Isis Pharmaceuticals Reports Data From a Phase 2 Study of Isis-CRP Rx in Patients With Rheumatoid Arthritis

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CARLSBAD, Calif., Aug. 5, 2013 /PRNewswire/ -- Isis Pharmaceuticals, Inc. (NASDAQ: ISIS) announced that patients treated with ISIS-CRP$_{Rx}$ achieved rapid, dose-dependent mean reductions of up to 67 percent in C-reactive protein (CRP) in a Phase 2 study in patients with rheumatoid arthritis (RA). Patients treated with ISIS-CRP$_{Rx}$ showed improvements in signs and symptoms of RA; however, these improvements were not statistically significant when compared to those observed in patients in the placebo group, which demonstrated a higher than expected response in both symptom score and CRP reduction. A Phase 2 study of ISIS-CRP$_{Rx}$ in patients with atrial fibrillation is currently ongoing with data anticipated in the first half of 2014.

"CRP is strongly associated with the presence and severity of many diseases, including numerous inflammatory and cardiovascular diseases. In this study, by treating patients with chronically elevated CRP with ISIS-CRP$_{Rx}$, we hoped to accomplish three things: to confirm in patients the substantial CRP-lowering activity we observed in our earlier clinical studies, to gain additional experience with the drug before testing it in more severe indications, and to evaluate whether lowering CRP correlates with an improvement in RA symptoms. The study accomplished its goals. We are pleased with the consistency of CRP lowering across all of our clinical studies, but we are disappointed that we did not see a greater impact on RA symptoms in these patients," said Richard Geary, Ph.D., senior vice president of development at Isis. "While we do not plan to further develop ISIS-CRP$_{Rx}$ for RA, we do plan to continue to evaluate ISIS-CRP$_{Rx}$ to treat other diseases."

The Phase 2 study was a randomized, placebo-controlled, multiple-dose study in patients with RA who had chronically elevated CRP. In this study, 51 patients received 100 mg, 200 mg or 400 mg dose of ISIS-CRP$_{Rx}$ or placebo for 12 weeks. Patients in the study treated with ISIS-CRP$_{Rx}$ achieved substantial, dose-dependent reductions in CRP early in treatment that were prolonged through the treatment process. Patients also experienced improvements in the signs and symptoms of RA, as measured by ACR20 and ACR50 scores. These improvements correlated with reductions in CRP, but were not sufficiently greater than improvements observed in the placebo groups to justify further development of ISIS-CRP$_{Rx}$ for RA.

ABOUT ISIS PHARMACEUTICALS, INC.
Isis is exploiting its leadership position in antisense technology to discover and develop novel drugs for its product pipeline and for its partners. Isis' broad pipeline consists of 28 drugs to treat a wide variety of diseases with an emphasis on cardiovascular, metabolic, severe and rare diseases, and cancer. Isis' partner, Genzyme, is commercializing Isis' lead product, KYNAMRO™, in the United States for the treatment of patients with HoFH. Genzyme is also pursuing marketing approval of KYNAMRO in other markets. Isis' patents provide strong and extensive protection for its drugs and technology. Additional information about Isis is available at www.isispharm.com.

ISIS PHARMACEUTICALS' FORWARD-LOOKING STATEMENT
This press release includes forward-looking statements regarding the development, activity, therapeutic potential and safety of ISIS-CRP$_{Rx}$. Any statement describing Isis' goals, expectations, financial or other projections, intentions or beliefs, including the commercial potential of KYNAMRO, is a forward-looking statement and should be considered an at-risk statement. Such statements are subject to certain risks and uncertainties, particularly those inherent in the process of discovering, developing and commercializing drugs that are safe and effective for use as human therapeutics, and in the endeavor of building a business around such drugs. Isis' forward-looking statements also involve assumptions that, if they never materialize or prove correct, could cause its results to differ materially from those expressed or implied by such forward-looking statements. Although Isis' forward-looking statements reflect the good faith judgment of its management, these statements are based only on facts and factors currently known by Isis. As a result, you are cautioned not to rely on these forward-looking statements. These and other risks concerning Isis' programs are described in additional detail in Isis' annual report on Form 10-K for the year ended December 31, 2012 and its most recent quarterly report on Form 10-Q, which are on file with the SEC. Copies of these and other documents are available from the Company.

SOURCE Isis Pharmaceuticals, Inc.

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