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OTHER TRIALS AND ACTIVITIES BY BIG MEMBER GROUPS

ABCSG

AUSTRIAN BREAST AND COLORECTAL CANCER STUDY GROUP

ABCSG 63 / ERIKA (Elacestrant and RIbociclib in Ki67-tested endocrine responsive breAst cancer) trial to start study recruitment in Q2 2024

ABCSG 63 is an innovative, investigator-initiated trial in its final set-up phase, to be conducted in two countries under the academic sponsorship of ABCSG, and at approximately 18 trial sites with the recruitment target of 120 patients.

It is designed as an open label, two-arm, two-step, randomised, phase II study in endocrine-responsive HER-2 negative early breast cancer patients. The present study plans to evaluate the therapeutic potential and the safety of a combination of the orally available SERD elacestrant and the CDK4/6 inhibitor ribociclib. The primary study endpoint is defined as the proportion of the PEPI score of 0 at the time of surgery. "Compared to neoadjuvant chemo/immunotherapy, preoperative systemic endocrine treatment is still not standardised and needs scientific optimisation both in terms of finding the most effective treatment as well as in selecting the appropriate patients", said ABCSG president Michael Gnant, Professor of Surgery at the Medical University of Vienna. ABCSG's vice president Christian Singer, Head of the Center for Breast Health at the Medical University of Vienna added: "With a modern SERD and an effective CDK 4/6 inhibitor, we are confident that this treatment can be defined as a potential new standard of neoadjuvant care for patients with hormone-responsive disease."

Tamoxifen and AIs (in combination with GnRH agonists in premenopausal women) represent the current standard of care in HR-positive early breast cancer but are not clearly defined as a standard treatment in the neoadjuvant setting, except for frail and very old patients. Combining endocrine therapies with CDK4/6 inhibitors is standard of care in the metastatic setting for hormone-receptor positive disease, but again not well defined in the neoadjuvant setting.

In the upcoming ERIKA trial, patients will be randomised 1:1 to receive either 1 cycle of elacestrant and ribociclib or AI (plus GnRH agonist in pre-/perimenopausal women and men) and ribociclib (step 1) after which endocrine-responsive tumours will be identified via a local Ki-67 assessment. Endocrine-responsive patients will continue study treatment for further 5 cycles in each arm (step 2), whereas patients who do not demonstrate an endocrine response will not be randomised and leave the study (and potentially move on to another clinical trial). Furthermore, an extensive collection of tumour tissue and blood samples is an integral part of the study protocol in order to facilitate translational research projects.

Given the exciting study design, ABCSG and the study's collaborative partners are eager to initiate this new research project in 2024, once again leaving a strong academic footprint in the current clinical trial landscape for the benefit of breast cancer patients.

Contribution by:
Prof. Michael Gnant, MD, FACS, FEBS
ABCSG President, Professor of Surgery at the Medical University of Vienna
Prof. Christian F. Singer, MD, MPH
ABCSG Vice President, Head of the Center for Breast Health at the Medical University of Vienna

Professors Christian Singer and Michael Gnant
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