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	- 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	- 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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Registrierung in anderen Studienregistern	ClinicalTrials.gov NCT03096847 (primäres Register) EudraCT 2016-002556-24