

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	<ul style="list-style-type: none">- 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 $\geq 20\%$ (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	<ul style="list-style-type: none">- 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).

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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.

Alter

18 Jahre und älter

Molekularer Marker

HER2/neu neg./ER pos.

HER2/neu neg./PR pos.

Prüfzentren

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Sponsor

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**Registrierung in anderen
Studienregistern**

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