycardia (rapid heart beat).

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.

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