Questcor To Commence Phase 2 Study of Acthar for Acute Respiratory Distress Syndrome

October 22, 2013

ANAHEIM, Calif., Oct. 22, 2013 /PRNewswire/ -- Questcor Pharmaceuticals, Inc. (NASDAQ: QCOR) announced today that it will commence a Phase 2 study to explore the efficacy and safety of H.P. Acthar® Gel (repository corticotropin injection) for Acute Respiratory Distress Syndrome (ARDS). The Company's Investigational New Drug (IND) application for the study has been reviewed by the U.S. Food and Drug Administration (FDA) and is now active. ARDS is an acute life-threatening lung condition that can result from pulmonary and non-pulmonary infections or a multitude of other serious conditions. Based on our understanding of its potential mechanism of action, Questcor believes that Acthar could have both steroid-independent and steroid-dependent protective effects in this condition.

The study will seek to enroll up to 210 patients in a 4-week randomized, placebo controlled trial designed to explore the efficacy and safety of several dosing regimens of Acthar in patients with moderate to severe ARDS. The primary objective of the study will be to determine if Acthar increases the number of ventilator-free days during the 28-day treatment period. Secondary endpoints include whether Acthar therapy diminishes mortality, organ failure and the length of hospital or ICU stay.

"Despite advances in supportive care, there are no pharmacologic therapies that address acute respiratory distress syndrome, an urgent medical condition that results in mortality rates from 25 percent to over 40 percent of patients," said Dr. David Young, Questcor's Chief Scientific Officer. "While Acthar's exact mechanism of action is unknown, based on our understanding from scientific literature and nonclinical data, we believe Acthar may be beneficial in ARDS patients via its potential anti-inflammatory and immune-modulatory properties that could reduce lung inflammation and injury, making ARDS a compelling area to investigate further."

The ARDS study will be the second company-sponsored IND study Questcor has initiated in 2013. Questcor has company-sponsored clinical studies underway to investigate the safety and efficacy of Acthar in the treatment of amyotrophic lateral sclerosis (ALS), diabetic nephropathy, idiopathic membranous nephropathy and lupus. For more information on studies related to Acthar, please visit http://www.clinicaltrials.gov.

About ARDS
Acute respiratory distress syndrome (ARDS) is the sudden failure of the respiratory system, and can result from exposure to diverse direct and indirect insults, including respiratory and non-pulmonary infections, aspiration of gastric contents, trauma and transfusion reactions. A person with ARDS has rapid breathing, difficulty getting enough air into the lungs, low blood oxygen levels and often requires mechanical ventilatory support. Multi-organ failure often develops as a consequence of or in association with this condition. It is estimated there are approximately 141,500 incident cases of ARDS in the U.S. each year.

About Questcor
Questcor Pharmaceuticals, Inc. is a biopharmaceutical company focused on the treatment of patients with serious, difficult-to-treat autoimmune and inflammatory disorders. Questcor also provides specialty contract manufacturing services to the global pharmaceutical industry through its wholly-owned subsidiary BioVectra Inc. Questcor's primary product is H.P. Acthar® Gel (repository corticotropin injection), an injectable drug that is approved by the FDA for the treatment of 19 indications. Of these 19 indications, Questcor currently generates substantially all of its net sales from the following approved indications: the treatment of proteinuria in the nephrotic syndrome (NS) of the idiopathic type, the treatment of acute exacerbations of multiple sclerosis (MS) in adults, the treatment of infantile spasms (IS) in infants and children under two years of age, and the treatment of certain rheumatology related conditions. With respect to NS, the FDA has approved Acthar to "induce a diuresis or a remission of proteinuria in the nephrotic syndrome without uremia of the idiopathic type or that due to lupus erythematosus." Questcor has announced its intention to initiate a pilot commercialization effort for Acthar for the treatment of respiratory manifestations of symptomatic sarcoidosis. The FDA-approved package insert for Acthar includes "symptomatic sarcoidosis" under the heading "Respiratory Diseases". Questcor is also exploring the possibility of developing markets for other FDA-approved indications and the possibility of pursuing FDA approval of additional indications not currently on the Acthar label where there is high unmet medical need. Questcor also has agreed to acquire certain international rights for Synacthen® (tetracosactide) and Synacthen Depot®, and has licensed the right to develop and seek FDA approval for these products in the United States. For more information about Questcor, please visit 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 "believes," "continue," "could," "ensuring," "estimates," "expects," "growth," "may," "momentum," "plans," "potential," "remain," "should," "start," "substantial," "sustainable" or "will" 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:

- Research and development risks, including risks associated with our work in the area of ARDS, our reliance on third-parties to conduct research and development, and the ability of research and development to generate successful results;
- Our reliance on Acthar for substantially all of our net sales and profits and the possible FDA approval and market introduction of competitive products;
- The lack of patent protection for Acthar;

- Our ability to effectively manage our growth, including the expansion of our sales forces, planned international expansion, recent acquisitions, and our reliance on key personnel;
- The risk of product liability lawsuits;
- Other risks discussed in Questcor's annual report on Form 10-K for the year ended December 31, 2012 as filed with the Securities and Exchange Commission, or SEC, on February 27, 2013, and other documents filed with the SEC.

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 of this release.

SOURCE Questcor Pharmaceuticals, Inc.