

IN EVERY ISSUE

## Breast Cancer & MDS

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### Comparable Prevention Effect Sparks Debate

One of the largest global breast cancer prevention trials ever conducted found that a drug that treats and prevents osteoporosis called Evista (raloxifene) is as effective in preventing invasive breast cancer as standard tamoxifen, but questions surround the impact of side effects associated with each drug.

The STAR trial (Study of Tamoxifen and Raloxifene), which enrolled nearly 20,000 postmenopausal women with a high risk of breast cancer, compared the effects of daily Evista with tamoxifen for five years and found both drugs reduce the risk of invasive breast cancer by half. Despite this finding, it remains unclear which drug is superior. Tamoxifen was associated with fewer cases of noninvasive (in situ) breast cancer, a risk factor for invasive cancer. But tamoxifen increased the risk of cataracts and led to more uterine cancers and blood clots than Evista. Authors of an editorial published in the *Journal of the American Medical Association* wrote: “Although media coverage of the early release of data from the STAR trial suggest a clear ‘winner’ in raloxifene, the data from clinical endpoints and patient-reported symptoms suggest a less clear conclusion. Assuming U.S. regulatory approval of raloxifene to prevent breast cancer, physicians should discuss these two similar options carefully with their eligible and interested patients.”

Like tamoxifen, Evista is a selective estrogen receptor modulator (SERM), which helps prevent estrogen from binding to cancer cells and inhibits cancer cell growth. As a SERM, Evista also stops the thinning of bone tissue and increases the amount of good tissue, hence lowering the risk of bone fracture. Approved for treating and preventing osteoporosis in postmenopausal women in 1997, Evista is currently prescribed to nearly half a million postmenopausal women for bone health. Since both drugs have similar side effects, women who have taken tamoxifen and are looking for agents to improve bone health should find alternatives, such as Fosamax (alendronate) or Actonel (risedronate), in order to avoid increasing the risk of side effects like blood clots.

Tamoxifen is the only Food and Drug Administration-approved drug for breast

cancer prevention, but the makers of Evista intend to file the drug for approval for invasive breast cancer risk reduction in postmenopausal women this year. Evista has not been tested in premenopausal women or breast cancer survivors, so tamoxifen is still the only choice for those groups.

For details on the STAR trial, go to [www.nsabp.pitt.edu/STAR/Index.asp](http://www.nsabp.pitt.edu/STAR/Index.asp) and for more on Evista, visit [www.evista.com](http://www.evista.com).

### Third Drug Approved for Treating Myelodysplastic Syndromes

The Food and Drug Administration approved Dacogen (decitabine), an injection therapy for myelodysplastic syndromes (MDS), in early May after trial results showed Dacogen reduced the number of abnormal cells invading the bone marrow and renewed normal function of blood cells in up to half of patients. Now the third drug approved for MDS in the past two years, Dacogen joins Vidaza (azacitidine) and Revlimid (lenalidomide) for treating the bone marrow disease, which is diagnosed in an estimated 7,000 to 12,000 Americans each year.

The approval was based in part on results from a trial comparing Dacogen with supportive care for patients with intermediate or high-risk MDS. The trial found that 17 percent of patients had a response to treatment, more than half of which were complete hematologic responses (blood counts returned to normal). Thirty-nine percent of patients treated with Dacogen became transfusion independent, and mortality and leukemia risk decreased. Furthermore, most responses were seen within three months of treatment (two cycles of therapy), though a different study found repeated treatments necessary. Common side effects of Dacogen include neutropenia and thrombocytopenia.

In normal cells, tumor suppressor genes and proteins serve as cellular guardians that ensure normal cellular functioning and growth. In MDS cells, many of these tumor suppressors have been silenced, allowing abnormal growth. Dacogen restores tumor suppressor function, allowing them to recognize abnormal growth and restore normal functioning of the cell.

For more information on Dacogen, visit [www.dacogen.com](http://www.dacogen.com)