

## **KURZPROTOKOLL** **MonarchE**

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| <b>Öffentlicher Titel</b>   | Abemaciclib und adjuvante Hormontherapie bei Hormonrezeptor-positivem, HER2-negativem Brustkrebs                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| <b>Wissenschaftl. Titel</b> | A Randomized, Open-Label, Phase 3 Study of Abemaciclib Combined With Standard Adjuvant Endocrine Therapy Versus Standard Adjuvant Endocrine Therapy Alone in Patients With High Risk, Node Positive, Early Stage, Hormone Receptor Positive, Human Epidermal Receptor 2 Negative, Breast Cancer                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| <b>Kurztitel</b>            | MonarchE                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
| <b>Studienart</b>           | multizentrisch, prospektiv, Therapiestudie, randomisiert, offen/unverblindet, Pharma-Studie, zweiarmig                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| <b>Studienphase</b>         | Phase III                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| <b>Erkrankung</b>           | Geschlechtsorgane: Brustkrebs: adjuvant                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| <b>Einschlusskriterien</b>  | <ul style="list-style-type: none"><li>- The participant is <math>\geq 18</math> years of age (or per local regulations).</li><li>- The participant has confirmed HR+, HER2-, early stage resected invasive breast cancer without evidence of distant metastases.</li><li>- The participant must have undergone definitive surgical treatment for the current malignancy.</li><li>- The participant must have tumor tissue for biomarker analysis available prior to randomization.</li><li>- The participant must have axillary lymph node involvement by tumor and have one of the following indicating a higher risk of relapse: (a) 4 or more axillary lymph nodes involved with cancer; (b) Tumor size of at least 5 centimeters; (c) Grade 3 histology; (d) Ki67 index by central analysis of <math>\geq 20\%</math> (for study cohort 2)</li><li>- The participant must be randomized within 12 weeks of completion of last non-endocrine treatment.</li><li>- If the participant is currently receiving or initiating standard adjuvant endocrine therapy at time of study entry, she/he must not have received more than 8 weeks prior to randomization.</li><li>- Participants must have recovered from the acute effects of chemotherapy and radiotherapy and from surgical side effects following definitive breast surgery.</li><li>- Women regardless of menopausal status.</li><li>- Women of reproductive potential must have a negative serum pregnancy test and agree to use highly effective contraceptive methods.</li><li>- The participant has a Eastern Cooperative Oncology Group (ECOG) performance status <math>\leq 1</math>.</li><li>- The participant has adequate organ function.</li><li>- The participant is able to swallow oral medications.</li></ul> |
| <b>Ausschlusskriterien</b>  | <ul style="list-style-type: none"><li>- Stage IV (M1) disease (American Joint Committee on Cancer [AJCC] TNM Staging System for breast cancer - 7th edition).</li><li>- Stage IA disease (AJCC TNM Staging System for breast cancer - 7th edition).</li><li>- The participant has a history of any other cancer (except non-melanoma skin cancer or carcinoma in situ of the cervix), unless in complete remission with no therapy for a minimum of 5 years.</li><li>- Females who are pregnant or lactating.</li><li>- The participant has previously received treatment with any CDK4 and CDK6 inhibitor.</li><li>- The participant is receiving concurrent exogenous hormone therapy (for example, birth control pills or hormone replacement therapy).</li><li>- The participant has previously received endocrine therapy for breast cancer prevention (tamoxifen or raloxifene or aromatase inhibitors).</li></ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |

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- The participant has serious preexisting medical condition(s) that, in the judgment of the investigator, would preclude participation in this study.
- The participant has a personal history of any of the following conditions: syncope of cardiovascular etiology, ventricular arrhythmia of pathological origin or sudden cardiac arrest.
- The participant has active bacterial infection, fungal infection, or detectable viral infection.
- The participant has received an experimental treatment in a clinical trial within the last 30 days or 5 half-lives, whichever is longer.

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| <b>Alter</b>                                     | 18 Jahre und älter                                       |
| <b>Molekularer Marker</b>                        | HER2/neu neg./ER pos.<br>HER2/neu neg./PR pos.           |
| <b>Sponsor</b>                                   | Eli Lilly and Company                                    |
| <b>Registrierung in anderen Studienregistern</b> | EudraCT 2016-004362-26<br>ClinicalTrials.gov NCT03155997 |