



PRESS RELEASE

Thursday, December 7, 2017

Ovarian Suppression Reduces Recurrence for Young Breast Cancer Patients

SAN ANTONIO –The International Breast Cancer Study Group (IBCSG) presented updated results after longer follow-up of the randomized, phase III SOFT and TEXT clinical trials of adjuvant endocrine therapy for premenopausal women with hormone receptor-positive breast cancer at the 2017 San Antonio Breast Cancer Symposium.

On December 7th, updates of SOFT and a TEXT/SOFT combined analysis were presented by Dr. Gini Fleming and by Dr. Prudence Francis on behalf of Dr. Olivia Pagani.

For the combined analysis of the TEXT and SOFT studies, after a median follow-up of 9 years, results confirmed statistically significant improvements in disease outcomes with exemestane versus tamoxifen used in combination with triptorelin ovarian suppression. Adjuvant exemestane plus ovarian function suppression, compared with tamoxifen plus ovarian function suppression, showed sustained absolute improvements in disease-free survival and freedom from distant recurrence of 4.0% and 2.1% at 8 years, respectively. The majority of patients had HER2-negative tumors (86% of the population) and had clinically-meaningful benefits, especially those patients deemed at sufficient risk of recurrence to receive adjuvant chemotherapy, for whom the absolute improvements in disease-free survival were 7% - 9%, and absolute improvements in freedom from distant recurrence were 5% - 7%, across TEXT and SOFT respectively. No difference in overall survival after 9 years median follow-up was observed. No new safety concerns were detected.

For the SOFT study, adding ovarian function suppression to tamoxifen significantly decreased the relative risk of disease-free survival events by 24% versus tamoxifen-alone (hazard ratio [HR]=0.76 (95% confidence interval [CI] 0.62-0.93), P=0.009) in the overall population after 8 years median follow-up, resulting in a 4.2% absolute benefit at 8 years. Furthermore, the clinical benefit was particularly clear in women under age 35, with a relative risk reduction of 44% (HR=0.66 (95% CI 0.41-1.07)) corresponding to an 8.7% absolute benefit at 8 years. A small overall survival benefit was seen, being more evident in women who remained premenopausal after receiving adjuvant chemotherapy. The speakers stressed the critical importance of a very long-term follow-up of these young women, and follow-up of the over 5700 participants continues.

“To optimally translate the absolute improvements seen in the trial populations into clinical practice, oncologists need to discuss and weigh potential benefits and toxicity with each individual premenopausal patient with hormone-receptor positive breast cancer” said Dr. Prudence Francis in conclusion of her presentation.

The TEXT and SOFT trials are phase III, randomized clinical trials that enrolled 2,672 and 3,066 premenopausal women with hormone receptor-positive early breast cancer, respectively, between November 2003 and April 2011. In the two trials, 4,690 women were randomized to 5 years adjuvant treatment with exemestane+ovarian function suppression or with tamoxifen+ovarian function suppression. SOFT included a third treatment assignment, 5 years of tamoxifen alone. Ovarian suppression was achieved by monthly injections of the GnRH

agonist triptorelin (most common choice in SOFT and TEXT), surgical removal of both ovaries, or radiation of the ovaries. In both trials, the women may also have received chemotherapy as part of adjuvant treatment, as decided with their doctor.

Tamoxifen alone has been the standard adjuvant hormonal treatment for premenopausal women with hormone-sensitive breast cancer. The trials were designed to determine the value of ovarian suppression in reducing breast cancer recurrence in young women receiving tamoxifen, and to determine whether further reduction in recurrence would be achieved by using the aromatase inhibitor exemestane in combination with ovarian suppression. The aromatase inhibitor exemestane requires suppression of estrogen produced by the ovaries to be effective in premenopausal women.

The trials are led by the International Breast Cancer Study Group (IBCSG), in partnership with the Breast International Group (BIG) and the North American Breast Cancer Group (NABCG), and supported by IBCSG, Pfizer, Ipsen, the U.S. National Cancer Institute (NCI), and the Breast Cancer Research Foundation (BCRF).

References: SABCS Abstract #851 GS4-02 (Update of the combined TEXT and SOFT trials) and SABCS Abstract #844 GS4-03 (update of the SOFT trial),

About the International Breast Cancer Study Group (IBCSG)

The IBCSG is one of the world's leading groups in breast cancer research. The IBCSG pioneers research in combined hormonal therapy and chemotherapy, timing and duration of adjuvant therapies and quality of life of breast cancer patients. The latest generation of clinical trials in the adjuvant setting addresses tailored treatment for subgroups of patients, as IBCSG also expands its research into neoadjuvant treatment and therapy for advanced disease. In addition to clinical trials, IBCSG conducts extensive programs in translational research, database studies, quality of life and statistical methodology. The goal of clinical research within IBCSG is to give the patients a longer survival and symptom-free period after primary treatment, and to improve their quality of life.

For more information, visit <http://www.ibcsg.org>

About Breast International Group (BIG)

The Breast International Group (BIG) is an international not-for-profit organisation for academic breast cancer research groups from around the world, based in Brussels, Belgium. Global collaboration is crucial to make significant advances in breast cancer research, reduce unnecessary duplication of effort, share data, contribute to the faster development of better treatments, and increase the likelihood of cures for patients. Therefore, BIG facilitates breast cancer research at the international level, by stimulating cooperation between its members and other academic networks, and collaborating with, but working independently from, the pharmaceutical industry. Founded by leading European opinion leaders in 1999, BIG now constitutes a network of about 60 collaborative groups from Europe, Canada, Latin America, Asia and Australasia. These entities are tied to several thousand specialised hospitals and research centres worldwide. More than 30 clinical trials are run or are under development under the BIG umbrella at any one time. BIG also works closely with the US National Cancer Institute (NCI) and the North American Breast Cancer Groups (NABCG), so that together they act as a strong integrating force in the breast cancer research arena.

For more information, visit www.BIGagainstbreastcancer.org.