SESSION 5

S13. Impact of Tamoxifen as a Preventive Agent in Clinical Practice and Update of the STAR Trial

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With the publication of the NSABP P-1 Trial results and the subsequent approval of tamoxifen for breast cancer risk reduction by the U.S. Food and Drug Administration, tamoxifen and the concept of chemoprevention have received substantial attention in both the medical and lay communities in the United States. Access to the Gail Model on web sites, computer disks, and hand-held calculators has resulted in increasing numbers of women obtaining individualized breast cancer risk assessments. Physicians have been cautious in using tamoxifen for breast cancer prevention while they develop an understanding of the balance between breast cancer risks and the toxicities of the drug. However, tamoxifen's use in patients with LCIS and atypical hyperplasia appears to be increasing.

In July 1999, accrual to the Study of Tamoxifen and Raloxifene (STAR), the second NSABP breast cancer prevention trial, opened at more than 500 centers throughout the United States, Canada, and Puerto Rico. In this study, more than 22,000 postmenopausal women will be randomized to receive either tamoxifen, the benefits of which have now been proven, or raloxifene, which appears promising. The primary aim of the trial is to determine if raloxifene is as good as or better than tamoxifen in breast cancer prevention with fewer side effects. As of November 20, 2001, 11,800 women (53.6% of the targeted accrual) had been randomized, and the trial was on schedule to achieve its sample size in the originally projected 5-year period. Ten percent of the women are 35-49 years of age, 50% are 50-59, and 40% are 60 or older. Twenty-eight percent of the women randomized have a Gail Model score of a 5% or greater 5-year risk of developing breast cancer, and 76% have at least one first-degree relative who has or had breast cancer.