



Eisai Inc. Receives Complete Response Letter from the U.S. Food and Drug Administration for Dacogen® (decitabine) for Injection sNDA in Acute Myeloid Leukemia

DUBLIN, Calif.--(BUSINESS WIRE)-- Astex Pharmaceuticals, Inc. (NASDAQ: ASTX) today announced that the U.S. Food and Drug Administration has issued a Complete Response Letter to partner Eisai for their supplemental New Drug Application (sNDA) for Dacogen® (decitabine) for Injection for patients with acute myeloid leukemia (AML) in adults 65 years of age or older who are not considered candidates for induction therapy.

The FDA declined to approve the application because the pre-specified analysis of the primary endpoint in the study (DACO-016) did not demonstrate statistically significant superiority of Dacogen over the control arm (p=0.11).

A separate Marketing Authorization Application was submitted to the European Medicines Agency (EMA) in May 2011 by Janssen for Dacogen in the treatment of patients with AML. It is expected the EMA will issue a decision on this application later this year.

About DACOGEN

DACOGEN is currently approved for the treatment of MDS in about 30 countries. DACOGEN is licensed to Eisai Co., Ltd and Eisai has licensed rights outside of North America to Janssen-Cilag International NV and other Janssen affiliates. Astex receives royalties on global sales of DACOGEN.

DACOGEN is approved, in the United States, 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.

Important Safety Information

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. After administration of the recommended dosage for the first cycle, treatment for subsequent cycles should be adjusted if indicated by dose adjustment guidelines. 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. Women of childbearing potential should be counseled to use effective contraception during this time. Men should be advised not to father a child while receiving treatment with DACOGEN and for 2 months following completion of treatment. DACOGEN may cause fetal harm. Men with female partners of childbearing potential should use effective contraception during this time.

In a phase 3 clinical trial in MDS patients, the highest incidence of Grade 3 or Grade 4 adverse events in the DACOGEN arm was 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 a single-arm study in MDS patients, the highest incidence of Grade 3 or Grade 4 adverse events was neutropenia (37%), thrombocytopenia (24%), and anemia (22%). Seventy-eight percent of patients had dose delays, the median duration of this delay was 7 days. 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 hematologic recovery from a previous DACOGEN treatment cycle requires more than 6 weeks when administering the 3-day dosing, then the next DACOGEN cycle should be delayed and dosing temporarily reduced. When administering the 5-day dosing, the DACOGEN cycle should be delayed until there is hematologic recovery. If the following nonhematologic toxicities are present, DACOGEN treatment should not be restarted until the toxicity is resolved: (1) serum creatinine ≥ 2 mg/dL; (2) SGPT, total bilirubin $\geq 2 \times$ ULN; and (3) active or uncontrolled infection.

Because there are no data on use of DACOGEN in patients with renal or hepatic dysfunction, DACOGEN should be used with caution in these patients.

For DACOGEN full prescribing information, please click [here](#).

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 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>.

Forward-Looking Statements

This press release contains "forward-looking" statements within the meaning of Section 21A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, and is subject to the safe harbor created thereby. Actual results could differ materially from those projected in the forward-looking statements as a result of a number of risks and uncertainties. These forward-looking statements include, but are not limited to, statements regarding the expected timing of EMA approval of a new indication for Dacogen. Important additional factors that could cause actual results to differ materially from the expectations reflected in the forward-looking statements include, but are not limited to: risks and uncertainties related to the regulatory decision of the EMA and whether Dacogen will achieve approval for any additional patient indications. In general, our future success is dependent upon numerous factors, including our ability to generate pre-clinical development candidates for selection into clinical testing, obtaining regulatory approval of product development programs, conducting and completing clinical trials, obtaining regulatory approval of our products and product candidates, creating opportunities for future commercialization of compounds, and accurately assessing and disclosing the risks associated with Dacogen and other drugs we develop. References made to the discussion of risk factors are detailed in the Company's filings with the Securities and Exchange Commission (the "SEC") including reports on its most recently filed Form 10-K and Form 10-Q. These forward-looking statements are made only as of the date hereof, and we disclaim any obligation to update or revise the information contained in any such forward-looking statements, whether as a result of new information, future events or otherwise.

Astex Pharmaceuticals, Inc.

Timothy L. Enns, 925-560-2810

Senior Vice President

Corporate Communications & Marketing

tim.enns@astx.com

or

Astex Pharmaceuticals, Inc.

Susanna Chau, 925-560-2845

Manager

Investor Relations

susanna.chau@astx.com

or

The Trout Group

Alan Roemer, 646-378-2945

Managing Director

aroemer@troutgroup.com

or

College Hill

Melanie Toyne-Sewell (Europe), +44 20 7866 7866

Rebecca Skye Dietrich (US), 857-241-0795

astex@collegehill.com

Source: Astex Pharmaceuticals, Inc.

News Provided by Acquire Media