



December 16, 2022

Press Release

Japan Breast Cancer Research Group
Representative Director
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Results of the POSITIVE study (IBCSG 48-14 / BIG 8-13)
presented at the San Antonio Breast Cancer Symposium (SABCS)

Breast cancer is most diagnosed in middle-aged and older women, but approximately 3.7% of newly diagnosed patients in Japan each year are under the age of 40. Many of these young patients hope to have and raise children in the future, while at the same time having concerns that pregnancy could cause their cancer worsen. Moreover, postoperative endocrine therapy for breast cancer can last long as 5 to 10 years, and patients must interrupt the treatment to achieve pregnancy.

The POSITIVE trial is a study to evaluate the safety of interrupting endocrine therapy for the purpose of pregnancy, aiming to verify the risk of breast cancer recurrence due to temporary interruption of adjuvant endocrine therapy. The result of POSITIVE trial, presented at the San Antonio Breast Cancer Symposium, held on December 6-10, 2022, showed that breast cancer patients who paused their endocrine therapy to try to get pregnant experienced short-term rates of breast cancer recurrence similar to women who did not pause therapy for pregnancy, and many went on to conceive and deliver healthy babies.

From December 2014 through December 2019, the study enrolled patients from 116 centers across 20 countries, 518 women aged 42 or younger who desired to become pregnant, opting to pause endocrine therapy for approximately two years to try to get pregnant. Before pausing their treatment, women had completed between 18 and 30 months of adjuvant endocrine therapy. At a median follow-up of 41 months, 44 participants (8.9 percent) had experienced a recurrence of breast cancer, which is similar to the 9.2 percent rate in other study examined adjuvant endocrine therapy in premenopausal women. On the other hand, as ER+ breast cancer can recur many years after the initial diagnosis, the researchers are continuing to follow the study participants to assess recurrence risk over time.

For further information, please see the following press releases from SABCS and ETOP-IBCSG/BIG.
SABCS press release link;

<https://bigagainstbreastcancer.org/wp-content/uploads/2022/12/First-results-of-POSITIVE-study-SABCS-press-release.pdf>

ETOP-IBCSG press release link;

<https://bigagainstbreastcancer.org/young-women-with-breast-cancer-can-safely-have-a-baby-study-shows/>

The study is sponsored and conducted by the International Breast Cancer Study Group (IBCSG), a division of ETOP-IBCSG Partners Foundation, and by the Alliance for Clinical Trials in Oncology in North America, in collaboration with the Breast International Group (BIG).

Japan Breast Cancer Research Group (hereinafter called JBCRG) has been a member of the BIG since 2004 and has contributed to international collaborative research. 62 patients from 17 JBCRG member sites participated in POSITIVE study. We would like to thank all the patients who bravely participated in this study and their families as well as the medical professionals at the participating sites who enthusiastically supported to carry out this study.

In addition, this study in Japan has been financially supported by donations made to JBCRG. We would like to acknowledge the following donors for their support: ELC Japan K.K. and the co-sponsors of its Breast Cancer Awareness Campaign, Pink Ring (patient organization of young women with breast cancer), and individual donors. We would like to thank all of you again for your continuous support.

JBCRG will continue to promote clinical research for the creation of tomorrow's medical care envisioning a future without the threat of breast cancer. We look forward to your continued support and cooperation.

For inquiries, please contact:

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Secretariat

<https://jbcrg.jp/en/contact/>