TPS620 **Poster Session**

EORTC-2129-BCG: Elacestrant for treating ER+/HER2- breast cancer patients with ctDNA relapse (TREAT ctDNA).

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Background: (Neo)adjuvant systemic treatment, with chemotherapy and/or endocrine therapy (ET), substantially reduces the recurrence rates of estrogen receptor positive (ER+) human epidermal growth factor receptor 2 negative (HER2-) early-stage breast cancer (BC). However, recurrences still occur up to 20 years after diagnosis. Circulating tumor DNA (ctDNA) has emerged as a useful biomarker for surveillance in several solid tumors. ctDNA-based detection of molecular recurrence could allow the start of effective therapies before the clinical evidence of metastases. Elacestrant, a selective ER degrader, approved in the advanced setting of ER+/HER2- ESR1-mutated BC following progression on a CDK4/6-inhibitor, could be used at the time of ctDNA-based molecular relapse to delay or prevent the clinical manifestation of distant metastasis. **Methods:** TREAT ctDNA is an European Organisation for Research and Treatment of Cancer (EORTC)-led intergroup international, multicentre, randomised, open label, superiority phase III trial to evaluate adjuvant elacestrant vs standard ET in patients with ER+/HER2- BC. The study comprises a screening and a randomised phase based on ctDNA status using a clinically-validated, tumor-informed molecular residual disease ctDNA assay (Signatera). Screening phase: 1960 patients with intermediate to high-risk stage II or III ER+/HER2- BC on medium to long duration ET will be screened for a ctDNA-based molecular relapse every 6 months. Randomised phase: 220 ctDNA-positive patients without imaging evidence of recurrence will be randomised 1:1 between continuing current ET versus switching to elacestrant for a duration of at least 7 years of ET in total. Participants will undergo intensive follow-up for 3 years with computed tomography and bone scans, in addition to the standard annual breast imaging. The primary endpoint of the study is distant metastasis free survival and secondary endpoints are invasive disease-free survival, relapse-free survival, overall survival, safety and quality of life. Recruitment started in December 2023 in Belgium, is open in 12 countries at 74 sites and anticipates up to 120 enrolling sites in 2025. Overall study status and databases status will be periodically reviewed by the IDMC. Clinical trial identification: EU trial number 2022-501453-36-00. NCT05512364. Study conducted under the Breast International Group (BIG) umbrella. Collaborative groups: GIM, CTI, SUCCESS, SOLTI, HeCOG, HORG, BOOG, SweBCG and ETOP-IBCSG. Clinical trial information: 2022-501453-36-00. Research Sponsor: BERLIN-CHEMIEAG MENARINI from Germany.