KURZPROTOKOLL
M14-011

Öffentlicher Titel	Phase III Studie zu Sicherheit und Wirksamkeit von Veliparib bei triple-negativem Brustkrebs im Frühstadium
Wissenschaftl. Titel	A Randomized, Placebo-Controlled, Double-Blind, Phase 3 Study Evaluating Safety and Efficacy of the Addition of Veliparib Plus Carboplatin Versus the Addition of Carboplatin to Standard Neoadjuvant Chemotherapy Versus Standard Neoadjuvant Chemotherapy in Subjects With Early Stage Triple Negative Breast Cancer (TNBC)
Kurztitel	M14-011
Studienart	multizentrisch, Therapiestudie, randomisiert, doppelblind, dreiarmig
Studienphase	Phase III
Erkrankung	Geschlechtsorgane: Brustkrebs: neoadjuvant
Ziele	- Pathological Complete Response (pCR). - Pathological complete response (pCR) in the breast tissue and the lymph node tissue will be assessed upon completion of pre-operative systemic therapy and definitive surgery. Subjects who do not complete definitive surgery for reasons other than withdrawal of consent will be considered not to have achieved pCR. - Rate of eligibility for breast conservation after therapy (BCR). [Time Frame: At the time of definitive surgery - Whether a subject is eligible for breast conserving surgery will be determined by the subject's surgeon prior to chemotherapy and after completion of chemotherapy. - Event Free Survival (EFS) [Time Frame: Up to 10 years from first dose of study drug. - Overall Survival (OS) [Time Frame: Up to 10 years from first dose of study drug. - Clinical Response Rate (CRR) - pCR plus minimal residual disease (defined as residual cancer burden [RCB] class I) - Eastern Cooperative Oncology Group (ECOG) performance status. - Breast cancer related quality of life (QoL).
Einschlusskriterien	- Histologically confirmed invasive breast cancer by core needle or incisional biopsy (excisional biopsy is not allowed). Tumors must be clinical stage T2-3 N0-2 or T1 N1-2 per AJCC Staging Edition 7 or clinical stage T2-3 N0-2 or T1 N1-2 by physical exam or radiologic studies. - Documented Breast Cancer Gene (BRCA) germline mutation testing. - Estrogen Receptor (ER)-, Progesterone Receptor (PR)-, and Human Epidermal Growth Factor Receptor (HER)2-negative (triple-negative) cancer of the breast. - ECOG Performance status of 0 to 1. - Women must be determined to be not of childbearing potential (surgically sterile, or postmenopausal defined as amenorrheic for at least 12 months) by the Investigator OR they must have a negative serum pregnancy test prior to randomization.
Ausschlusskriterien	- Previous anti-cancer treatment (cytotoxic chemotherapy, immunotherapy, biologic therapy radiotherapy or investigational agents) with therapeutic intent for current breast cancer. - Previous treatment with carboplatin, paclitaxel, doxorubicin, cyclophosphamide and a Poly-(ADP-ribose)-Polymerase (PARP) inhibitor. - Concurrent treatment with an ovarian hormonal replacement therapy or with hormonal agents such as raloxifene, tamoxifen or other selective estrogen receptor modulator (SERM). Subjects must have discontinued use of such agents prior to beginning study treatment. - A history of seizure within 12 months prior to study entry. - Pre-existing neuropathy from any cause in excess of Grade 1.
Alter	18 Jahre und älter

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Molekularer Marker	Triple neg (HER2/ER/PR neg)
Fallzahl	624
Prüfzentren	**Sana Klinikum Offenbach** (Nachbeobachtung) 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 (Hauptsponsor) German Breast Group
Registrierung in anderen Studienregistern	ClinicalTrials.gov NCT02032277 EudraCT 2013-002377-21