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.
Prüfzentren	**Sana Klinikum Offenbach** (Rekrutierung beendet) Starkenburgring 66 63069 Offenbach Benjamin Schnappauf Tel: 069 8405-7032 Fax: 069 8405-4486 benjamin.schnappauf@sana.de **Agaplesion Markus Krankenhaus** (Rekrutierung beendet) Wilhelm-Epstein-Straße 4 60431 Frankfurt am Main Madeleine Modrow Tel: 069 953366754 Fax: 069 95338916754 madeleine.modrow@fdk.info
Sponsor	Eli Lilly and Company
Registrierung in anderen Studienregistern	EudraCT 2016-004362-26 ClinicalTrials.gov NCT03155997