European Regulatory Authorities Approve Isis' Manufacturing Facility

August 3, 2012

Isis Receives GMP Certification from the EMA for Production to Support KYNAMRO™ Commercial Launch

CARLSBAD, Calif., Aug. 3, 2012 /PRNewswire/ -- Isis Pharmaceuticals, Inc. (NASDAQ: ISIS) announced today that it has successfully completed a pre-approval inspection of its manufacturing facility located in Carlsbad, California. As part of the inspection, the European Medicines Agency (EMA) conducted an extensive review of Isis' manufacturing facility and processes and Isis' Good Manufacturing Practices (GMP) Quality systems to ensure product manufactured is of appropriate and reliable quality. The EMA's approval of the Isis manufacturing facility allows Isis to supply Genzyme with KYNAMRO™ drug substance to support commercial launch in Europe.

"Isis is the leading antisense drug discovery company with a broad pipeline of more than two dozen drugs in development. As we have increased the efficiency of our drug discovery technology, we have also improved the manufacturing processes of antisense drugs. As a result, we have significantly reduced the cost of manufacturing and increased our capacity, which will support the numerous potential commercial products that could be coming out of our pipeline in the near-term," said B. Lynne Parshall, J.D., Chief Operating Officer, Chief Financial Officer and Secretary of Isis. "The European regulatory approval of our manufacturing facility is an important milestone for Isis and a validation of our high standards and excellence in manufacturing antisense drugs. This approval is also an essential step in a successful commercial KYNAMRO™ launch in Europe. We expect the FDA to conduct a similar inspection later this year."

Isis is the leader in manufacturing oligonucleotide drugs and an inventor of proprietary inventions that support many aspects of oligonucleotide drug manufacturing, including improving manufacturing efficiency and capacity. Isis adheres to strict GMP conditions and operates a state-of-the-art, commercial-scale manufacturing facility that is capable of producing a number of different clinical drugs, including drugs to support the preclinical, clinical and initial commercial needs for Isis and its partners.

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 25 drugs to treat a wide variety of diseases with an emphasis on cardiovascular, metabolic, severe and rare diseases, and cancer. Isis' partner, Genzyme, plans to commercialize Isis' lead product, KYNAMRO™, in the United States and Europe following regulatory approval. 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 Isis' business and its collaboration with Genzyme, a Sanofi company, its current and future manufacturing capabilities, its drug discovery and development pipeline, and the development, activity, therapeutic potential and safety of KYNAMRO™ in treating patients with high cholesterol. Any statement describing Isis' goals, expectations, financial or other projections, intentions or beliefs, including the planned commercialization 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, 2011 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.

In this press release, unless the context requires otherwise, "Isis," "Company," "we," "our," and "us" refers to Isis Pharmaceuticals and its subsidiaries, including Regulus Therapeutics Inc., its jointly owned subsidiary.

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