KURZPROTOKOLL
NATALEE

Öffentlicher Titel	Phase III Studie zu Ribociclib adjuvant bei HR+/HER2- Brustkrebs
Wissenschaftl. Titel	A Phase III, multicenter, randomized, open-Label Trial to evaluate efficacy and safety of ribociclib with endocrine therapy as an adjuvant Treatment in patients with Hormone receptor-positive, HER2-negative, early breast cancer (New Adjuvant TriAl with Ribociclib (LEE011): NATALEE).
Kurztitel	NATALEE
Studienart	multizentrisch, prospektiv, Therapiestudie, randomisiert, offen/unverblindet, Pharma-Studie, zweiarmig
Studienphase	Phase III
Erkrankung	Geschlechtsorgane: Brustkrebs: adjuvant
Einschlusskriterien	- Patient is >= 18 years-old at the time of PICF signature - Patient is female with known menopausal status at the time of randomization or initiation of adjuvant ET (whichever occurs earlier), or male - Patient with histologically confirmed unilateral primary invasive adenocarcinoma of the breast with a date of initial cytologic or histologic diagnosis within 18 months prior to randomization - Patient has breast cancer that is positive for ER and/or PgR - Patient has HER2-negative breast cancer - Patient has available archival tumor tissue from the surgical specimen - Patient after surgical resection where tumor was removed completely, with the final surgical specimen microscopic margins free from tumor, and belongs to one of the following categories: anatomic stage group II or III - If indicated, patient has completed adjuvant and/or neoadjuvant chemotherapy according to the institutional guidelines - If indicated, patient has completed adjuvant radiotherapy according to the institutional guidelines - Patient has an Eastern Cooperative Oncology Group (ECOG) Performance Status of 0 or 1 - Patient has no contraindication for the adjuvant ET in the trial and is planned to be treated with ET for 5 years
Ausschlusskriterien	- Patient has received any CDK4/6 inhibitor - Patient has received prior treatment with tamoxifen, raloxifene or AIs for reduction in risk ("chemoprevention") of breast cancer and/or treatment for osteoporosis within the last 2 years prior to randomization. Patient is concurrently using hormone replacement therapy - Patient has received prior treatment with anthracyclines at cumulative doses of 450 mg/m^2 or more for doxorubicin, or 900 mg/m^2 or more for epirubicin - Patient with a known hypersensitivity to any of the excipients of ribociclib and/or ET - Patient with distant metastases of breast cancer beyond regional lymph nodes (stage IV according to AJCC 8th edition) and/or evidence of recurrence after curative surgery - Patient is concurrently using other anti-neoplastic therapy with the exception of adjuvant ET - Patient has had major surgery, chemotherapy or radiotherapy within 14 days prior to randomization - Patient has not recovered from clinical and laboratory acute toxicities related to prior anti-cancer therapies - Patient has a concurrent invasive malignancy or a prior invasive malignancy whose treatment was completed within 2 years before randomization

- Patient has known HIV infection, Hepatitis B or C infection
- Clinically significant, uncontrolled heart disease and/or cardiac repolarization abnormality
- Patient is currently receiving any of the following substances within 7 days before randomization - Concomitant medications, herbal supplements, and/or fruits that are known as strong inhibitors or inducers of CYP3A4/5 or Medications that have a narrow therapeutic window and are predominantly metabolized through CYP3A4/5
- is currently receiving or has received systemic corticosteroids <=2 weeks prior to starting trial treatment
- Patient has impairment of GI function or GI disease that may significantly alter the absorption of the oral trial treatments
- Patient has any other concurrent severe and/or uncontrolled medical condition that would, in the Investigator's judgment, cause unacceptable safety risks, contraindicate patient participation in the clinical trial or compromise compliance with the protocol
- Participation in other studies involving investigational drug(s) within 30 days prior to randomization or within 5 half-lives of the investigational drug(s) (whichever is longer), or participation in any other type of medical research judged not to be scientifically or medically compatible with this trial
- Pregnant or breast-feeding (lactating) women or women who plan to become pregnant or breast-feed during the trial

Alter	18 Jahre und älter
Molekularer Marker	HER2/neu neg. PR HER2/neu neg./ER pos. ER HER2/neu neg./PR pos.
Prüfzentren	**Agaplesion Markus Krankenhaus** (Geschlossen) Wilhelm-Epstein-Straße 4 60431 Frankfurt am Main PD Dr. med. Marc Thill Tel: 069 95332228 Fax: 069 95332733 marc.thill@fdk.info
Sponsor	Novartis Pharma
Registrierung in anderen Studienregistern	EudraCT 2018-002998-21 ClinicalTrials.gov NCT03701334 (primäres Register)