KURZPROTOKOLL
monarcHER

Öffentlicher Titel	Phase II Studie zu Abemaciclib + Trastuzumab mit oder ohne Fulvestrant bei metastasiertem HR- und HER2-positivem Brustkrebs
Wissenschaftl. Titel	A Phase 2, Randomized, Multicenter, 3-Arm, Open-Label Study to Compare the Efficacy of Abemaciclib plus Trastuzumab with or without Fulvestrant to Standard-of-Care Chemotherapy of Physician's Choice plus Trastuzumab in Women with HR+, HER2+ Locally Advanced or Metastatic Breast Cancer
Kurztitel	monarcHER
Studienart	multizentrisch, Therapiestudie, offen/unverblindet, dreiarmig
Studienphase	Phase II
Erkrankung	Geschlechtsorgane: Brustkrebs: Zweitlinie oder höher
Einschlusskriterien	- Have diagnosis of HR+, HER2+ metastatic breast cancer on the primary tumor or metastatic lesion - Have unresectable locally advanced recurrent breast cancer or metastatic breast cancer - Have adequate tumor tissue available and collected prior to randomization - Have previously received at least two HER2 directed therapies for advanced disease - Must have received trastuzumab emtansine (TDM1) in any disease setting - Must have received a taxane in any disease setting - Have discontinued all previous therapies for cancer (except trastuzumab) for at least 21 days for myelosuppressive agents or 14 days for non-myelosupprevice agents - Have postmenopausal status - Have performance status of 0 to 1 on the ECOG scale - Must have LVEF of 50% or higher at baseline
Ausschlusskriterien	- Have visceral crisis - Known CNS metastases that are untreated, symptomatic or require steroids to control symptoms - Received prior treatment with any CDK4 or CDK6 inhibitor - Have had major surgery within 14 days prior to randomization - Received treatment with a drug that has not received regulatory approval for any indication within 14 to 21 days of randomization for non-myelosuppressive or non-myelosupprevice agent, respectively - Have serious preexisting medical conditions that would preclude participation in this study - Have a history within the last 6 months of symptomatic congestive heart failure, myocardial infarction or unstable angina - Have a personal history within the last 12 months of any of the following conditions: syncope of cardiovascular etiology, ventricular tachycardia, ventricular fibrillation or sudden cardiac arrest
Alter	18 Jahre und älter
Molekularer Marker	PR ER HER2/neu pos.
Fallzahl	225
Sponsor	Eli Lilly and Company
Registrierung in anderen Studienregistern	EudraCT 2015-003400-24