



Astex Announces FDA ODAC Meeting of sNDA Application for Dacogen in Treatment of Elderly AML

DUBLIN, Calif.--(BUSINESS WIRE)-- Astex Pharmaceuticals, Inc. (NASDAQ: ASTX), today announced the pre-publication notice of the Food and Drug Administration (FDA), Oncologic Drugs Advisory Committee (ODAC) Meeting to discuss the supplemental new drug application (sNDA) for *Dacogen*® (decitabine) for Injection, an application submitted by Eisai, Inc. The proposed indication for this product is for the treatment of elderly acute myelogenous leukemia (AML).

The ODAC meeting will be held on February 9, 2012 at FDA White Oak Campus in Silver Spring, MD and will be open to the public. *Dacogen* will be discussed during the morning session, beginning at 8 a.m. ET.

The General Function of the Committee is to provide advice and recommendations to the Agency on FDA's regulatory issues. FDA intends to make background material available to the public no later than two business days before the meeting. If FDA is unable to post the background material on its website prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's website after the meeting. Background material is available at <http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm>.

About AML

Acute myeloid leukemia 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 67, and is slightly more common among men than women. The most common symptoms of AML include weight loss, tiredness, fever, night sweats, and loss of appetite. AML can sometimes spread to other parts of the body including the lymph nodes, liver and spleen. In 2008, there were slightly more than 13,000 new cases of AML reported and nearly 9,000 deaths in the United States.

About Dacogen

Dacogen (decitabine) for Injection is indicated for treatment of patients with myelodysplastic syndromes (MDS), including previously treated and untreated, de novo and secondary MDS of all French-American-British (FAB) subtypes (refractory anemia, refractory anemia with ringed sideroblasts, refractory anemia with excess blasts, refractory anemia with excess blasts in transformation, chronic myelomonocytic leukemia), and Intermediate-1, Intermediate-2 and High-Risk International Prognostic Scoring System (IPSS) groups.

A five-day dosing regimen for *Dacogen* was approved by the FDA for the treatment of MDS. *Dacogen* was first approved by the FDA as a three-day dosing regimen for the treatment of patients with MDS on May 2, 2006.

Dacogen is currently approved for the treatment of MDS in about 30 countries outside of the United States, where it is being developed and marketed by Janssen-Cilag International NV and other affiliates of Cilag GmbH International, the licensing partner of Eisai.

Important Safety Information for MDS Patients

Treatment with *Dacogen* is associated with neutropenia and thrombocytopenia. Complete blood and platelet counts should be performed as needed to monitor response and toxicity, but at a minimum prior to each dosing cycle. Clinicians should consider the need for early institution of growth factors and/or antimicrobial agents for the prevention or treatment of infections in patients with MDS.

Dacogen may cause fetal harm when administered to a pregnant woman. Women of childbearing potential should be advised to avoid becoming pregnant while receiving treatment with *Dacogen* and for 1 month following completion of treatment. Men should be advised not to father a child while receiving treatment with *Dacogen*, and for 2 months following completion of treatment.

In the MDS Phase 3 controlled clinical trial, the highest incidence of Grade 3 or Grade 4 adverse events in the *Dacogen* arm were neutropenia (87%), thrombocytopenia (85%), febrile neutropenia (23%), and leukopenia (22%). Bone marrow

suppression was the most frequent cause of dose reduction, delay, and discontinuation. Six patients had fatal events associated with their underlying disease and myelosuppression (anemia, neutropenia, and thrombocytopenia) that were considered at least possibly related to drug treatment. Of the 83 *Dacogen*-treated patients, 8 permanently discontinued therapy for adverse events; compared to 1 of 81 patients in the supportive care arm.

In the MDS single-arm study, the highest incidence of Grade 3 or Grade 4 adverse events were neutropenia (37%), thrombocytopenia (24%), and anemia (22%). Seventy-eight percent of patients had dose delays. Hematologic toxicities and infections were the most frequent causes of dose delays and discontinuation. Eight patients had fatal events due to infection and/or bleeding that were considered at least possibly related to drug treatment. Nineteen of 99 patients permanently discontinued therapy for adverse events.

Other commonly occurring reactions include fatigue, pyrexia, nausea, cough, petechiae, constipation, diarrhea, and hyperglycemia.

If hematological recovery from a previous *Dacogen* treatment cycle requires more than 6 weeks, then the next *Dacogen* cycle should be delayed and dosing temporarily reduced. If the following non-hematologic toxicities are present, *Dacogen* treatment should not be restarted until the toxicity is resolved 1) serum creatinine greater than or equal to 2 mg/dL; 2) SGPT, total bilirubin greater than or equal to 2 X ULN; and 3) active or uncontrolled infection.

There are no data on the use of *Dacogen* in patients with renal or hepatic dysfunction; therefore, *Dacogen* should be used with caution in these patients.

The full prescribing information for *Dacogen* is available on the Eisai website at www.eisai.com.

About Astex Pharmaceuticals

Astex Pharmaceuticals is dedicated to the discovery and development of novel 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 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>.

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