

Updates

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AUSTRIAN BREAST AND COLORECTAL CANCER STUDY GROUP



Advancing personalised breast cancer treatment: new ABCSG studies

At the forefront of clinical and translational breast cancer research, the Austrian Breast & Colorectal Cancer Study Group (ABCSG) continues to push the boundaries of treatment options by developing new clinical trials that focus on tailoring therapies based on individual patient and tumour molecular profiles. These efforts are critical to ensuring that patients receive the most appropriate treatments, minimising unnecessary interventions and improving outcomes. In the background of this scientific setting, new ABCSG trials are about to start, two of which anticipate enrolling patients from early 2025.

ABCSG 61 / TEODOR (Neoadjuvant **TrE**atment **Optimization** driven by **ctDNA** and **endO**crine **R**esponsiveness) is a prospective, randomised, controlled, open-label, multicentre phase II study. The trial will focus on patients with HR-positive, HER2-negative, early and locally advanced breast cancer who are ctDNA-negative and endocrine-responsive. Using baseline (negative) ctDNA status and endocrine sensitivity (measured by Ki67 dynamics) for selection, patients will be randomised to receive either neoadjuvant chemotherapy or endocrine therapy. With the larger goal of optimising treatment selection and minimising overtreatment in patients who may not need pre-operative chemotherapy, this protocol aims to determine the efficacy of endocrine therapy compared to chemotherapy in these selected patients. Efficacy will be measured using the modified Preoperative Endocrine Prognostic Index (PEPI) score and pCR.

“The growing precision of breast cancer treatment, guided by biomarkers and molecular profiles, allows us to better tailor therapies to each patient’s individual tumour biology and, in certain subpopulations, to avoid chemotherapy and its associated side effects. De-escalation strategies, such as focusing on endocrine therapy when appropriate, are crucial to reducing treatment burden while maintaining excellent



Professor Michael Gnant at NIFA 2024
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outcomes,” emphasises ABCSG President Professor Michael Gnant. With 256 patients participating across 15 sites in Austria, ABCSG 61 / TEODOR aims to improve personalised treatment strategies for women with early-stage breast cancer.

ABCSG 63 / ERIKA (Elacestrant and **R**ibociclib in **Ki67**-tested endocrine responsive **breAst** cancer) takes a similarly personalised approach, focusing on endocrine-responsive, HER2-negative early breast cancer. In this open-label, two-arm, randomised neoadjuvant phase II trial, patients will receive either elacestrant plus ribociclib or an aromatase inhibitor

(AI) plus ribociclib, with the addition of a GnRH agonist in pre-/perimenopausal women. By incorporating the dynamics of tumour proliferation marker Ki67 as a determining factor is assessing whether patients are endocrine-sensitive, this study aims to provide deeper insights into the efficacy of targeted endocrine therapies in the neoadjuvant setting. The primary objective is to evaluate the superiority of elacestrant plus ribociclib compared to AI (and GnRH agonist) plus ribociclib in endocrine-responsive early breast cancer, measured by the modified Preoperative Endocrine Prognostic Index (PEPI) score at the time of surgery.

"We are in a position of having more and more access to a wide range of potent agents in the early breast cancer setting, with substances such as oral SERDs. One of our important tasks is to test these against standards, also by determining who will likely benefit most from the addition of these novel drugs," says study PI and ABCSG vice president Professor Christian Singer. With 18 sites planned across Austria and Germany, ABCSG 63 / ERIKA will enrol 120 patients, with the first randomisations scheduled for early 2025.

These two trials represent the latest in ABCSG's commitment to expanding personalised breast cancer care in partnership with biotech and pharma companies in the field of molecular testing/ctDNA assays, focusing on tailored treatment plans based on cutting-edge molecular profiling and biomarker-driven approaches.



Professor Christian Singer at NIFA 2024
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25 Years of BIG: congratulations for a legacy of global collaboration

Global collaboration is an essential cornerstone of cancer research, particularly in large (adjuvant) phase III trials that have ambitious timelines and require the commitment of multiple partners with the operational and scientific quality necessary to conduct successful research. For 25 years, the Breast International Group (BIG) has played a pivotal role in advancing breast cancer trials, enabling key clinical questions to be addressed through a network of strong academic and industrial partners.

ABCSG has proudly contributed to BIG-led and co-led studies and held leadership positions on the BIG Executive Board for over 10 years. In this context, it is crucial to maintain effective collaborative models that allow for academic independence while working closely with industry. *"We must continue to develop new strategies and approaches to ensure that academic research retains its strong, independent presence while working closely with pharmaceutical companies, even as we navigate an increasingly complex regulatory environment,"* says ABCSG President Professor Michael Gnant.

As we celebrate 25 years of the Breast International Group, we reflect on a remarkable journey that has transformed breast cancer research. Over the past two decades, the BIG network has fostered collaboration among diverse institutions and researchers, paving the way for significant advances in clinical practice and treatment options. Together, we have tackled pressing questions and challenged established paradigms.

As we look to the future, our vision is to continue to strengthen our network by embracing innovative approaches to research and fostering new collaborations between academic and industry partners. Our goal is to remain at the forefront of breast cancer research and ensure that our collective efforts translate into improved care for patients worldwide.

The importance of the BIG network serves as a testament to the power of collaboration in tackling the complexities of breast cancer and achieving meaningful progress. Together, we have built a legacy of excellence that will undoubtedly shape the future of breast cancer research for many years to come.

Happy 25th anniversary, BIG, and here's to many more years of fruitful collaboration!

Contribution by Professor Michael Gnant, President of ABCSG, past member of the BIG Executive Board.