PRESS RELEASE
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Ovarian Suppression Reduces Recurrence and Can Improve Survival in Young Breast Cancer Patients

CHICAGO – New data show better outcomes for young breast cancer patients treated with ovarian suppression, with highest-risk patients experiencing the most benefit. The International Breast Cancer Study Group (IBCSG) reported updated, statistically significant 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. On June 4th, the overall results of the trials were published in the New England Journal of Medicine.

In the SOFT study, adding ovarian function suppression to tamoxifen significantly decreased the relative risk of disease-free survival events by 24% versus tamoxifen-alone in the overall population after 8 years median follow-up, resulting in a 4.2% absolute benefit at 8 years. The absolute benefit was larger in women who remained premenopausal after receiving chemotherapy before starting ovarian suppression. The clinical benefit was particularly clear in women under age 35, with an 8.6% absolute benefit at 8 years. Further reduction in recurrence was seen with the use of the aromatase inhibitor exemestane plus ovarian function suppression. An overall survival benefit is now seen at 8 years, with the use of ovarian function suppression, particularly in women who remained premenopausal after receiving adjuvant chemotherapy. However, the frequency of side effects was higher than reported for treatment with tamoxifen alone.

After a median follow-up of 9 years, the combined analysis of the TEXT and SOFT studies confirmed statistically significant improvements in disease outcomes with exemestane versus tamoxifen used in combination with 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. Women with HER2-negative breast cancer experienced the most clinical benefit, especially those who also received adjuvant chemotherapy due to a higher risk of recurrence. In these higher-risk groups, absolute improvements in disease-free survival and freedom from distant recurrence were 7-9% and 5-7% across TEXT and SOFT, respectively with exemestane plus ovarian suppression. No difference in overall survival after 9 years median follow-up was observed when comparing the two groups treated with ovarian suppression.

Concurrent with this publication, on June 4th Dr. Meredith Regan presented a further analysis of the SOFT and TEXT results at the 2018 American Society of Clinical Oncology Annual Meeting. Her presentation detailed the absolute improvements in freedom from distant metastases that might be achieved across the spectrum, from very high risk of recurrence to a low risk of recurrence, utilizing treatment with exemestane plus ovarian suppression, or tamoxifen plus ovarian suppression versus tamoxifen alone.

“These new results may help women and their physicians decide whether the potential benefits of treatment with aromatase inhibitors plus ovarian suppression are worth the potential side effects,” said Dr. Regan. “Very long-term follow-up of these 5700 young women remains critical.”
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:
Regan MM, et al. Absolute improvements in freedom from distant recurrence with adjuvant endocrine therapies for premenopausal women with hormone receptor-positive (HR+) HER2-negative breast cancer (BC): Results from TEXT and SOFT. ASCO Abstract #503

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

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 59 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.