Cinical Trial Results Indicate Acthar May Significantly Reduce Disease Activity in Patients with Systemic Lupus Erythematosus

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- Significant clinical response to Acthar was observed in patients experiencing active disease while on conventional SLE maintenance therapies -
- Findings supported by recent preclinical data demonstrating potential immunomodulatory activity and efficacy of Acthar in a mouse model of SLE -

ANAHEIM, Calif., May 5, 2014 /PRNewswire/ -- Questcor Pharmaceuticals, Inc. (Nasdaq: QCOR) today announced that results from the first modern clinical study examining the use of H.P. Acthar® Gel (repository corticotropin injection) in systemic lupus erythematosus (SLE) has been published in the journal *LUPUS.* This independent investigator-initiated ten patient study was conducted at Fiechtner Research, a rheumatology research center, and evaluated the efficacy of Acthar in reducing SLE disease activity among patients who presented with moderately to severely active disease despite receiving traditional SLE maintenance treatments. Acthar is approved by the Food and Drug Administration (FDA) for 19 indications, including for use during an exacerbation or as maintenance therapy in selected cases of systemic lupus erythematosus.

The paper appears in the current online edition of the journal and can be accessed on the *LUPUS* website: http://lup.sagepub.com.

"The results of our study indicate that Acthar appears to be a viable treatment option for patients with SLE," said Justus J. Fiechtner, MD, MPH, principal investigator and lead author of the paper. "Some patients on traditional lupus maintenance therapies can experience breakthrough disease activity, and our study has shown that Acthar may be an effective therapeutic alternative in such patients."

The results obtained during this trial reveal that Acthar treatment resulted in significant improvements in certain clinical outcome measures that indicate a reduction of lupus disease activity. The drug was generally well-tolerated during the course of the study. Of the ten patients participating in the trial, one patient experienced self-limiting bilateral edema and another patient had a sinus infection that resolved with one course of antibiotic therapy. No other adverse events were reported or observed.

"Rheumatologists and lupus patient groups alike have indicated to us that this patient population has a significant need for additional treatment options," said Steve Cartt, Chief Operating Officer of Questcor. "We are looking forward to working with both doctors and patient support groups to build awareness in the rheumatology community that Acthar is a currently available, FDA-approved SLE treatment option, particularly for those patients in need of new treatment alternatives. Questcor remains committed to further building the body of scientific and clinical evidence for Acthar in the treatment of SLE."

A paper reporting findings from a Questcor-sponsored preclinical research study of Acthar, also recently published online in the journal *LUPUS*, lends further support to the potential clinical efficacy of Acthar in SLE. These preclinical data suggest that Acthar attenuates B cell development, circulating autoantibody titers and manifestations of disease in the kidney in a mouse strain often used to model systemic lupus erythematosus and lupus nephritis.

About the Clinical Study Design
Men and women aged 18 - 75 who met American College of Rheumatology (ACR) criteria for SLE and who presented with chronic, moderately-to-severely active diseases, and a disease flare while receiving standard treatments were eligible for participation. Patients were recruited from a single site, Fiechtner Research, in Lansing, Michigan. All of the ten patients who ultimately participated in the trial were female. The participants self-administered Acthar 1 mL (80 U/mL) for 7-15 days and were assessed weekly for 28 days. Outcome measures included Physician and Patient Global Assessments, SLEDAI-2K, Lupus Quality of Life (QoL) scale, Functional Assessment of Chronic Illness Therapy-Fatigue (FACIT-Fatigue) scale, erythrocyte sedimentation rate (ESR), and C-reactive protein (CRP). Student's t-test compared data obtained at Days 7, 14, and 28 with those from baseline.

Highlights of the Study Results
The primary endpoint of SLEDEI-2K improvement was reached at all observation times ($P < 0.05$) and statistically significant improvements were observed for most other parameters. No treatment-related serious or unexpected adverse events were observed.

About Systemic Lupus Erythematosus
Systemic lupus erythematosus (SLE) is an autoimmune disease in which the body's immune system mistakenly attacks healthy tissue. It can affect the skin, joints, kidneys, brain, and other organs. The underlying cause of autoimmune diseases is not fully known. There is no cure for SLE. The goal of treatment is to control symptoms. Severe symptoms that involve the heart, lungs, kidneys, and other organs often need treatment from specialists.

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. For more information about Questcor, please visit www.questcor.com.

About H.P. Acthar® Gel
Questcor's H.P. Acthar Gel (repository corticotropin injection), is an injectable drug 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 on-label indications: the treatment of proteinuria in the nephrotic syndrome of the idiopathic type, or NS, the treatment of acute exacerbations of multiple sclerosis, or MS, in adults, the treatment of infantile spasms, or IS, in infants and children under two years of age, and the treatment of certain rheumatology related conditions, including the treatment SLE. With respect to nephrotic syndrome, 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 is also exploring the possibility of developing other on-label indications and the possibility of pursuing FDA approval of additional indications not currently on the Acthar label where there is high unmet medical need. For more information about Questcor, please visit www.acthar.com.

Cautionary Statements Related to Forward-Looking Statements
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 Questcor's work in the area of SLE, and the ability of research and development to generate successful results;
- Our reliance on Acthar for substantially all of our net sales and profits;
- The lack of patent protection for Acthar; and the possible FDA approval and market introduction of additional competitive products;
- Our ability to continue to generate revenue from sales of Acthar to treat on-label indications associated with NS, rheumatology-related conditions, MS, or IS, and our ability to develop other therapeutic uses for Acthar; and
- Other risks discussed in Questcor's annual report on Form 10-K for the year ended December 31, 2013 as filed with the Securities and Exchange Commission, or SEC, on February 26, 2014, 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.

For more information, please visit www.questcor.com or www.acthar.com.

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