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DACOGEN(R) Approved in the European Union for the Treatment of Acute Myeloid Leukemia

New Treatment Offers Clinically Significant Benefit for Patients

DUBLIN, Calif., Sept. 28, 2012 (GLOBE NEWSWIRE) -- Astex Pharmaceuticals, Inc. (Nasdaq:ASTX), a pharmaceutical company dedicated to the discovery and development of novel small molecule therapeutics, announced that Janssen-Cilag International NV was notified that the European Commission has approved the marketing authorization for DACOGEN® (decitabine) for 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.[i] DACOGEN also has been granted Orphan Drug designation for the treatment of AML.

The data in support of the marketing authorization is based on the Phase 3 DACO-016 trial that compared decitabine to patients' choice with physician advice of either supportive care or low-dose cytarabine in the treatment of older patients with AML. The analysis of the protocol-specified results demonstrated an increase of 54 percent in median overall survival in patients taking decitabine (7.7 months for decitabine patients, compared to 5.0 months for patients in the comparator arm; HR=0.85, 95 percent CI: 0.69 to 1.04, p=0.108). An updated analysis of mature survival data confirmed this strong trend for improved overall survival and provided clinically significant evidence of the efficacy of decitabine (HR=0.82; 95 percent CI: 0.68 to 0.99; nominal p=0.037).[ii]

"We are pleased that elderly AML patients who are not candidates for standard induction chemotherapy in the European Union can now be offered treatment with DACOGEN, the world's first medicine approved and labelled specifically for elderly AML," said James S.J. Manuso, PhD, chairman and chief executive officer of Astex Pharmaceuticals.

DACO-016, with 485 study subjects, is the largest AML trial to date in older patients. It was a Phase 3, randomized, open-label trial, in newly diagnosed patients ≥65 years of age with de novo or secondary AML and poor- or intermediate-risk cytogenetics. Patients were enrolled globally at 65 clinical sites. Of the 485 patients, 242 were randomized to decitabine and 243 to patient's treatment choice of supportive care or low-dose cytarabine (majority of patients, 88%). Patients treated with decitabine received a 1-hour infusion, once daily for 5 consecutive days every 4 weeks. Patients treated with cytarabine received 20 mg/m2 subcutaneously once daily 10 consecutive days every 4 weeks. The median duration of treatment for patients on the decitabine arm was 4.4 months, compared with 2.4 months in the cytarabine group. [ii]

Adverse events (AEs) were consistent with the known decitabine safety profile and no major differences between the treatment arms were observed. The most frequently reported Grade 3 or 4 hematologic AEs were thrombocytopenia, anemia, neutropenia, and febrile neutropenia. [ii]

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.[iii] 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.[iv]

About DACOGEN® (decitabine)

DACOGEN is a DNA hypomethylating agent currently approved for the treatment of myelodysplastic syndromes (MDS) in more than 35 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 their strategic partner, Eisai Inc. and its affiliates. These marketing rights flow from a worldwide license from Astex Pharmaceuticals to Eisai, Inc. Astex receives royalties from Eisai Inc. on the global sales of DACOGEN for any indication starting at 20% and escalating to a maximum of 30%.

In accordance with Astex's license agreement with Eisai, Astex may receive up to $17.5 million in future payments if milestones are achieved for Dacogen globally.

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 from Eisai in North America and from Janssen-Cilag in the rest of the world.

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

Forward-Looking Statements

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.

References

[i] DACOGEN® SPC, approved 20.09.2012. The approved SPC is due to be published on the EC Community Register of medicinal products: http://ec.europa.eu/health/documents/community-register/html/newproc.htm#h.

[ii] Kantarjian HM 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, Journal of Clinical Oncology, 2012.

[iii]Cancer Research UK: Acute Myeloid Leukaemia. Key facts available via http://cancerhelp.cancerresearchuk.org/type/aml (accessed September 2012)

[iv]McClennan, J et al. Treatment advances have not improved the early death rate in acute promyelocytic leukemia. Haematologica. 2012 January; 97(1): 133—136.

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