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Media Release

4 February = World Cancer Day

THEME 2021: “TOGETHER, ALL OUR ACTIONS MATTER”

BIG’s de-escalation trials

International collaboration to optimise personalised treatment

This year’s theme of World Cancer Day is “Together, all our actions matter”. The Breast International Group (BIG)’s large global network of over 50 academic breast cancer research groups is at the fore of today’s breast cancer research. Founded on the idea that working together internationally is essential to making strides towards curing breast cancer, BIG’s clinical trials have led to practice-changing achievements, paving the way towards more personalised treatment of breast cancer.

Together for better treatments

A number of BIG’s trials aim to test the possibility to safely reduce the amount and/or the length of some breast cancer treatments – or avoid them entirely –, without increasing the risk of the cancer coming back or affecting a patient’s quality of life. The use of cutting-edge genomic tests is closely linked to some of these “de-escalation” studies.

None of BIG’s achievements would be possible without the willingness to work together. To test new treatments with enough patients to be confident about the results, clinical research should not be limited to one institution, or even one country. The single strongest opportunity for success comes from combining resources and multi-disciplinary expertise from around the globe to establish research priorities, improve collaboration, and reduce unnecessary duplication of effort to generate results more quickly. Therefore, BIG thinks globally and acts locally, helping breast cancer patients from all over the world.

BIG’s de-escalation studies

BIG’s de-escalation studies contribute to breast cancer treatments being tailored more precisely to individual patient needs. Today, four large international long-term breast cancer de-escalation trials are being run or about to be launched under the BIG umbrella: **DCIS** (BIG 3-07 / TROG 07.01), **MINDACT** (BIG 3-04 / EORTC 10041), **EXPERT** (BIG 16-02 / ANZ 1601) and **DECRESCENDO** (BIG 19-02 / IJB-EBC-Decrescendo-2020).

Important results from the **DCIS** study (ductal carcinoma in situ), run in 11 countries around the world, showed that individualising radiotherapy for women with DCIS of the breast reduces recurrence after surgery. DCIS is a condition in which abnormal cells are contained within the milk ducts of the breast. It is not an invasive breast cancer but if left untreated, it may turn into an invasive breast cancer.

Presented last December at the San Antonio Breast Cancer Symposium, a leading annual international breast cancer congress, the study reported that after breast conserving surgery, higher radiation doses to the part of the breast where the DCIS was found, in addition to radiotherapy of the whole breast, significantly reduced its risk of returning in patients with higher-risk DCIS. Compared to 5 weeks of whole breast radiotherapy, the study also shows that the shorter, more convenient 3 weeks of radiotherapy did not increase recurrence.



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Tailoring radiation doses and number of treatments to the recurrence risks in patients undergoing radiotherapy for DCIS after surgery are of intense international interest. These results will likely have a significant impact on how patients with DCIS are best managed worldwide. It could also lead to better use of healthcare resources by minimising over or under-treatment of patients with DCIS.

The DCIS study was activated in Australia and New Zealand in 2007, and internationally in 2009. It is run under the BIG umbrella and *Trans-Tasman Radiation Oncology Group (TROG) Cancer Research* is the coordinating group and study sponsor.

In the **MINDACT** study, carried out by the *European Organisation for Research and Treatment of Cancer (EORTC)* in close collaboration with BIG in 9 countries throughout Europe, researchers showed that up to 46% of high-risk patients with early stage breast cancer could avoid chemotherapy and its likely side effects if a sophisticated tumour genomic test (MammaPrint®) showed their cancer was unlikely to come back. The study, published in 2016 in the *New England Journal of Medicine*¹, demonstrated the importance of moving towards using the biological characteristics of a tumour to help safely exclude the need for a treatment which has previously been thought necessary.

In 2020, results of the longer follow-up of patients participating in the MINDACT study confirmed the utility of the MammaPrint test and the possibility to substantially and safely de-escalate the use of post-surgery chemotherapy for some groups of patients, thereby sparing many from an unpleasant treatment and its short and long-term side effects.

In the **EXPERT** trial (*public name: BIG radio tuning*), BIG, together with *Breast Cancer Trials Australia & New Zealand (BCT-ANZ)*, is studying whether some patients with low risk early breast cancer could be spared radiotherapy after breast conserving surgery. As in MINDACT, a genomic test on breast cancer tumours is being used to determine the risk of the cancer coming back. In patients at low risk of recurrence, the combination of standard radiotherapy and hormone treatment is being compared with hormone treatment alone.

The results of the EXPERT trial, which will be run in 9 countries around the globe, could influence how 2 in 5 women with breast cancer are treated. If the study proves that certain patients do not need radiation therapy, many women affected by this disease may be spared its potential side effects, and healthcare systems could also make significant savings.

DECRESCENDO, an international BIG study in collaboration with the *Clinical Trials Support Unit of the Jules Bordet Institute (JIB-CTSU, Brussels, Belgium)*, will shortly start recruiting patients in 12 countries to participate in the study. While the MINDACT and EXPERT trials base de-escalation decisions on a test of tumour biology performed at study entry, in DECRESCENDO, clinicians will identify patients with lymph node-negative, hormone receptor-negative, HER2-positive breast cancer suitable for chemotherapy de-escalation based on their response to pre-surgical treatment. Those whose tumours show a complete response after surgery will be spared further chemotherapy and receive only anti-HER2 treatment.

Long-term persistence and resilience are needed in academic research

For over 20 years, BIG has been conducting global breast cancer clinical trials and research programmes. Despite the Covid-19 pandemic and all the challenges it poses, BIG's network has continued its efforts to advance breast cancer research, demonstrating persistence and resilience, which is needed when conducting large international academic trials.

¹ Cardoso F, van't Veer LJ, Bogaerts J, et al. 70-Gene Signature as an Aid to Treatment Decisions in Early-Stage Breast Cancer. *N Engl J Med* 2016; 375:717-729)



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BIG trials also follow patients long after the experimental treatment ends, with the aim to detect long-term side effects, improve treatment therapies and patients' quality of life.

Over 30 clinical trials or research programmes are being run or are under development under the BIG umbrella at any one time. Since 1999, more than 95,000 patients have participated in BIG's studies.

Breast cancer – facts and figures

Today, breast cancer represents 1 in 4 cancers diagnosed among women globally. About 1 in 8 women will be diagnosed with breast cancer over the course of her lifetime. Because of its high prevalence in low- and middle-income countries, female breast cancer has now become the most commonly diagnosed cancer, even surpassing lung cancer. For men, the lifetime risk of developing breast cancer is about 1 in 800. It has been estimated that by the end of 2020, approximately 2.3 million people, amongst whom about 1% were men, would have been diagnosed with breast cancer across the globe.

Female breast cancer incidence rates are the highest in Australia/New Zealand (about 95%), Western Europe (about 90%), Northern America (about 90%), Northern Europe (about 86%) and Southern Europe (about 80%). These rates far exceed those for other cancers in both developed and developing countries, making it the most commonly diagnosed cancer in women: about one quarter of all new cancer cases worldwide. It is also the leading cause of cancer death in women (1 in 6), and the fifth-leading cause of cancer mortality worldwide with an estimated 685,000 deaths per year (*Source: Globocan Report, Dec. 2020*).

About the 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 international level, by stimulating cooperation between its members and other academic networks, and collaborating with, but working independently from, the pharmaceutical industry.

In 1999, BIG was founded by leading European opinion leaders with the aim to address fragmentation in European breast cancer research. Research groups from other parts of the world rapidly expressed interest in joining BIG and, two decades later, BIG represents a network of over 50 like-minded research groups from around the world. These entities are tied to several thousand specialised hospitals, research centres and world-class breast cancer experts across approximately 70 countries on 6 continents. 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.

BIG's research is supported in part by its philanthropy unit, known as **BIG against breast cancer**. This denomination is used to interact with the general public and donors, and to raise funds for BIG's purely academic breast cancer trials and research programmes. **BIG against breast cancer** conducts vital fundraising to help finance academic clinical trials and research programmes that have no commercial interest but are crucial for patients with breast cancer. The funds raised provide the means for BIG's member groups (made up of breast cancer experts across the globe), and their affiliated hospitals, to finance their efforts and patients' participation in one or more BIG studies. 94.1% of all funds BIG received in 2019, including from **BIG against breast cancer's** philanthropic activity, were spent directly on BIG's research.

For more information, visit www.BIGagainstbreastcancer.org



Note to editors (not for publication):

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