



THE MDS FOUNDATION SAYS NICE DECISION AGAINST VIDAZA[®] DENIES ESSENTIAL TREATMENT OPTION AND DENIGRATES THE VALUE OF PATIENTS' LIVES

VIDAZA is the only licensed drug shown in clinical trials to improve survival

Crosswicks, NJ, USA (4 March 2010) — The Myelodysplastic Syndromes (MDS) Foundation today issued a statement highly critical of a draft decision not to make available to UK patients the only drug approved by the European Medicines Agency (EMA) for MDS. MDS is a malignant bone marrow disease with a median survival of less than one year that can also progress to an aggressive form of leukemia called AML. VIDAZA (azacitidine) is crucial to the treatment of this disease, especially for MDS patients over the age of 65 who are not eligible for bone marrow transplants—the majority of MDS patients. Despite this critical need, the National Institute for Health and Clinical Excellence (NICE) in the UK issued a final ruling saying that VIDAZA should not be funded because NICE claims it is not cost-effective.

“This negative appraisal of VIDAZA from NICE denies MDS and AML patients access to the only drug proven to prolong their lives. It is an affront to all patients with haematological malignancies and devalues their very existence,” said Kathy Heptinstall, Operating Director of the Myelodysplastic Syndromes Foundation. “In addition to prolonging life, VIDAZA has also been shown to improve the quality of life for MDS patients, many of whom have no other treatment options.”

Specifically, the MDS Foundation notes:

- VIDAZA is the only drug available in the UK to significantly extend survival for higher-risk patients with MDS, based on the largest international study in this disease category
- VIDAZA delays progression to AML
- VIDAZA improves quality of life for many patients by eliminating the need for frequent blood transfusions that can themselves lead to serious side effects including iron overload
- VIDAZA is approved and reimbursed in approximately 30 countries worldwide

COST ISSUES:

The MDS Foundation also challenged the NICE assertion that VIDAZA is not cost-effective. The foundation says NICE compared VIDAZA to low-cost palliative care and transfusions instead of to chemotherapy which is more expensive, although less tolerable. In so doing, the MDS Foundation believes NICE failed to act fairly in accordance with its own appraisal procedures and violated last year's policy change specifically intended to allow greater access to life-extending medicines. Regardless, the number of MDS patients requiring VIDAZA treatment is small, less than 700 per year in the UK, so VIDAZA would not have a major budget impact.

“We have seen VIDAZA transform patients' lives from a debilitating state to an active, normal life where they can once again be a contributing member to their families and to society,” said David Hall, Chairman of the MDS UK Patient Support Group and an MDS patient. “We join the MDS Foundation and a group of patient advocacy organizations in expressing both anger and disappointment in the NICE decision to deny patients the care they so desperately need.”

The MDS Foundation and the MDS Patient Support Group will work with both NICE and the drug's manufacturer, Celgene, to appeal and ultimately to attempt to reverse this negative decision.

About the MDS Foundation

The Myelodysplastic Syndromes Foundation, Inc. is a multi-disciplinary organization devoted to the prevention, treatment, and study of the myelodysplastic syndromes and is the only international organization devoted to MDS and a related leukemia, AML. 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 <http://www.mds-foundation.org>.