KURZPROTOKOLL
Aphinity

Öffentlicher Titel	Pertuzumab in der adjuvanten Therapie von operablem, HER2-positivem Brustkrebs
Wissenschaftl. Titel	A Randomized Multicenter, Double-blind, Placebo-controlled Comparison of Chemotherapy Plus Trastuzumab Plus Placebo Versus Chemotherapy Plus Trastuzumab Plus Pertuzumab as Adjuvant Therapy in Patients With Operable HER2-positive Primary Breast Cancer
Kurztitel	Aphinity
Studienart	multizentrisch, prospektiv, randomisiert, Pharma-Studie, doppelblind, zweiarmig
Studienphase	Phase III
Erkrankung	Geschlechtsorgane: Brustkrebs: adjuvant
Ziele	- Ipsilateral invasive breast tumor recurrence (ie, an invasive breast cancer involving the same breast parenchyma as the original primary lesion); - Ipsilateral local-regional invasive breast cancer recurrence (ie, an invasive breast cancer in the axilla, regional lymph nodes, chest wall and/or skin of the ipsilateral breast); - Distant recurrence (ie, evidence of breast cancer in any anatomic site – other than the two abovementioned sites – that has either been histologically confirmed or clinically diagnosed as recurrent invasive breast cancer); - Contralateral invasive breast cancer; - Death attributable to any cause including breast cancer, non-breast cancer or unknown cause (but cause of death should be specified if at all possible). - The secondary efficacy endpoints of the present trial include OS (overall survival), DFS (disease-free survival), IDFS (invasive disease-free survival) including second primary non-breast cancer, RFI (recurrence-free interval) and DRFI (distant recurrence-free interval). Additionally, cardiac and overall safety, as well as quality of life will be evaluated.
Einschlusskriterien	- Adult patients. >/= 18 years of age - Non-metastatic primary invasive HER2-positive carcinoma of the breast that is adequately excised, and that is either node-positive (except T0), or node-negative but with presence of at least one risk factor as defined by the protocol (the latter option only applies to protocol version A. Node-negative patients are NOT allowable under protocol version B.) - Eastern Cooperative Oncology Group (ECOG) performance status </=1 - The interval between definitive surgery for breast cancer and the first dose of chemotherapy must be no more than 8 weeks (56 days). All procedures, including randomization, must occur during this period. The first cycle of chemotherapy must be administered within 7 days of randomization or on Day 56, whichever occurs first. - Known hormone receptor status (estrogen receptor and progesterone receptor) - Baseline LVEF >/= 55% - Women of childbearing potential and male participants with partners of childbearing potential must agree to use effective contraception (as defined by the protocol) by the patient and/or partner for the duration of the study treatment and for at least 6 months after the last dose of study drug
Ausschlusskriterien	- History of any prior (ipsi- and/or contralateral) invasive breast cancer - History of non-breast malignancies within the 5 years prior to study entry, except for carcinoma in situ of the cervix, carcinoma in situ of the colon, melanoma in situ, and basal cell and squamous cell carcinomas of the skin - Any "clinical" T4 tumor as defined by TNM, including inflammatory breast cancer - Any previous systemic chemotherapy for cancer or radiotherapy for cancer - Prior use of anti-HER2 therapy for any reason or other prior biologic or immunotherapy for cancer

	- Concurrent anti-cancer treatment in another investigational trial - Serious cardiac or cardiovascular disease or condition - Pregnant or lactating women
Alter	18 Jahre und älter
Molekularer Marker	HER2/neu pos.
Sponsor	Roche Pharma AG (Hauptsponsor)
Förderer	Roche Pharma AG
Registrierung in anderen Studienregistern	ClinicalTrials.gov NCT01358877 EudraCT 2010-022902-41