

IN EVERY ISSUE

# Prostate Cancer & MDS

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## FDA Delays Review for Second Prostate Cancer Therapy

Satraplatin, an oral platinum chemotherapy for hormone-refractory prostate cancer that would be marketed under the brand name Orplanta, was expected to breeze through the Food and Drug Administration's advisory committee on its way to possible approval, but in July, the committee instead voted unanimously for the FDA to await more trial data. Provenge (sipuleucel-T), a vaccine for hormone-refractory prostate cancer, was also sent back for more trial data in May.

The phase III SPARC (Satraplatin and Prednisone Against Refractory Cancer) study is examining whether adding Orplanta to standard prednisone extends survival. The study, which began in 2003, includes 950 men with hormone-refractory prostate cancer that did not respond to prior chemotherapy. In June 2006, interim data showed a slight overall survival benefit, but was not considered statistically significant. The study's primary goal was to show Orplanta improved progression-free survival, which it did, increasing median progression-free survival from 9.7 weeks to 11.1 weeks, a 13 percent improvement.

Critics weren't impressed by the approximate 10-day improvement, but SPARC investigators noted at the 2007 American Society of Clinical Oncology Prostate Cancer Symposium in February that improvement increased over time. At six months, 30 percent of patients receiving Orplanta were free of disease progression, compared with 17 percent in the prednisone-only group, and at one year, 16 percent of patients on Orplanta were progression-free compared with 7 percent taking prednisone. Side effects of Orplanta include mild to moderate decreased blood cell counts and vomiting. For more, visit [www.gpc-biotech.com](http://www.gpc-biotech.com).

## Vidaza Extends Survival in MDS

Vidaza (azacitidine) may work better than previously thought, according to new data released in August from the largest clinical trial to study high-risk myelodysplastic syndromes (MDS).

Vidaza, an injectable drug, extended overall survival in high-risk MDS by more than nine months, from 15 months with conventional therapy to 24.4 months with Vidaza. Survival at two years improved from 26 percent with conventional therapy to close to 51 percent with Vidaza. The drug's impact on survival represents the most significant improvement seen in MDS. Common side effects

of Vidaza include nausea, anemia, and thrombocytopenia (low platelet count).

The trial also marks the first cancer drug to show survival benefit by employing epigenetics, a treatment approach that changes the regulation of gene expression by interfering with the DNA process that silences certain genes, thus restoring tumor suppressor function and normal functioning of the cell.

MDS is a set of blood disorders that occur when mutated stem cells in the bone marrow produce dysfunctional blood cells called blasts, resulting in low numbers of one or more types of blood cells. An estimated 10,000 to 15,000 new cases of MDS are diagnosed each year in the United States, but some experts estimate the number is actually much higher. Twenty percent of MDS cases eventually develop into aggressive acute myeloid leukemia, which is harder to cure than leukemia not associated with MDS.

Initially approved in 2004 as the first drug for treating MDS, Vidaza was shown to delay the development of leukemia, decrease blasts, and reduce the frequency of blood transfusions. Two other drugs have since been approved for the disease— Revlimid (lenalidomide) in late 2005 and Dacogen (decitabine) in 2006.

The Food and Drug Administration granted fast-track status for an oral formulation of Vidaza in late August. The drug is also being tested in multiple myeloma, acute myeloid leukemia, chronic lymphocytic leukemia, and hormone-resistant prostate cancer. For more, visit [www.vidaza.com](http://www.vidaza.com).