CHARITÉ

Comprehensive Cancer Center
Universitätstumorzentrum

Studientitel	**ECLIPSE: A phase II study investigating preoperative combination strategies for immunotherapy in patients with untreated, operable ER+, HER2-negative primary breast cancer**	
EudraCT-Nummer	**2016-004424-38**	
ClinTrials.gov identifier	**NCT03395899**	
Sponsor	Queen Mary University of London	
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Studienziel	To determine whether adding immune-modulatory agents to atezolizumab increases the probability of an immune response over atezolizumab alone in patients with operable ER+ breast cancer.	
Wichtigste Einschlusskriterien	1. Willing and able to provide written informed consent prior to study entry 2. Female ≥ 18 years of age 3. Eastern Cooperative Oncology Group (ECOG) Performance Status 0 to 21 4. Histologically confirmed operable primary breast cancer 5. Palpable breast tumour of any size, or tumour with an ultrasound / MRI size of ≥ 1 cm or mammogram 6. ER+ tumours defined as tumours with ≥1% of tumour cells positive for ER on IHC staining or an IHC score (Allred) of ≥ 3 7. HER2-negative tumours defined as 0, 1+ or 2+ intensity on IHC and no evidence of amplification of the HER2 gene on ISH. 8. Patients with either: (a) Luminal B breast cancer defined as: high Ki67 defined as ≥20% and /or histological grade 3 and / or Luminal B according to PAM50 assay or (b) Non-Luminal B breast cancer 9. Adequate haematologic and end-organ function within 28 days prior to the first study treatment	

	10. Patients of childbearing potential are eligible provided they have a negative serum or urine pregnancy test within 14 days of Day 1 Cycle 1 of study treatment, preferably as close to the first dose as possible. Patients must agree to use adequate contraception, defined as those methods with a failure rate of < 1 % per year, (IUD, oral contraceptive, sub dermal implant and double barrier (condom with a contraceptive sponge or contraceptive pessary) beginning 14 days before the first dose of study drug and for 5 months after the last dose of investigational product . 11. Ability to comply with the protocol 12. Representative formalin-fixed paraffin embedded (FFPE) breast tumour samples with an associated pathology report that are determined to be available and sufficient for central testing OR tumour accessible for biopsy.