

Recently it has been a struggle for many. A long hard winter, a poor economy, and concerns about future employment; but no match to the challenge facing those patients newly diagnosed with breast cancer. The effort and success is well appreciated by all as each patient's move from diagnosis to treatment. We all know the benefit of testing, but often this is the most difficult period of time for our patients. There may be a delay in scheduling, one test may lead to another, another test requires additional tissue sampling, and those results may even delay or cancel a surgery. Keeping patients calm and positive is undoubtedly a challenge.



Much effort is made to reduce our patient's stress and maintain energy during the testing phase. I have taken on the responsibility of scheduling all testing, updating patients with results and keeping them "in the loop". I have been very fortunate to work closely with many health care providers and ancillary staff to expedite this process. This has made it possible for me to arrange same day testing. I will continue to coordinate the testing, inform patients of results, and schedule consults with specialists to ensure quality care. It has been my pleasure to work so closely with your patients, and we appreciate your confidence in us. I am a phone call away for both you and your patients.

Sandy Schwark, R.N., BSN

### **Topical Tamoxifen Promising for Cyclic Mastalgia**

Afimoxifene, a novel Tamoxifen gel applied directly to the breasts, performed favorably as topical therapy for moderate to severe cyclic mastalgia in premenopausal women in a phase II clinical trial.

Although the topical antiestrogen's developer, ASCEND Therapeutics Inc., plans to seek an initial indication for cyclic mastalgia, there also is strong interest in developing Afimoxifene as a treatment for male gynecomastia as well as for breast cancer chemoprevention, Dr. Amit Goyal said at the San Antonio Breast Cancer Symposium.

Oral Tamoxifen, bromocriptine, danazol, and progestins have demonstrated efficacy in treating cyclic mastalgia; however, their systemic side effects render them poorly suited for long-term treatment of a chronic problem. In contrast, transdermal Afimoxifene is highly effective within the breast yet has very low systemic levels, thus reducing the risk of systemic toxicities, he continued.

In a pharmacokinetic study, 16 healthy premenopausal women applied 4 mg. of Afimoxifene to their breasts daily for 21 days. At steady state, achieved after 2 weeks of therapy, mean plasma 4-hydroxytamoxifen levels were just 1/18 of those measured in 19 healthy controls taking 20 mg/day of oral Tamoxifen.

Based upon those encouraging findings, Dr. Goyal and his co-investigators next carried out the phase II trial involving 127 premenopausal women with moderate to severe cyclic mastalgia. They were randomized to placebo or either 2 mg. or 4 mg. of Afimoxifene daily for 4 menstrual cycles.

Significant differences in efficacy between the 4-mg. dose and placebo were documented after 2 cycles. After 4 cycles, mean pain intensity measured on a visual analog scale for the 7 worst days per cycle was 64% lower in women on 4 mg/day of Afimoxifene than in the placebo group. Physician global assessments of breast nodularity and tenderness showed reductions of 70% and 67%, respectively, relative to placebo. The 2-mg. dose showed less robust albeit favorable trends on all end points, he continued.

Chemoprevention of breast cancer is a particularly exciting potential application for the topical selective estrogen-receptor modulator.

"The main reason why some women and some physicians are reluctant to use oral Tamoxifen, even though we know from the National Surgical Adjuvant Breast and Bowel Project study that it works, is because of side effects. If we can show Afimoxifene works to prevent breast cancer as well as oral Tamoxifen, I think that would be an important advance", Dr. Goyal said. That will require a large, lengthy, and costly phase III clinical trial, he noted.