

Media Release

4 February = World Cancer Day

DECRESCENDO, a new large clinical trial to test a less intensive chemotherapy treatment for patients with HER2-positive breast cancer

Brussels (Belgium), 4 February 2022 - A new international clinical study was recently opened in France and Belgium – with the first patient enrolled on 17 January – to assess if it is possible to give a less intensive chemotherapy treatment, and reduce related side effects, without increasing the risk of cancer recurrence, for patients with HER2-positive, hormone receptor-negative breast cancer.

DECRESCENDO, a large phase II multicentre study, is being sponsored by the Institut Jules Bordet and conducted by its Clinical Trials Support Unit (IJB-CTSU, Brussels, Belgium), in collaboration with the Breast International Group (BIG), and will involve a total of **1,065 patients** from about **164 hospitals** in 12 countries worldwide.

HER2-positive breast cancer is an aggressive form of the disease that accounts for about 15-20% of all breast cancer cases¹. Patients with early HER2-positive disease usually receive a combination of multiple chemotherapy drugs and surgery, combined with an anti-HER2 treatment, and continue with the latter for up to one year after surgery. While results are encouraging, with more than 90% of the patients alive and free of cancer recurrence after five years², the combination of chemotherapy and HER2 blockade can cause adverse side effects – such as hair loss, nausea, vomiting, fatigue or even cardiac toxicity –, most of which can be attributed to chemotherapy.

In DECRESCENDO, patients will receive a less intensive chemotherapy treatment prior to surgery (one drug instead of the conventional 2 to 4 drugs). In addition, clinicians will identify patients whose tumours show a complete response to treatment after surgery and who can be spared further chemotherapy and receive only the anti-HER2 treatment. The goal of this study is to show that this new treatment regimen is as effective as the conventional one, but with less potential to cause side effects.

*“With more and more ‘weapons’ targeting the Achille’s heel of this cancer – namely the HER2 receptor –, it makes sense to cautiously simplify chemotherapy, which causes most of the treatment side effects... and this is the goal pursued by DECRESCENDO”, says **Professor Martine Piccart**, Co-Principal Investigator of the study, Scientific Director at the Institut Jules Bordet, Brussels, Belgium, Co-founder of the Breast International Group and President of *BIG against breast cancer*.*

*“I think DECRESCENDO may be a practice-changing study. If our hypothesis is correct, we will significantly reduce the incidence of potentially serious side effects due to chemotherapy, such as heart failure. At the same time, patients will receive a treatment that is as effective as current standards, but almost entirely targeted against the biological weaknesses of the cancer, thus avoiding much of the toxicity often associated with chemo drugs”, says **Professor Gabriele Zoppoli**, Co-Principal Investigator of the study and Assistant Medical Director at the Ospedale Policlinico San Martino, Genova, Italy, and Member of the Board of Directors, Gruppo Oncologico Italiano di Ricerca Clinica (GOIRC).*

Towards better personalised treatments

BIG's de-escalation studies, including DECRESCENDO, contribute to breast cancer treatments being tailored more precisely to individual patient needs. These trials test the possibility to safely reduce the amount and/or the duration 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 prospect of safely de-escalating breast cancer treatment is of great interest to patients, who can receive an optimal therapy with fewer side effects that is better tailored to their individual condition. Likewise, reducing the incidence of severe side effects also benefits healthcare systems, thanks to the optimised allocation of resources and reduced use of the facilities for unnecessary emergencies.

The DECRESCENDO trial is being led by academic research groups, as part of a clinical research collaboration with Roche (providing study drug and funding).

Facts & figures

* **± 2,3 million people** were diagnosed with breast cancer in 2020.

* Breast cancer represents **about 1 in 4** of all new cancer cases in women worldwide.

* For men, the lifetime risk of developing breast cancer is **about 1 in 800**.

* Breast cancer is the **most commonly diagnosed cancer** in the world, with Belgium having the highest incidence worldwide.

Source: Globocan 2020

* **12 countries** are involved in the DECRESCENDO study: Argentina, Australia, Belgium, Canada, France, Ireland, Israel, Italy, New Zealand, South Korea, Sweden, Switzerland.

* **12 BIG research groups** are participating in the study: Australian New Zealand Breast Cancer Trials Group (BCT-ANZ), Canadian Cancer Trials Group (CCTG), Cancer Trials Ireland (CT-IRE), European Organisation for Research and Treatment of Cancer (EORTC), Grupo Argentino de Investigación Clínica en Oncología (GAICO), Italian Oncology Group for Clinical Research (GOIRC), International Breast Cancer Study Group (IBCSG), Institut Jules Bordet – Clinical Trials Support Unit (IJB-CTSU), Korean Cancer Study Group (KCSG), Swedish Association of Breast Oncologists (SABO), Sheba Breast Collaborative Group (SBCG), Unicancer Breast Group (UCBG).

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 Dr Martine Piccart and Dr Aron Goldhirsch 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 National Clinical Trials Network (NCTN), 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.

For more information, visit www.BIGagainstbreastcancer.org



About the Institut Jules Bordet (IJB)

An integrated multidisciplinary centre unique in Belgium, Institut Jules Bordet is an autonomous hospital devoted exclusively to cancer.

For 80 years, Institut Jules Bordet has been providing its patients with diagnostic and therapeutic strategies at the forefront of progress to prevent, detect and actively combat cancer. The Institute pursues three missions: care, research and teaching. Its international reputation attracts the world's leading cancer experts. Its spirit of innovation has enabled it to participate in the development and discovery of major new methods of diagnosis and treatment with the aim of bringing the findings to the patient as rapidly as possible.

In May 2018, the Institut Jules Bordet received official accreditation and designation from the OECl (Organisation of European Cancer Institutes) as a "Comprehensive Cancer Centre", a quality label reserved for multidisciplinary cancer care institutions whose activities include research and teaching. It is the only Comprehensive Cancer Center accredited by the OECl in Belgium.

On 27 November 2021 the Institut Jules Bordet relocated to its new building on the ULB campus in Anderlecht. 80,000 m² dedicated entirely to high-tech care, research and training in the field of cancer while keeping the focus firmly on patient well-being. The Institut Jules Bordet offers 250 hospitalisation beds and 43 day hospitalisation beds.

The Institut Jules Bordet is also a part of the H.U.B, the University Hospital Brussels, which brings together the Erasmus Hospital, the Institut Jules Bordet and the Queen Fabiola Children's University Hospital. This university hospital group with an international reputation guarantees high quality care accessible to all and excellence in research and training, in particular thanks to new investments.

For more information, visit www.bordet.be

About the Clinical Trials Support Unit (CTSU)

The Clinical Trials Support Unit (IJB-CTSU) fights cancer through the design, set-up and conduct of innovative clinical trials that matter to patients.

At the "New" Institut Jules Bordet, researchers are able to exchange their ideas easily, design new projects in direct contact with clinicians and share the same tools in an optimal way. The translational research laboratories are grouped together on the same floor (10,000 m²) and benefit from brand new infrastructure equipped with the most advanced technologies. All the staff specifically devoted to research activities are located in the immediate vicinity of the medical staff, in the heart of the action.

Over the last two decades, the IJB-CTSU has been collaborating with the Breast International Group (BIG) to conduct international clinical trials such as **TAX 315**, **HERA**, **ALTTO**, **APHINITY**, **FINESSE**, **ALEXANDRA/IMpassion030** and **AURORA**. Since 2013, the IJB-CTSU has also been assisting researchers to develop and run investigator-initiated trials (phases I, II and III) for all cancer types, as well as for all treatment and diagnostic modalities. The strength of the IJB-CTSU team lies in its proximity to and interactions with the "real-world" of cancer care.

The IJB-CTSU proposes a wide range of services in clinical study management, from scientific support to operational activities. The IJB-CTSU promotes academic research while encouraging collaboration with other academic partners and pharmaceutical companies.

For more information, visit <https://ctsu.bordet.be/#/home>

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2. Patel A, Unni N and Peng Y. The Changing Paradigm for the Treatment of HER2-Positive Breast Cancer. Cancers (Basel). 2020 Aug; 12(8): 2081.