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DACOGEN(R) Receives a Positive Regulatory Recommendation in the European Union for Treatment of Acute Myeloid Leukemia

DUBLIN, Calif., July 20, 2012 (GLOBE NEWSWIRE) -- Astex Pharmaceuticals, Inc. (Nasdaq:ASTX), a pharmaceutical company dedicated to the discovery and development of novel small molecule therapeutics, today announced that Janssen-Cilag International NV was notified that the Committee for Medical Products for Human Use (CHMP) of the European Medicines Agency (EMA) granted a positive opinion recommending approval of DACOGEN® (decitabine) for Injection in the treatment of adult patients (age 65 years and above) with newly diagnosed de novo or secondary acute myeloid leukemia (AML), according to the World Health Organization (WHO) classification who are not candidates for standard induction chemotherapy. Janssen is the licensee for DACOGEN in territories outside of the United States, Canada and Mexico.

The CHMP is the committee responsible for the scientific assessment of products seeking centralized marketing authorization throughout the European Union. The CHMP's positive opinion is now referred for approval to the European Commission. Janssen anticipates receiving the regulatory decision from the Commission in the end of the third quarter of 2012.

The CHMP positive opinion is based on data from the DACO-016 trial, the largest AML trial to date in this population of older patients. This randomized, open-label, multi-center phase 3 clinical trial compared DACOGEN versus patient's choice with physician's advice of either supportive care or low-dose cytarabine in patients 65 years and older with newly diagnosed de novo or secondary acute myeloid leukemia and poor- or intermediate-risk cytogenetics. DACOGEN was administered at 20 mg/m² as a 1-hour intravenous infusion once daily for five consecutive days, repeated every four weeks, continued as long as the patient derived benefit. Key results from this study were published in the *Journal of Clinical Oncology* in June 2012¹.

"We are pleased to learn that the CHMP's review of data from the DACO-016 trial has resulted in a positive recommendation for DACOGEN in this indication," said James S.J. Manuso, PhD, chairman and chief executive officer of Astex Pharmaceuticals. "We look forward to the EMA's decision later this year with the hope that clinicians and patients in Europe may soon have access to this treatment option."

About Acute Myeloid Leukemia

Acute myeloid leukemia (AML) is an aggressive, fast-growing cancer that starts inside the bone marrow with production of abnormal blood cells. It is generally a disease of older adults, with an average patient age of 64 at diagnosis, and is slightly more common among men than women. The most common symptoms of AML include tiredness, shortness of breath, bruising or bleeding easily, fever and infections. AML can sometimes spread to other parts of the body including the lymph nodes, liver and spleen. When diagnosed, treatment is to be started with minimal delay as AML usually results in death within just a few months if left untreated. In older adults, induction chemotherapy leads to a high 30-day mortality, and most patients are not candidates for or are unwilling to undergo this intensive therapy. Therefore, treatment options are limited and overall, irrespective of therapy, median survival is merely 2.4 months.

About DACOGEN (decitabine)

DACOGEN is a DNA hypomethylating agent currently approved for the treatment of myelodysplastic syndromes (MDS) in more than 30 countries worldwide including key markets such as the United States, Brazil, China, India, Korea, Russia and Turkey.

Janssen-Cilag International NV and its affiliates hold marketing and development rights for DACOGEN in all markets except the United States, Canada and Mexico, where rights are maintained by our partner, Eisai Inc. and its affiliates. These marketing rights flow from a worldwide license from Astex Pharmaceuticals to Eisai, Inc. Astex Pharmaceuticals receives royalties from the global sales of DACOGEN for any indication.

About Astex Pharmaceuticals

Astex Pharmaceuticals is dedicated to the discovery and development of novel small molecule therapeutics with a focus on oncology. The Company is developing a proprietary pipeline of novel therapies and is creating de-risked products for partnership with leading pharmaceutical companies. Astex Pharmaceuticals co-developed DACOGEN® (decitabine) for

Injection and receives significant royalties on global sales.

For more information about Astex Pharmaceuticals, Inc., please visit <http://www.astx.com>.

The Astex Pharmaceuticals, Inc. logo is available at <http://www.globenewswire.com/newsroom/prs/?pkgid=12273>

This press release contains "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995. The reader is cautioned not to rely on these forward-looking statements. These statements are based on current expectations of future events. If underlying assumptions prove inaccurate or unknown risks or uncertainties materialize, actual results could vary materially from the expectations and projections of Astex Pharmaceuticals and its marketing partners. Risks and uncertainties include, but are not limited to, general industry conditions and competition; technological advances, new products and patents attained by competitors; challenges inherent in new product development, including obtaining regulatory approvals; challenges to patents; changes in behavior and spending patterns or financial distress of purchasers of health care products and services; changes to governmental laws and regulations and domestic and foreign health care reforms; trends toward health care cost containment; and increased scrutiny of the health care industry by government agencies. A further list and description of these risks, uncertainties and other factors can be found in the Astex Pharmaceuticals Annual Report on Form 10-K for the fiscal year ended December 31, 2011. Copies of this Form 10-K, as well as subsequent filings, are available online at www.sec.gov, www.astx.com or on request from Astex Pharmaceuticals. Astex Pharmaceuticals is not required to update any forward-looking statements as a result of new information or future events or developments.

Reference:

¹ Kantarjian M., Thomas XG, Dmoszynska A, et al. Multicenter, Randomized, Open-Label, Phase III Trial of Decitabine Versus Patient Choice, With Physician Advice, of Either Supportive Care or Low-Dose Cytarabine for the Treatment of Older Patients With Newly Diagnosed Acute Myeloid Leukemia. J Clin Oncol. 10.1200/JCO.2011.38.9429

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