PRESS RELEASE

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New Treatment Option for Young Women with Hormone-Sensitive Breast Cancer

The aromatase inhibitor exemestane is more effective than tamoxifen in preventing breast cancer recurrence in young women who also receive ovarian function suppression as adjuvant (post-surgery) treatment for hormone-sensitive early breast cancer. The International Breast Cancer Study Group (IBSCG) presented the combined results of the TEXT and SOFT clinical trials today at the 2014 American Society of Clinical Oncology (ASCO) Annual Meeting in Chicago and published the results online in the *New England Journal of Medicine* (nejm.org). Treatment with exemestane plus ovarian function suppression reduced the risk of developing any invasive cancer by 28%, and reduced the risk of developing invasive breast cancer recurrence by 34%, compared to treatment with tamoxifen plus ovarian function suppression. At 5 years from study entry, 92.8% of women remained free from breast cancer after treatment with exemestane plus ovarian function suppression; 88.8% after tamoxifen plus ovarian function suppression.

Treatment with an aromatase inhibitor such as exemestane, when compared with tamoxifen, has previously been demonstrated to benefit postmenopausal breast cancer patients. TEXT (Tamoxifen and Exemestane Trial) and SOFT (Suppression of Ovarian Function Trial) were conducted to determine whether this benefit could be extended to premenopausal women by combining exemestane with ovarian function suppression. Hormone-sensitive breast cancer, defined as estrogen and/or progesterone receptor-positive breast cancer, represents 79% of breast cancer diagnosed in women under age 50 in the United States.

The trials were 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 the IBSCG, Pfizer, Ipsen and the US National Cancer Institute.

Both TEXT and SOFT randomly assigned premenopausal women with hormone-sensitive breast cancer to treatment with exemestane plus ovarian function suppression for 5 years or to tamoxifen plus ovarian function suppression for 5 years. The two trials were designed to be complementary. They were conducted over the same time period, in the same general population, and have these two treatments in common. Combining them brings the results to doctors and patients sooner than if they were presented separately.Ovarian function suppression has been used for decades as a breast cancer treatment for premenopausal women, though whether it adds benefit when combined with other treatments is still uncertain. In these trials ovarian function suppression is combined with either tamoxifen or exemestane. In premenopausal women use of an aromatase inhibitor like exemestane requires suppression of estrogen

produced by the ovaries. In TEXT and SOFT, ovarian function suppression was achieved by use of monthly injections of the GnRH agonist triptorelin, surgical removal of both ovaries, or radiation therapy to the ovaries.

“These results provide a new treatment option for young women with hormone-sensitive breast cancer. The trials demonstrate that an aromatase inhibitor, previously recommended only for postmenopausal women, is also effective for premenopausal women when combined with ovarian function suppression,” said study co-chair Dr. Olivia Pagani, Breast Unit Clinical Director at the Oncology Institute of Southern Switzerland in Bellinzona, Switzerland, and a member of BIG. “As a physician who routinely recommends ovarian function suppression as adjuvant therapy for some young patients, these results will change my practice. I will combine ovarian function suppression with an aromatase inhibitor rather than with tamoxifen.”

In addition to assessing the effectiveness of the treatments at reducing recurrence, patient-reported quality of life assessments were collected throughout the 5 years as well as physician-reported side effects. “As clinicians we should be reassured that, in the two treatments studied, the patient-reported quality of life results were similar overall, as was the frequency of severe side effects,” said Dr. Barbara Walley, study co-chair and Medical Oncologist at the Tom Baker Cancer Centre in Calgary, Canada. “The side effects reported in this premenopausal population are similar to those in postmenopausal women in which tamoxifen and aromatase inhibitors are widely prescribed.” Follow-up of the young women participating in the trials continues, to assess long-term prognosis, tolerability and side effects.

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. Over 500 medical institutions, linked to BIG member groups or to the NABCG, from 27 countries enrolled women in the trials. 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 and analyzed in the research presented. SOFT included a third treatment assignment, tamoxifen alone, which will be analyzed in late 2014. The women may also have received chemotherapy as part of adjuvant treatment, as decided with their doctor.

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Reference: ASCO Abstract LBA1

About International Breast Cancer Study Group (IBCSG)

The International Breast Cancer Study Group (IBCSG) is a Swiss nonprofit cooperative breast cancer research organization that has conducted clinical research in adjuvant endocrine therapy and chemotherapy, timing and duration of adjuvant therapies, and quality of life for over 35 years.

www.ibcsg.org

About Breast International Group (BIG)

The Breast International Group (BIG) is a non-profit organisation for academic breast cancer research groups from around the world. Founded by leading European opinion leaders in 1999, BIG now constitutes a network of 49 collaborative groups based in Europe, Canada, Latin America, Asia and Australasia. BIG

also works closely with the US National Cancer Institute (NCI) and the North American Breast Cancer Group (NABCG). BIG facilitates and accelerates international breast cancer research by stimulating cooperation between its members and other academic networks, and collaborating with, but working independently from, the pharmaceutical industry.

www.BIGagainstbreastcancer.org