



## In the News

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**RALOXIFENE RESULTS**

Post-menopausal women taking raloxifene (Evista®, Lilly) for osteoporosis had significant reductions in the incidence of breast cancer, according to the results of a study presented at the 21st Annual San Antonio Breast Cancer Symposium held December 12-15, 1998.

A meta-analysis of 10,575 post-menopausal women enrolled in placebo-controlled osteoporosis trials of raloxifene was presented by V. Craig Jordan, Ph.D., professor of cancer pharmacology at Northwestern University Medical School in Chicago. The women were followed for a median of forty months.

Treatment with raloxifene resulted in a highly significant 55 percent reduction in the overall risk of breast cancer, from 3.8 cases per 1,000 patient-years in the placebo arm to 1.7 in the raloxifene arm. During the first six months of treatment there were no differences between the two groups. The two groups began to separate after six months. For patients treated for eighteen months or longer, treatment with

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raloxifene caused a substantial decrease (68 percent) in the risk of cancer, from 5.6 cases per 1,000 patient-years in the placebo arm to 1.8 cases in the raloxifene arm.

Nearly all the benefits of raloxifene were observed in reductions in invasive cancers, where there was a 63 percent decrease (from 3.1 cases per 1,000 patient-years to 1.1 cases) and in patients who were positive for the estrogen receptor (ER), where there was a 74 percent decrease in cancers (from 2.3 cases per 1,000 patient-years to 0.6 cases). There were no significant differences in the rate of noninvasive cancers or among patients who were ER negative.

"These data provide extremely firm information to go forward with the STAR (Study of Tamoxifen and Raloxifene) trial," Jordan stated. As an osteoporosis therapy, raloxifene has demonstrated safety in the breast. The next step, he said, is to "look at [raloxifene's] general performance...as an agent to prevent breast cancer in high-risk women, as opposed to the women in the osteoporosis trial, who were at normal risk for breast cancer." STAR is sponsored by the National Surgical Adjuvant Breast and Bowel Project (NSABP).

D. Lawrence Wickerham, M.D., associate chairman of the NSABP, noted the distinction between the enormity of data on tamoxifen, with more than ten million patient-years of experience, compared to raloxifene, with significantly less experience. "It took many years of long-term follow-up with tamoxifen to identify both the benefits and the infrequent but serious toxicities," Wickerham stated. "We're not at that point yet with raloxifene, and that's why we'll continue to need these longer-term true prevention trials."

According to Jordan, raloxifene should now be considered for use in "a woman in her sixties who wants to maintain her bone density, who is leading an active life, and who wants to decrease her risk for breast cancer but [is] ineligible for tamoxifen because she's not at high risk." Wickerham agreed, stating that "outside of clinical trials, the only group who should now get raloxifene are post-menopausal women who want to prevent osteoporosis. For now, pre-menopausal women should not take raloxifene." However, early studies are now underway at the National Cancer Institute testing raloxifene in pre-menopausal populations.

**NATIONWIDE TRIAL FOR AML**

Maxim Pharmaceuticals is enrolling patients in complete remission from acute myelogenous leukemia (AML) for a Phase III clinical trial of the drug Maxamine. In early clinical trials, patients treated in AML remission with Maxamine therapy may experience a substantial increase in leukemia-free survival. AML is the most

common form of acute leukemia in adults, and prospects for long-term survival are poor for the majority of patients.

Maxim Pharmaceuticals seeks to enroll approximately 125 patients in the United States for the study, which will take place at more than thirty medical centers nationwide. The study will evaluate AML patients' remission duration and

quality of life while they are treated with Maxamine and interleukin-2 (IL-2). Patients with acute myelogenous leukemia (AML) who are older than age 18 and currently in first or subsequent remission are eligible. Patients will not be charged for study treatments, tests, or medical visits during the study.

For more information, contact Catherine Mross at 1-888-562-9465.



**RELIEVING CANCER FATIGUE**

The Oncology Nursing Society has launched [www.cancerfatigue.org](http://www.cancerfatigue.org), an interactive, confidential Internet resource where cancer patients and caregivers can have their personal questions about cancer fatigue answered in a short time by oncology nurses. Cancer fatigue, often described by patients as a total lack of energy, is the most common side effect of cancer and its treatment, affecting 76 percent of cancer patients undergoing therapy.

Patients who access the site will also receive:

- answers to frequently asked questions about fatigue
- tips for coping with the condition
- information about cancer fatigue and its most common cause
- information on chemotherapy-induced anemia.

ONS created the web site as part of its *Fight Fatigue: It Helps!* campaign, a nationwide initiative to educate health care professionals about cancer fatigue and appropriate interventions.

**SUPPORT FOR CAREGIVERS AT HOME**

*Strength for Caring* is an educational program designed to teach family members the skills they need to help care for their loved ones at home. The program, which was developed at the University of Pennsylvania School of Nursing, will help family caregivers cope with emotional, physical, and financial stresses involved in providing care in addition to juggling the demands of family life and careers.

*Strength for Caring* is a comprehensive program led by health care professionals who have completed a facilitator-training module. Sessions will help caregivers to:

- understand cancer and its treatment
- meet the physical and emotional

- needs of patients with cancer
- deal with changing family roles
- improve their own physical and mental health.

*Strength for Caring* is currently available nationwide through a grant from Ortho Biotech. Health care professionals interested in initiating programs in their practices or becoming *Strength for Caring* facilitators may speak to their local Ortho Biotech product specialist or call 1-800-325-7504. General information about the program is also available for interested health care professionals at [www.oncolink.org](http://www.oncolink.org).

**TARGETING ORAL COMPLICATIONS OF CANCER TREATMENT**

A new health awareness campaign from the National Institute of Dental and Craniofacial Research (NIDCR) informs health care providers and patients about what they can do to reduce the risk and impact of oral complications. *Oral Health, Cancer Care, and You: Fitting the Pieces Together* addresses the fact that nearly one-third of patients undergoing radiation and chemotherapy treatment or bone marrow transplants are susceptible to oral complications that may compromise or even stop their treatment.

The program provides information to oncology and oral health professionals about the roles of each in preventing and managing oral complications. The materials also emphasize the importance of communication and cooperation between oncologists and dentists.

The patient is a key player in maintaining oral health during cancer treatment. Materials for patients explain the importance of ensuring a healthy mouth before treatment begins and how to care for the mouth during and after radiation or chemotherapy

to help prevent complications.

Campaign materials for health professionals and patients are available from the National Oral Health Information Clearinghouse at 1-877-216-1019 or at [www.aerie.com/nohicweb](http://www.aerie.com/nohicweb).

**A CALL FOR CLINICAL PATHWAYS FOR PAIN**

The Association of Community Cancer Centers is calling for the submission of clinical pathways for the management of pain in patients with cancer. The clinical pathways may be published in *Implementing an Effective Oncology Pain Management Program*, a special supplement to the September/October *Oncology Issues*. For more information, call 301-984-9496.

**DIGITAL DOCTORS**

Some physicians may flounder as sophisticated information systems spread. Others may welcome the new technology, acquire the requisite knowledge, and prosper. For those interested in securing a place in the latter group, a new book from the American College of Physician Executives (ACPE) offers a wealth of information and guidance for understanding informatics.

In *Digital Doctors*, Marshall Ruffin, M.D., M.P.H., M.B.A., an acknowledged leader in his field, provides the history, current status, and likely future direction of medical informatics. Throughout the book, he encourages greater involvement by physicians and others in computerized information systems. Although *Digital Doctors* was written with physicians in mind, it can be a valuable resource for anyone in health care management who relies on information. For more information or to order *Digital Doctors*, contact the ACPE at 813-287-2000 or on the Internet at [www.acpe.org](http://www.acpe.org). ■