



PRESS RELEASE

Monday, June 5, 2017
10:45 AM US Central Time (GMT-2:45)

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SOLE (Study of Letrozole Extension):

A phase III randomized clinical trial of continuous vs intermittent letrozole in postmenopausal women who have received 4-6 years of adjuvant endocrine therapy for lymph node-positive, early breast cancer

CHICAGO – Taking planned 3-month treatment breaks during long-term aromatase inhibitor treatment did not reduce the risk of recurrence of breast cancer compared with taking the aromatase inhibitor treatment continuously for 5 years for postmenopausal women with hormone-sensitive early breast cancer who had already completed 4 to 6 years of treatment for their breast cancer. The International Breast Cancer Study Group (IBCSG) presented the results of the phase III Study of Letrozole Extension (SOLE) trial today at the 2017 American Society of Clinical Oncology (ASCO) Annual Meeting.

“This is the first trial evaluating a de-escalation of extended adjuvant endocrine therapy,” said study chair Marco Colleoni, M.D., Director, Division of Medical Senology, European Institute of Oncology, Milan, Italy. “While disease-free survival was not statistically significantly improved by using extended intermittent letrozole rather than continuous letrozole over 5 years, the results of the SOLE study provide clinically-relevant information on the intermittent administration of extended letrozole for patients who could benefit from temporary treatment breaks.”

Patient-reported symptoms and quality of life assessed during the first 2 years of the extended letrozole treatment help put the treatments into perspective. There was a consistent pattern favoring the intermittent letrozole administration. For physical well-being, mood and sleep disturbances, there was less worsening from baseline, and for hot flashes, greater improvement was observed with the intermittent administration.

Researchers designed SOLE as a randomized, phase III clinical trial, of postmenopausal women with hormone-sensitive, lymph node-positive breast cancer who were breast cancer-free following 4 to 6 years of prior adjuvant (post-surgery) endocrine therapy. The prior endocrine therapy may have been either the selective estrogen receptor modulator (SERM) tamoxifen, or an aromatase inhibitor (letrozole, anastrozole or exemestane), or a sequence of both tamoxifen and aromatase inhibitor. Patients had completed their first approximately 5 years of prior endocrine therapy within the 12 months prior to enrollment into SOLE. Patients were randomly assigned to extend their endocrine therapy by either taking: an additional 5 years of continuous letrozole (2.5 mg orally daily) or 5 years of intermittent letrozole (2.5 mg orally daily; taken for the first 9 months during years 1 to 4, and then continuously for 12 months in year 5).

The trial hypothesis was that introducing 3 month treatment-free intervals during the course of five years of extended letrozole (an aromatase inhibitor) would reduce recurrence of breast cancer. In laboratory studies of mice with implanted breast cancer cells that had become resistant to letrozole treatment, the rise in estrogen levels during breaks of letrozole re-sensitized the breast cancer cells to letrozole when started after the break.

The SOLE trial enrolled almost 4900 patients between November 2007 and July 2012 in 22 countries worldwide. Trial treatment lasted 5 years; the women continue to be followed for life to assess long-term prognosis. The trial is led by the International Breast Cancer Study Group (IBCSG), in partnership with the Breast International Group (BIG), and supported by IBCSG and Novartis.

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Reference: ASCO 2017 Abstract 503

About the International Breast Cancer Study Group

The International Breast Cancer Study Group (IBCSG) is a non-profit organization founded as the 'Ludwig Breast Cancer Study Group' in 1977, which has conducted clinical research in adjuvant endocrine therapy and chemotherapy, timing and duration of adjuvant therapies, and quality of life for over 40 years. The IBCSG is headquartered in Bern, Switzerland as a foundation under Swiss law. The Statistical and Data Management Centers are in the United States (Boston, MA and Amherst, NY), and the central pathology review office is in Milan, Italy (www.ibcsg.org).

About the Breast International Group

The Breast International Group (BIG) is a not-for-profit organisation for academic breast cancer research groups from around the world, based in Brussels, Belgium. BIG facilitates breast cancer research at an 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 60 collaborative groups from Europe, Canada, Latin America, Asia and Australasia. These entities are tied to several thousand specialised hospitals and research centres worldwide.

www.BIGagainstbreastcancer.org