



## FDA Accepts for Review Questcor's Filing of Its Supplemental New Drug Application for H.P. Acthar® Gel for Treatment of Infantile Spasms

UNION CITY, Calif., Dec. 24, 2009 (GLOBE NEWSWIRE) -- Questcor Pharmaceuticals, Inc. (Nasdaq:QCOR) today announced the U.S. Food & Drug Administration (FDA) now considers that Questcor has provided a complete response to all prior action letters for its supplemental New Drug Application (sNDA) to market H.P. Acthar® Gel (repository corticotrophin injection) for the treatment of infantile spasms. The FDA has set the user fee goal date (PDUFA) of June 11, 2010 for this sNDA.

"The medical community and Questcor continue to believe that Acthar has an important role in the treatment of infantile spasms and we look forward to working with the FDA to answer any questions as they consider our application," said Don M. Bailey, President and CEO of Questcor. "We continue to expect the FDA will convene an Advisory Panel meeting to obtain independent expert advice on specific aspects of the sNDA," added Mr. Bailey.

Acthar is currently approved in the U.S. for the treatment of MS exacerbations, nephrotic syndrome and many other conditions. Acthar is not approved in the U.S. for the treatment of IS, a potentially life-threatening disorder that typically begins in the first year of life. However, pursuant to guidelines published by the American Academy of Neurology and the Child Neurology Society, many child neurologists use Acthar to treat infants afflicted with this condition. Previously, the FDA granted Orphan Designation to Acthar for the treatment of IS.

### About Questcor

Questcor Pharmaceuticals, Inc. is a pharmaceutical company that markets H.P. Acthar® Gel (repository corticotropin injection). H.P. Acthar Gel ("Acthar") is an injectable drug that is approved for the treatment of certain disorders with an inflammatory component, including the treatment of exacerbations associated with multiple sclerosis ("MS") and to induce a diuresis or a remission of proteinuria in the nephrotic syndrome without uremia of the idiopathic type or that is due to lupus erythematosus. In addition, Acthar is not indicated for, but is used in treating patients with infantile spasms ("IS"), a rare form of refractory childhood epilepsy, and opsoclonus myoclonus syndrome, a rare autoimmune-related childhood neurological disorder. The Company also markets Doral® (quazepam), which is indicated for the treatment of insomnia characterized by difficulty in falling asleep, frequent nocturnal awakenings, and/or early morning awakenings. For more information, please visit [www.questcor.com](http://www.questcor.com).

Note: Except for the historical information contained herein, this press release contains forward-looking statements that have been made pursuant to the Private Securities Litigation Reform Act of 1995. These statements relate to future events or our future financial performance. In some cases, you can identify forward-looking statements by terminology such as "may," "will," "if," "should," "forecasts," "expects," "plans," "anticipates," "believes," "estimates," "predicts," "potential," or "continue" or the negative of such terms and other comparable terminology. These statements are only predictions. Actual events or results may differ materially. Factors that could cause or contribute to such differences include, but are not limited to, the following:

- Questcor's ability to continue to successfully implement its Acthar-centric business strategy, including its expansion in the MS marketplace;
- Questcor's ability to manage its sales force expansion;
- FDA approval of and the market introduction of competitive products and our inability to market Acthar in IS prior to approval of IS as a labeled indication;
- Questcor's ability to operate within an industry that is highly regulated at both the Federal and state level;
- Regulatory changes or actions including Federal or State health care reform initiatives;
- Questcor's ability to accurately forecast the demand for its products;
- The gross margin achieved from the sale of its products;
- Questcor's ability to estimate the quantity of Acthar used by government entities and Medicaid-eligible patients;
- That the actual amount of rebates and chargebacks related to the use of Acthar by government entities, including the Department of Defense Tricare network, and Medicaid-eligible patients may differ materially from Questcor's estimates;
- Questcor's expenses and other cash needs for upcoming periods;

- The inventories carried by Questcor's distributors, specialty pharmacies and hospitals;
- Volatility in Questcor's monthly and quarterly Acthar shipments and end-user demand;
- Questcor's ability to obtain finished goods from its sole source contract manufacturers on a timely basis if at all;
- Questcor's ability to attract and retain key management personnel;
- Questcor's ability to utilize its NOLs to reduce income taxes on taxable income;
- Research and development risks, including risks associated with Questcor's sNDA for IS and its preliminary work in the area of nephrotic syndrome;
- Uncertainties regarding Questcor's intellectual property;
- The uncertainty of receiving required regulatory approvals in a timely way, or at all;
- Uncertainties in the credit and capital markets and the impact a further deterioration of these markets could have on Questcor's investment portfolio;
- As well as the risks discussed in Questcor's annual report on Form 10-K for the year ended December 31, 2008 and other documents filed with the Securities and Exchange Commission.

The risk factors and other information contained in these documents should be considered in evaluating Questcor's prospects and future financial performance.

Questcor undertakes no obligation to publicly release the result of any revisions to these forward-looking statements, which may be made to reflect events or circumstances after the date hereof or to reflect the occurrence of unanticipated events.

For more information, please visit [www.questcor.com](http://www.questcor.com) or [www.acthar.com](http://www.acthar.com).

CONTACT: Questcor  
Don Bailey  
510-400-0776  
dbailey@Questcor.com

EVC Group  
Investors  
Barbara Domingo  
415-896-5862  
Douglas Sherk  
415-896-6820  
Media  
Chris Gale  
646-201-5431