

**KURZPROTOKOLL**  
**monarcHER**

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| <b>Öffentlicher Titel</b>                        | Phase II Studie zu Abemaciclib + Trastuzumab mit oder ohne Fulvestrant bei metastasiertem HR- und HER2-positivem Brustkrebs   |
| <b>Wissenschaftl. Titel</b>                      | 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   |
| <b>Kurztitel</b>                                 | monarcHER   |
| <b>Studienart</b>                                | multizentrisch, Therapiestudie, offen/unverblindet, dreiarmlig  |
| <b>Studienphase</b>                              | Phase II  |
| <b>Erkrankung</b>                                | Geschlechtsorgane: Brustkrebs: Zweitlinie oder höher  |
| <b>Einschlusskriterien</b>                       | <ul style="list-style-type: none"><li>- Have diagnosis of HR+, HER2+ metastatic breast cancer on the primary tumor or metastatic lesion</li><li>- Have unresectable locally advanced recurrent breast cancer or metastatic breast cancer</li><li>- Have adequate tumor tissue available and collected prior to randomization</li><li>- Have previously received at least two HER2 directed therapies for advanced disease</li><li>- Must have received trastuzumab emtansine (TDM1) in any disease setting</li><li>- Must have received a taxane in any disease setting</li><li>- Have discontinued all previous therapies for cancer (except trastuzumab) for at least 21 days for myelosuppressive agents or 14 days for non-myelosuppressive agents</li><li>- Have postmenopausal status</li><li>- Have performance status of 0 to 1 on the ECOG scale</li><li>- Must have LVEF of 50% or higher at baseline</li></ul>   |
| <b>Ausschlusskriterien</b>                       | <ul style="list-style-type: none"><li>- Have visceral crisis</li><li>- Known CNS metastases that are untreated, symptomatic or require steroids to control symptoms</li><li>- Received prior treatment with any CDK4 or CDK6 inhibitor</li><li>- Have had major surgery within 14 days prior to randomization</li><li>- 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</li><li>- Have serious preexisting medical conditions that would preclude participation in this study</li><li>- Have a history within the last 6 months of symptomatic congestive heart failure, myocardial infarction or unstable angina</li><li>- 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</li></ul> |
| <b>Alter</b>                                     | 18 Jahre und älter  |
| <b>Molekularer Marker</b>                        | PR<br>ER<br>HER2/neu pos.   |
| <b>Fallzahl</b>                                  | 225   |
| <b>Sponsor</b>                                   | Eli Lilly and Company   |
| <b>Registrierung in anderen Studienregistern</b> | EudraCT 2015-003400-24  |