KURZPROTOKOLL
Katherine (TDM-1)

Öffentlicher Titel	Phase-III Studie mit Trastuzumab als adjuvante Therapie bei HER2-posititvem Brustkrebs
Wissenschaftl. Titel	A randomized, multicenter, open-label phase-III study to evaluate the efficacy and safety of transtuzumab emtasine versus trastuzumab as therapy for patients with HER2-positive adjuvant primary breast cancer who have residual tumor present pathology in the breast or axillary lymph nodes following preoperative therapy
Kurztitel	Katherine (TDM-1)
Studienart	multizentrisch, prospektiv, randomisiert, offen/unverblindet, Pharma-Studie, zweiarmig
Studienphase	Phase III
Erkrankung	Geschlechtsorgane: Brustkrebs: adjuvant
Einschlusskriterien	- Adult patients. >/= 18 years of age - HER2-positive breast cancer - Histologically confirmed invasive breast carcinoma - Clinical stage T1-4/N0-3/M0 at presentation (patients with T1a/bN0 tumors will not be eligible) - Completion of preoperative systemic treatment consisting of at least 6 cycles with a total duration of at least 16 weeks, including at least 9 weeks of trastuzumab and at least 9 weeks of taxane-based therapy - Adequate excision: surgical removal of all clinically evident disease in the breast and lymph nodes as specified in protocol - Pathological evidence of residual invasive carcinoma in the breast or axillary lymph nodes following completion of preoperative therapy - An interval of no more than 12 weeks between the date of surgery and the date of randomization - Known hormone-receptor status - Eastern Cooperative Oncology Group (ECOG) performance status 0 or 1 - Adequate hematologic, renal and liver function - Left ventricular ejection fraction (LVEF) >/= 50% at screening and no decrease in LVEF by more than 15% absolute points from pre-chemotherapy - Women of childbearing potential and men with partners of childbearing potential must be willing to use effective contraception as defined by protocol for the duration of study treatment and for at least 6 months after the last dose of study treatment - Documentation of hepatitis B virus and hepatitis C virus serology is required
Ausschlusskriterien	- Stage IV (metastatic) breast cancer - History of any prior (ipsi- or contralateral breast cancer except lobular carcinoma in situ - Evidence of clinically evident gross residual or recurrent disease following preoperative therapy and surgery - Progressive disease during preoperative therapyTreatment with any anti-cancer investigational drug within 28 days prior to commencing study treatment - History of other malignancy within the last 5 years except for appropriately treated carcinoma in situ of the cervix, non-melanoma skin carcinoma, Stage I uterine cancer, or other non-breast malignancies with a similar outcome to those mentioned above - Patients for whom radiotherapy would be recommended for breast cancer treatment but for whom it is contraindicated because of medical reasons - Current NCI CTCAE (Version 4.0) Grade >/= 2 peripheral neuropathy

	- History of exposure to the following cumulative doses of anthracyclines: Doxorubicin > 240 mg/m2 Epirubicin > 480 mg/m2 For other anthracyclines, exposure equivalent to doxorubicin > 240 mg/m2 - Cardiopulmonary dysfunction as defined by protocol - Prior treatment with trastuzumab emtansine - Current severe, uncontrolled systemic disease - Pregnant or lactating women - Any known active liver disease, e.g. due to HBV, HCV, autoimmune hepatic disorders, or sclerosing cholangitis - Concurrent serious uncontrolled infections or known infection with HIV - History of intolerance, including Grade 3 to 4 infusion reaction or hypersensitivity to trastuzumab or murine proteins
Alter	18 Jahre und älter
Molekularer Marker	HER2/neu pos.
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Sponsor	Roche Pharma AG
Förderer	Roche Pharma AG
Registrierung in anderen Studienregistern	ClinicalTrials.gov NCT01772472 EudraCT 2012-002018-37
Therapie	Trastuzumab und Pertuzumab versus Trastuzumab und Placebo