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. - 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. - 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. - 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. - 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
Sponsor	Alliance Foundation Trials, LLC.
Förderer	Alliance Foundation Trials, LLC.
Registrierung in anderen Studienregistern	ClinicalTrials.gov NCT02513394 EudraCT 2014-005181-30