

KURZPROTOKOLL RIBECCA

Öffentlicher Titel	Phase IIIb Studie mit Ribociclib (LEE011) und Letrozol bei Hormonrezeptor-positivem, HER2-negativem Brustkrebs
Wissenschaftl. Titel	A national phase IIIb, multi-center, open label study for women and men with hormone-receptor positive, HER2-negative locally advanced or metastatic breast cancer treated with ribociclib (LEE011) in combination with letrozole
Kurztitel	RIBECCA
Studienart	multizentrisch, Therapiestudie, offen/unverblindet, Pharma-Studie, zweiarmig
Studienphase	Phase III
Erkrankung	Geschlechtsorgane: Brustkrebs: Erstlinie Geschlechtsorgane: Brustkrebs: Zweitlinie oder höher
Einschlusskriterien	<ul style="list-style-type: none">- Adult >= 18 years old at the time of informed consent and has signed informed consent before any trial related activities.- Patients with advanced (locoregionally recurrent or metastatic) breast cancer not amenable to curative therapy- For inclusion in the 70 % arm: Men or postmenopausal women.- For the 30 % arm, also premenopausal or perimenopausal patients may be included- For premenopausal patients: Confirmed negative serum pregnancy test (beta-hCG) before starting study treatment or patient has had a hysterectomy- Patient has a histologically and/or cytologically confirmed diagnosis of estrogen-receptor positive and/or progesterone receptor positive breast cancer- Patient has HER2-negative breast cancer- Measurable disease- ECOG performance status 0 or 1 or 2- Patient has adequate bone marrow and organ function- Standard 12-lead ECG values assessed by the local laboratory
Ausschlusskriterien	<ul style="list-style-type: none">- Patient with symptomatic visceral disease or any disease burden that makes the patient ineligible for endocrine therapy per the investigator's best judgment- Prior CDK4/6 inhibitor- Prior mTOR-inhibitor- Known hypersensitivity to any of the excipients of ribociclib , letrozole (or goserelin if pre- or perimenopausal)- Current inflammatory breast cancer (< 4 weeks before enrollment)- Concurrently using other anti-cancer therapy- Had major surgery within 14 days prior to starting study drug or has not recovered from major side effects
Alter	18 Jahre und älter
Molekularer Marker	HER2/neu neg./ER pos. HER2/neu neg./PR pos.
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Sponsor

Novartis Pharma

**Registrierung in anderen
Studienregistern**

ClinicalTrials.gov NCT03096847 (primäres Register)

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