KURZPROTOKOLL
SOLAR-1

Öffentlicher Titel	Phase III Studie zu Alpelisib mit Fulvestrant bei Männern und postmenopausalen Frauen mit fortgeschrittenem Brustkrebs
Wissenschaftl. Titel	A Phase III Randomized Double-blind, Placebo Controlled Study of Alpelisib in Combination With Fulvestrant for Men and Postmenopausal Women With Hormone Receptor Positive, HER2-negative Advanced Breast Cancer Which Progressed on or After Aromatase Inhibitor Treatment
Kurztitel	SOLAR-1
Studienart	multizentrisch, Therapiestudie, randomisiert, Pharma-Studie, doppelblind, zweiarmig
Studienphase	Phase III
Erkrankung	Geschlechtsorgane: Brustkrebs: Zweitlinie oder höher
Ziele	- To determine whether treatment with alpelisib plus fulvestrant prolongs progression-free survival compared to fulvestrant and placebo in men and postmenopausal women with hormone receptor positive (HR+), HER2-negative advanced breast cancer, who received prior treatment with an Aromatase Inhibitor either as (neo)adjuvant or for advanced disease. - To determine whether treatment with alpelisib in combination with fulvestrant prolongs overall survival (OS) compared to treatment with placebo in combination with fulvestrant for patients with PIK3CA mutant status - To establish proof of concept of treatment benefit with alpelisib in combination with fulvestrant with respect to PFS for patients with PIK3CA non-mutant status - To evaluate the two treatment arms with respect to OS for patients with PIK3CA non-mutant status - To evaluate the two treatment arms and cohorts of interest with respect to centrally assessed PFS, overall response rate (ORR) and clinical benefit rate - Further secondary objectives and details are described in the protocol
Einschlusskriterien	- If female, patient is postmenopausal - Patient has identified PIK3CA status - Patients may be: - a. relapsed with documented evidence of progression more than 12 months from completion of (neo)adjuvant endocrine therapy with no treatment for metastatic disease - b. relapsed with documented evidence of progression on or within 12 months from completion of (neo)adjuvant endocrine therapy with no treatment for metastatic disease - c. relapsed with documented evidence of progression more than 12 months from completion of adjuvant endocrine therapy and then subsequently progressed with documented evidence of progression after one line of endocrine therapy for metastatic disease - d. newly diagnosed advanced breast cancer, then relapsed with documented evidence of progression after one line of endocrine therapy - Patient has recurrence or progression of disease during or after AI therapy (i.e. letrozole, anastrozole, exemestane). - Patient has a histologically and/or cytologically confirmed diagnosis of estrogen-receptor positive breast cancer by local laboratory and has HER2 negative breast cancer - Patient has either measurable disease per RECIST 1.1 criteria OR at least one predominantly lytic bone lesion must be present - Patient has adequate bone marrow function
Ausschlusskriterien	- Patient with symptomatic visceral disease or any disease burden that makes the patient ineligible for endocrine therapy per the investigator's best judgment

	- Patient has received prior treatment with chemotherapy (except for neoadjuvant/ adjuvant chemotherapy), fulvestrant, any PI3K, mTOR or AKT inhibitor (pre-treatment with CDK4/6 inhibitors is allowed) - Patient with inflammatory breast cancer at screening - Patients with Child pugh score B or C - Patients with an established diagnosis of diabetes mellitus type I or not controlled type II - Patient has Eastern Cooperative Oncology Group (ECOG) performance status 2 or more - Patient with CNS involvement unless he/she is at least 4 weeks from prior therapy completion to starting the study treatment and has stable CNS tumor at time of screening and not receiving steroids and/or enzyme inducing ant-epileptic medications for brain metastases - Patient has participated in a prior investigational study within 30 days prior to enrollment or within 5 half-lives of the investigational product, whichever is longer - Patient has a history of acute pancreatitis within 1 year of screening or a past medical history of chronic pancreatitis
Alter	18 Jahre und älter
Molekularer Marker	HER2/neu neg./ER pos. HER2/neu neg./PR pos.
Fallzahl	560
Prüfzentren	**Centrum für Hämatologie und Onkologie Bethanien** (Rekrutierung beendet) Im Prüfling 17-19 60389 Frankfurt am Main Ilka Kabisch Tel: 069 56005627 Fax: 069 56005625 ilka.kabisch@chop-studien.de
Sponsor	Novartis Pharma
Registrierung in anderen Studienregistern	ClinicalTrials.gov 02437318 EudraCT 2015-000340-42