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## THE MDS FOUNDATION SUPPORTS THE FDA'S DECISION TO EXPAND VIDAZA LABEL TO INCLUDE OVERALL SURVIVAL DATA

-- Results from Clinical Trial Found that VIDAZA is the Only Agent to Extend Survival in Patients with Higher-Risk Myelodysplastic Syndromes --

**Crosswicks, NJ – (August 22, 2008)** – The Myelodysplastic Syndromes (MDS) Foundation supports the decision by the U.S. Food & Drug Administration (FDA) to extend the label for VIDAZA (azacitidine) to include data from the AZA-001 clinical trial. Results from the trial found that azacitidine is the only agent which has been shown to extend survival in MDS patients.

Data from the AZA-001 trial was recently presented at this year's American Society of Clinical Oncology (ASCO) Annual Meeting and found that azacitidine nearly doubled the two-year survival rate for higher-risk MDS patients compared to conventional care regimens (CCR) with a mean survival of 24.5 months compared to 15 months for patients who received CCR.

"We are extremely encouraged by the results of the AZA-001 trial which for the first time showed that survival could be extended for patients with higher-risk MDS," said Kathy Heptinstall, Operating Director of the Myelodysplastic Syndromes Foundation, "Roughly 30 percent of patients diagnosed with MDS will progress to acute myeloid leukemia (AML), but treatment with VIDAZA significantly delays this progression. VIDAZA not only has great survival data in MDS, but can also prevent progression to AML."

Results from the trial also showed that azacitidine reduced the need for blood transfusions in higher-risk MDS patients with nearly half (45 percent) of patients who were transfusion dependent at the start of the trial achieving transfusion independence.

Additionally, azacitidine was shown to delay the progression of MDS to acute myeloid leukemia (AML). Roughly 30 percent of patient diagnosed with MDS will progress to AML. The delay in progression is especially significant because patients with MDS are typically over the age of 65. According to the National Institute of Health, in this patient group, the average 5-year survival rate after diagnosis with AML is only approximately four percent.

MDS is a primary neoplasm of the bone marrow that is more prevalent than any of the leukemias. MDS affects the function of blood cells, either red blood cells, white blood cells or platelets. The incidence of MDS is underestimated.

## **About the MDS Foundation**

The Myelodysplastic Syndromes Foundation, Inc. is a multi-disciplinary, international organization devoted to the prevention, treatment, and study of the myelodysplastic syndromes. The organization is based upon the premise that international cooperation will accelerate the process leading to the control and cure of these diseases. For further information, please visit <a href="http://www.mds-foundation.org">http://www.mds-foundation.org</a>.