KURZPROTOKOLL
PALLAS

Öffentlicher Titel	Phase III Studie zu adjuvanter endokriner Therapie mit und ohne Palbociclib bei Her2-negativem, Hormonrezeptor-positivem Brustkrebs im Frühstadium
Wissenschaftl. Titel	PALbociclib CoLlaborative Adjuvant Study: A Randomized Phase III Trial of Palbociclib With Standard Adjuvant Endocrine Therapy Versus Standard Adjuvant Endocrine Therapy Alone for Hormone Receptor Positive (HR+) / Human Epidermal Growth Factor Receptor 2 (HER2)-Negative Early Breast Cancer (PALLAS)
Kurztitel	PALLAS
Studienart	multizentrisch, randomisiert, offen/unverblindet, Pharma-Studie, zweiarmig
Studienphase	Phase III
Erkrankung	Geschlechtsorgane: Brustkrebs: adjuvant

Einschlusskriterien

- Signed informed consent prior to study specific procedures.
- Age 18 years (or per national guidelines).
- Pre- and postmenopausal women or men with Stage II (Stage IIA limited to max. 1000 patients) or Stage III early invasive breast cancer
- Patients with multicentric and/or multifocal and/or bilateral early invasive breast cancer are eligible if all histopathologically examined tumors meet pathologic criteria for ER+ and/or PR+ and HER2-.
- Patients must have histologically confirmed ER+ and/or PR+, HER2-, early invasive breast cancer.
- Patients must have undergone breast surgery for the current malignancy. FFPE tumor tissue block must be confirmed to be received at the central sample repository prior to randomization.
- ECOG performance status 0-1.
- Patients must be able and willing to swallow and retain oral medication.
- Serum or urine pregnancy test must be negative in premenopausal women within 14 days of randomization, or in women with amenorrhea of less than 12 months at time of randomization.
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- Patients must either be initiating or have already started adjuvant hormonal treatment
- Patients who already received neo/adjuvant endocrine therapy are eligible as long as they are enrolled within 12 months of initial histological diagnosis and after completing no more than 6 months of adjuvant endocrine therapy.
- Absolute neutrophil count 1,500/µL
- Platelets 100,000/ mm3
- Hemoglobin 10g/dL
- Total serum bilirubin ULN; or total bilirubin 3.0 × ULN with direct bilirubin within normal range in patients with documented Gilbert's Syndrome.
- Aspartate amino transferase (AST or SGOT) and alanine amino transferase (ALT or SGPT) 1.5 × institutional ULN.
- Serum creatinine within normal institutional limits or creatinine clearance 60 mL/min/1.73 m2 for patients with serum creatinine levels above institutional ULN.

Ausschlusskriterien	- Concurrent therapy with other Investigational Products. - Prior therapy with any CDK inhibitor. - Patients with Stage I or IV breast cancer are not eligible. - History of allergic reactions attributed to compounds of chemical or biologic composition similar to palbociclib. - Patients receiving any medications or substances that are potent inhibitors or inducers of - CYP3A isoenzymes within 7 days of randomization. - Uncontrolled intercurrent illness that would limit compliance with study requirements. - Pregnant women, or women of childbearing potential without a negative pregnancy test within 14 days prior to randomization. - Patients with a history of any malignancy are ineligible (for exceptions see: Pallas - Protocol, v1.0, Exclusion criteria 8). - Patients who previously received endocrine therapy within 5 years prior to diagnosis of the current malignancy. - Patients on combination antiretroviral therapy. - Patients with clinically significant history of any liver disease. - Patients receiving concurrent exogenous hormone therapy (topical vaginal estrogen therapy is allowable).
Alter	18 Jahre und älter
Molekularer Marker	HER2/neu neg./ER pos. HER2/neu neg./PR pos.
Fallzahl	4600
Prüfzentren	**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 **Centrum für Hämatologie und Onkologie Bethanien** (Rekrutierung beendet) Im Prüfling 17-19 60389 Frankfurt am Main Dr. rer. nat. Peter Feilen Tel: 069 560056-182 Fax: 069 560056-25 peter.feilen@chop-studien.de **Klinikum Frankfurt Höchst** (Rekrutierung beendet) Klinik für Gynäkologie und Geburtshilfe Gotenstraße 6-8 65929 Frankfurt am Main Prof. Dr. Joachim Rom joachim.rom@varisano.de
Sponsor	Alliance Foundation Trials, LLC.
Förderer	Alliance Foundation Trials, LLC.
Registrierung in anderen Studienregistern	ClinicalTrials.gov NCT02513394 EudraCT 2014-005181-30