**Soy Strikes Out for Breast Cancer Risk Reduction**

**BY JACOB LINCECUM**

**SAN ANTONIO —** Six months on a mixed soy isoflavone dietetic supplement produced no significant change in breast epithelial cell proliferation in healthy women at high risk for breast cancer in a phase IIb randomized trial.

“These results argue against the efficacy of soy isoflavones supplementation of the adult Western diet for purposes of breast cancer prevention, but also do not suggest an adverse effect on the breast,” Dr. Seema A. Khan declared at the San Antonio Breast Cancer Symposium.

The study included 99 women with an elevated breast cancer risk score or a history of completely treated unilateral breast cancer who were randomized to 6 months of placebo or the soy isoflavone supplement, each serving containing 150 mg of genistein, 74 mg of daidzein, and 11 mg of glycitein.

The primary study end point was change over time in Ki-67, a measure of breast epithelial cell proliferation that reflects cancer risk. The samples were obtained by random fine-needle aspiration.

Among the 43 postmenopausal participants, there was no difference in Ki-67 between the treatment and control arms at 6 months. Among the premenopausal women, there was actually an unwell response but nonsignificant trend for greater Ki-67 labeling in the soy supplement group, especially in samples obtained during the luteal phase, reported Dr. Khan, professor of surgery at Northwestern University, Chicago.

Study compliance was not an issue. Plasma genistein concentrations at 6 months averaged 269.8 mg/ml in the treatment arm, compared with 2.5 mg/ml in the control group.

The phase IIb study was undertaken in response to epidemiologic evidence that consumption of soy isoflavones confers protection against development of breast cancer in Asian populations (Br. J. Cancer 2008;99:9-14), among whom soy isoflavone–rich food products such as miso soup, tofu, and natto are popular.

However, a Japanese study presented at the San Antonio meeting suggested that it is consumption of soy isoflavones early in life that’s the key to possible reduction of breast cancer risk decades later in middle-aged Japanese women.

Dr. Masakazu Toi of Kyoto (Japan) University presented a population-based case-control study involving 355 breast cancer patients aged 40-55 years and 710 age- and region-matched controls. They underwent structured interviews by blinded interviewers regarding their past consumption of soy isoflavone–containing foods during three specific periods of their life: age 10-12 years, around age 20, and 10-15 years prior to the index date.

The three periods, 29% of all subjects with breast cancer fell into the lowest quartile for average daily soy consumption, as did 20% of controls.

In a multivariate logistic regression analysis, women in the top quartile for average daily soy consumption during the three time periods of interest were 53% less likely to have breast cancer than those in the lowest quartile (P = .0006).

The Japanese investigators also identified an inverse relationship between breast cancer risk and consumption of beverages containing Lactobacillus casei strain Shirota during the same stages of early life.