

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, dreiarmlig
Studienphase	Phase II
Erkrankung	Geschlechtsorgane: Brustkrebs: Zweitlinie oder höher
Einschlusskriterien	<ul style="list-style-type: none">- 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-myelosuppressive 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	<ul style="list-style-type: none">- 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-myelosuppressive 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

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Prüfzentren

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Sponsor

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**Registrierung in anderen
Studienregistern**

EudraCT 2015-003400-24