KURZPROTOKOLL
MonarchE

Öffentlicher Titel	Abemaciclib und adjuvante Hormontherapie bei Hormonrezeptor-positivem, HER2-negativem Brustkrebs
Wissenschaftl. Titel	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
Kurztitel	MonarchE
Studienart	multizentrisch, prospektiv, Therapiestudie, randomisiert, offen/unverblindet, Pharma-Studie, zweiarmig
Studienphase	Phase III
Erkrankung	Geschlechtsorgane: Brustkrebs: adjuvant
Einschlusskriterien	- The participant is >=18 years of age (or per local regulations). - The participant has confirmed HR+, HER2-, early stage resected invasive breast cancer without evidence of distant metastases. - The participant must have undergone definitive surgical treatment for the current malignancy. - The participant must have tumor tissue for biomarker analysis available prior to randomization. - 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 >=20% (for study cohort 2) - The participant must be randomized within 12 weeks of completion of last non-endocrine treatment. - 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. - Participants must have recovered from the acute effects of chemotherapy and radiotherapy and from surgical side effects following definitive breast surgery. - Women regardless of menopausal status. - Women of reproductive potential must have a negative serum pregnancy test and agree to use highly effective contraceptive methods. - The participant has a Eastern Cooperative Oncology Group (ECOG) performance status <=1. - The participant has adequate organ function. - The participant is able to swallow oral medications.
Ausschlusskriterien	- Stage IV (M1) disease (American Joint Committee on Cancer [AJCC] TNM Staging System for breast cancer - 7th edition). - Stage IA disease (AJCC TNM Staging System for breast cancer - 7th edition). - 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. - Females who are pregnant or lactating. - The participant has previously received treatment with any CDK4 and CDK6 inhibitor. - The participant is receiving concurrent exogenous hormone therapy (for example, birth control pills or hormone replacement therapy). - The participant has previously received endocrine therapy for breast cancer prevention (tamoxifen or raloxifene or aromatase inhibitors).

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