KURZPROTOKOLL
M12-914

Öffentlicher Titel	Phase III Studie zu Veliparib bei Her2-negativem metastasiertem oder fortgeschrittenem inoperablem mit BRCA-assoziiertem Brustkrebs
Wissenschaftl. Titel	A Phase 3 Randomized, Placebo-controlled Trial of Carboplatin and Paclitaxel With or Without Veliparib (ABT-888) in HER2-negative Metastatic or Locally Advanced Unresectable BRCA-associated Breast Cancer
Kurztitel	M12-914
Studienart	multizentrisch, Therapiestudie, randomisiert, doppelblind, zweiarmig
Studienphase	Phase III
Erkrankung	Geschlechtsorgane: Brustkrebs: Erstlinie Geschlechtsorgane: Brustkrebs: Zweitlinie oder höher
Ziele	- Progression-free survival (PFS) - Overall survival (OS) - Clinical benefit rate (CBR) - Objective response rate (ORR) - Progression-free survival 2 (PFS2) - Duration of overall response (DOR) - Change in Eastern Cooperative Oncology Group (ECOG) Performance Status - Change in quality of life (QOL)
Einschlusskriterien	- Histologically or cytologically confirmed breast cancer that is either locally advanced or metastatic. Locally advanced breast cancer must not be amenable to surgical resection or radiation with curative intent. - Suspected deleterious or deleterious BRCA1 and/or BRCA2 germline mutation. - Breast cancer must be HER2-negative. - Measurable or non-measurable (but radiologically evaluable) disease per Response Evaluation Criteria In Solid Tumors (RECIST), version 1.1 on computed tomography (CT) scan (within 28 days of randomization) with at least one lesion outside previously irradiated areas. - ECOG Performance status of 0 to 2. - Adequate hematologic, renal, and hepatic function (within 28 days of randomization).
Ausschlusskriterien	- More than two prior lines of cytotoxic chemotherapy (e.g., gemcitabine, doxorubicin, capecitabine) for metastatic disease. - a. Regimens received in the adjuvant/neoadjuvant setting or for locally advanced breast cancer within the past 6 months will also be considered toward the maximum of 2 prior lines of therapy. Adjuvant/neoadjuvant chemotherapy for one cancer event will count as one prior line of therapy, if received within the past 6 months. - b. Previous treatments with hormonal therapy (tamoxifen, aromatase inhibitors) and signal transduction agents (e.g., erlotinib, gefitinib, everolimus, bevacizumab) are allowed and are not counted towards the prior line of therapy. - Progressed or recurred within 12 months of completing platinum therapy or received > 1 prior line of platinum therapy for breast cancer in any setting (adjuvant or neoadjuvant). - Prior therapy with PARP inhibitors. - Prior taxane therapy administered for the treatment of metastatic breast cancer with the below exceptions: - a. Prior taxane therapy for metastatic breast cancer is allowed if the patient received 1 full cycle (i.e., therapy discontinued within 4 weeks for subjects receiving weekly paclitaxel or Abraxane; therapy discontinued within 3 weeks for subjects receiving paclitaxel or docetaxel every 3 weeks) in the absence of progression or if taxane therapy for metastatic disease was > 12 months prior to C1D-2.

	- b. Use of taxanes as adjuvant therapy or to treat locally advanced disease is permitted, if given more than 6 months prior to C1D-2 - Known history of allergic reaction to cremophor-paclitaxel, carboplatin, Azo-Colourant Tartrazine (also known as FD&C Yellow 5 or E102), Azo-Colourant Orange Yellow-S (also known as FD&C Yellow 6 or E110) or known contraindications to any study supplied drug. - Active CNS metastases or leptomeningeal disease.
Alter	18 Jahre und älter
Molekularer Marker	BRCA HER2/neu neg.
Fallzahl	270
Prüfzentren	**Sana Klinikum Offenbach** (Rekrutierung beendet) Ambulantes Onkologisches Zentrum Starkenburgring 66 63069 Offenbach n.a. Melanie Moschitz Tel: 069 8405 5815 Fax: 069 8405 4486 Melanie.Moschitz@sana.de
Sponsor	AbbVie
Registrierung in anderen Studienregistern	ClinicalTrials.gov NCT02163694 EudraCT 2014-000345-70