

Eisai Will Initiate First Head-to-Head Study Comparing Dacogen[®] (decitabine for injection) and Vidaza[®] (azacitidine) in Patients with Myelodysplastic Syndromes

Randomized Comparator Study to Evaluate Efficacy of Commercially Available Hypomethylating Agents

Woodcliff Lake, NJ, December 2, 2008 – Eisai Corporation of North America today announced that it plans to initiate the first clinical trial evaluating the activity of Dacogen[®] (decitabine for injection) compared to Vidaza[®] (azacitidine) in adult patients with intermediate-1, intermediate-2 or high-risk myelodysplastic syndromes (MDS), a potentially life-threatening group of bone marrow diseases that limit the production of functional blood cells. The head-to-head trial will be conducted in the United States and will directly compare Dacogen[®] to Vidaza[®] with a primary endpoint of complete response rate (including marrow complete response).

“Previous to the introduction of the hypomethylating agents, supportive care was the only treatment option for patients living with MDS,” said Dr. Hagop M. Kantarjian, chairman of the Leukemia Department and professor of medicine, University of Texas M.D. Anderson Cancer Center. “This study, for the first time, will provide physicians with important information to understand how these two agents compare when treating patients with MDS, who currently have a generally poor prognosis, with life expectancies shorter than those with lung cancer.”

Study Design

This randomized, multi-center, open-label study will be conducted among 228 adult patients with intermediate-1, intermediate-2 and high-risk MDS. Patients will be randomized on a 1:1 ratio to either Dacogen[®] or Vidaza[®]. Each treatment arm will be stratified by IPSS risk group and type of MDS (primary vs. secondary).

The study’s primary objective is to compare the complete response rates, including bone marrow response rates, for Dacogen[®] versus Vidaza[®].

“Findings from this trial could help clarify the fundamental differences between Dacogen and Vidaza and ultimately help clinicians with treatment selection,” said Dr. Anastasios Raptis, co-director, Myelodysplastic Syndrome Program, attending, Stem Cell Transplant Program and clinical assistant professor of medicine, University of Pittsburgh School of Medicine. “This study takes into account recent data that suggest that treatment of patients should continue for as long as they receive clinical benefit or until their disease progresses.”

Eisai is committed to a clinical development program to optimize the utility of Dacogen[®] for patients with MDS. To advance the understanding of optimal treatment for MDS, hematological malignancies and other cancers, there are currently more than 30 ongoing trials with Dacogen[®] either as a single agent or in combination with other therapies.

About MDS

Myelodysplastic syndromes, or MDS, are a group of diseases of the bone marrow characterized by the production of poorly functioning and immature blood cells. People with MDS may experience a variety of symptoms and complications, including anemia, bleeding, infection, fatigue and weakness. Those patients with high-risk MDS may experience bone marrow failure, which may lead to death from bleeding and infection. Over time, MDS can progress to acute leukemia, or AML. The Aplastic Anemia and MDS International Foundation currently estimates that up to 30,000 new cases of MDS are diagnosed annually in the United States.