

Phase 1 multi-center, open label dose escalation trial that will assess the maximum tolerated dose, dose limiting toxicities and safety of a seven day, multi-cycle oral dosing regimen of oral Azacitidine in patients with MDS and AML. In addition, the trial will examine pharmacokinetics and pharmacodynamic effects of orally administered Azacitidine, as compared with parenteral Vidaza.

### About the Trial Design

This was the largest randomized study ever conducted in higher-risk MDS. The study was a multi-center, randomized, open-label, parallel-group, Phase 3 trial of subcutaneous (SC) Vidaza (administered at 75/mg/m<sup>2</sup>/day SC for seven consecutive days every 28 days) plus best supportive

care versus CCR plus best supportive care for the treatment of MDS. CCR consisted of one of three physician selected regimens: best supportive care alone, low-dose cytarabine plus best supportive care or standard chemotherapy plus best supportive care. EPO and prophylactic G-CSF use was not permitted. The CCR represented standard of care within the territories where the trial was conducted. The study evaluated 358 higher-risk MDS patients at sites in the U.S., Europe and Australia. Patients were randomized on a 1:1 ratio to either Vidaza or the CCR with stratification by FAB subtypes (RAEB or RAEB-T) and IPSS subgroups (INT-2 or HIGH). Investigators selected the CCR option for each individual patient prior to randomization. The primary objective of the

trial was to demonstrate superiority in survival of Vidaza plus best supportive care versus CCR plus best supportive care in higher-risk MDS patients. Secondary objectives of the trial included transfusion independence, hematologic status, hematologic response and hematologic improvement, episodes of infections requiring intravenous antibiotics, time to relapse after complete response (CR) or partial response (PR), time to disease progression, time to transformation to AML, time to transformation or death from any cause, safety and toxicity and pharmacoeconomics.

Visit [www.vidaza.com](http://www.vidaza.com) for more information on MDS, Vidaza and full prescribing information. **OA**

# Practice Resources

## Clinical trial information and patient assistance programs

### Clinical Trial Opportunities and Resources

A listing of clinical trial resources, online matching services, hotlines and more provided as a service to OA members.

#### AMGEN

[www.amgentrials.com](http://www.amgentrials.com)

AmgenTrials.com is dedicated to bringing education and awareness of Amgen's clinical trials to patient and healthcare communities.

#### MGI PHARMA, INC.

For a list of current trials contact MGI's Medical Communications department at **800-562-5580**.

#### MILLENNIUM PHARMACEUTICALS, INC.

##### 866-VELCADE

Find information about Millennium-sponsored clinical trials for cancer therapies.

#### NOVARTIS ETRIALS

[www.novartisclinicaltrials.com/etrial/home.do](http://www.novartisclinicaltrials.com/etrial/home.do)

**Hotline: 800-340-6843**

Find the information you need to make educated decisions about participating in a Novartis clinical trial. Whether you are a patient or a caregiver, Novartis' goal is to answer your questions and help you understand the trial experience.

#### ROCHE

[www.roche-trials.com](http://www.roche-trials.com)

This website is designed to provide up to date information on new and completed clinical studies.

#### SANOFI AVENTIS

[www.aventisoncology.com/clinical\\_start.htm](http://www.aventisoncology.com/clinical_start.htm)

##### CLINICAL TRIAL MATCHING & REFERRAL SERVICE:

The Clinical Trial Matching & Referral Service, powered by [emergingmed.com](http://emergingmed.com), is designed to provide a fast, simple, and confidential way to obtain information about cancer clinical trials sponsored or supported by Aventis Pharmaceuticals. This service is free.

Questions? Call toll free **1-800-Rx-Trial** or send an email to: [contactus@88rxtrial.com](mailto:contactus@88rxtrial.com).