

PRESS RELEASE

Brussels, 8 December 2022



YOUNG WOMEN WITH BREAST CANCER CAN SAFELY HAVE A BABY, STUDY SHOWS

PAUSING ENDOCRINE TREATMENT TO TRY TO GET PREGNANT CAN BE DONE WITHOUT ADDITIONAL RISK OF RECURRENCE IN THE SHORT TERM

About 20% of women¹ with breast cancer are diagnosed in their reproductive years and for many of these women, fertility and pregnancy are priority concerns. Results of the POSITIVE study, also called BIG Time for Baby, will be presented at the [2022 San Antonio Breast Cancer Symposium](#). They show that young women with breast cancer who paused their endocrine treatment to try to get pregnant were able to do so safely. The rates of breast cancer coming back were similar to women who did not interrupt their treatment, and most were able to conceive and deliver healthy babies.

Breast cancer in young women

The majority of young women with early breast cancer have a hormone-sensitive, so called estrogen receptor-positive (ER+) disease, meaning the cancer cells are fed by their own hormones. These women therefore receive endocrine treatment to block the natural production of hormones in order to reduce the risk of the cancer returning. Endocrine therapy may be prescribed for 5-10 years and impacts the ovaries, preventing conception while on treatment.

POSITIVE, a global academic study

From December 2014 through December 2019, 518 women aged 42 or younger who desired to become pregnant enrolled in the study, accepting 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. The study enrolled patients from 116 hospitals across 20 countries, in 4 continents.

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). The study concept was initiated within the BIG-NCTN (National Clinical Trials Network) Endocrine Working Group and then developed and coordinated globally by the IBCSG to address this important, patient-oriented, unmet medical need.

Professor David Cameron, BIG Chair: *"BIG grew out of the belief that international collaboration is crucial to finding answers to pressing questions in breast cancer research. Studies like POSITIVE are only possible thanks to the effort of many, working together, and sharing ideas and resources to make a real difference in the lives of patients with breast cancer."*

¹ According to a recent publication in 2020, the incidence of BC for premenopausal women is 20% [https://doi.org/10.1016/S2214-109X\(20\)30215-1](https://doi.org/10.1016/S2214-109X(20)30215-1)

Encouraging first results

So far, the study researchers have found that the percentage of women whose breast cancer came back (8.9%) was comparable to what occurred in patients enrolled [in other studies](#) (9.2%).

In addition, with a total of 365 babies born to women in the study, the rates of conception and childbirth were similar to or higher than rates in the general population. The study, therefore, provides encouraging guidance to younger women diagnosed with breast cancer who may be hoping to have children. Any such decisions should be made in close consultation with health professionals, however, as each woman's situation is unique. The researchers will continue to follow the women enrolled in the study to assess breast cancer recurrence risk over time and ensure women will complete their endocrine treatment after the planned pause. Although the current results are very encouraging, as ER+ breast cancer can recur many years after the initial diagnosis, so the long-term follow-up is essential.

Professor Olivia Pagani, IBCSG POSITIVE international study chair: *"The primary results of the POSITIVE trial confirm pregnancy can be a realistic objective for women who had an estrogen dependent breast cancer and definitively break the taboo that having a baby can increase the risk of the cancer coming back. Family planning, abruptly interrupted by the disease, can be safely restored."*

Professor Richard Gelber, IBCSG POSITIVE Trial Senior Statistician: *"A global collaboration was required to answer this important question as young women with breast cancer around the world were choosing to interrupt their anti-cancer hormonal treatment in order to complete child-bearing without data indicating that this practice would not increase their risk of a breast cancer recurrence. The POSITIVE Trial results can reassure these women and provide evidence to empower them to make informed decisions about having a child."*

The press release issued by the San Antonio Breast Cancer Symposium [can be found here](#).

About

About the **International Breast Cancer Study Group (IBCSG)**

IBCSG as part of ETOP IBCSG Partners Foundation is one of the world's leading groups in breast cancer research. 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 we also expand our research into neoadjuvant treatment, chemotherapy and immunotherapy for advanced disease. In addition to clinical trials, ETOP IBCSG Partners Foundation conduct extensive programs in translational research, database studies, quality of life and statistical methodology. The International Breast Cancer Study Group is dedicated to innovative clinical research to improve the prognosis of women with breast cancer. Patients and investigators from six continents cooperate by participating in extensive clinical trials in breast cancer populations. www.etop.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)

Funding

This study was funded globally by IBCSG; Frontier Science & Technology Research Foundation Southern Europe; *BIG against breast cancer* and Baillet Latour Fund; Pink Ribbon Switzerland; Swiss Cancer League; San Salvatore Foundation; Rising Tide Foundation for Clinical Research; Swiss Cancer Research Group; Clinical Cancer Research Foundation of Eastern Switzerland; Gateway for Cancer Research; Breast Cancer Research Foundation; Roche Diagnostics International Ltd; Swiss Cancer Foundation; Piajoh Fondazione di Famiglia; Gruppo Giovani Pazienti “Anna dai Capelli Corti”; Verein Bärigüf; Schweizer Frauenlauf; C&A; Dutch Cancer Society; Norwegian Breast Cancer Society; Pink Ribbon Norway; ELGC K.K. Japan; Pink Ring Japan; Korea Breast Cancer Foundation; Yong Seop Lee and other private donors. In North America, funding came from the National Cancer Institute; Canadian Cancer Society; Canada Foundation for Innovation; RETHINK Breast Cancer; and the Gilson Family Foundation.

Note to the editor – not for publication:

Pictures can be downloaded here:

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