

## *Clinical Trial in the Spotlight*

July 2009

### **Phase 3 Open-Label Study of Amonafide L-Malate in Combination with Cytarabine compared to Daunorubicin in Combination with Cytarabine in Patients with Secondary Acute Myeloid Leukemia (AML)**

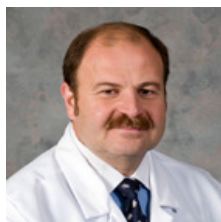
This is an open-label, randomized, Phase 3, multi-center study. It is designed to assess the safety and efficacy of the study drug amonafide in combination with cytarabine. This combination will be compared to the standard induction regimen of daunorubicin and cytarabine in patients with previously untreated secondary AML. Approximately 150 centers and 420 patients will participate in this study worldwide.

Patients will be randomized to one of two treatment arms. Treatment will be given on days 1 through 7 for one or two cycles depending on response. Amonafide is a DNA intercalating agent and non-ATP-dependent inhibitor of topoisomerase II. In three Phase I clinical trials, amonafide demonstrated anti-leukemic activity, both as monotherapy and in combination with cytarabine. In a previous Phase II study, a trend toward improved response rate and overall survival has been observed for the amonafide-cytarabine regimen.

Eligibility Criteria include the following:

- 18 years of age or older
- Must have newly diagnosed (previously untreated) Secondary AML, defined as AML occurring after: prior leukemogenic therapy for a non-myeloid condition, or antecedent MDS documented by bone marrow aspirate/biopsy at least 3 months prior to initial diagnosis of AML
- Eastern Cooperative Group (ECOG) performance status of 0-2
- Left Ventricular Ejection Fraction (LVEF) that is greater than or equal to 50%
- Adequate renal function and adequate hepatic function

### ***About our lead investigator....***



Ahmad Samer Al-Homsi, M.D. is the Chief of Hematological Malignancies and Blood and Marrow Transplantation at Roger Williams Medical Center, and is an Associate Professor of Medicine at Boston University. Dr. Al-Homsi attended Damascus University School of Medicine, in Damascus, Syria. He was a resident at Christ Hospital and Medical Center in Oak Lawn, Illinois and a Hematology and Oncology Fellow at the University of Massachusetts Medical Center in Worcester, Massachusetts. Dr. Al-Homsi is board certified in Internal Medicine, Hematology, and Medical Oncology, and specializes in Hematological Malignancies, Blood and Marrow Transplantation, and Hemostasis and Thrombosis. He is an active member of the American Society of Hematology, and the American Society of Bone Marrow Transplantation.

*To learn more about this trial and other clinical trials offered at Roger Williams Medical Center  
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