

## **KURZPROTOKOLL** **Katherine (TDM-1)**

<b>Öffentlicher Titel</b>	Phase-III Studie mit Trastuzumab als adjuvante Therapie bei HER2-positivem Brustkrebs
<b>Wissenschaftl. Titel</b>	A randomized, multicenter, open-label phase-III study to evaluate the efficacy and safety of trastuzumab emtansine 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
<b>Kurztitel</b>	Katherine (TDM-1)
<b>Studienart</b>	multizentrisch, prospektiv, randomisiert, offen/unverblindet, Pharma-Studie, zweiarmig
<b>Studienphase</b>	Phase III
<b>Erkrankung</b>	Geschlechtsorgane: Brustkrebs: adjuvant
<b>Einschlusskriterien</b>	<ul style="list-style-type: none"><li>- Adult patients. <math>\geq</math> 18 years of age</li><li>- HER2-positive breast cancer</li><li>- Histologically confirmed invasive breast carcinoma</li><li>- Clinical stage T1-4/N0-3/M0 at presentation (patients with T1a/bN0 tumors will not be eligible)</li><li>- 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</li><li>- Adequate excision: surgical removal of all clinically evident disease in the breast and lymph nodes as specified in protocol</li><li>- Pathological evidence of residual invasive carcinoma in the breast or axillary lymph nodes following completion of preoperative therapy</li><li>- An interval of no more than 12 weeks between the date of surgery and the date of randomization</li><li>- Known hormone-receptor status</li><li>- Eastern Cooperative Oncology Group (ECOG) performance status 0 or 1</li><li>- Adequate hematologic, renal and liver function</li><li>- Left ventricular ejection fraction (LVEF) <math>\geq</math> 50% at screening and no decrease in LVEF by more than 15% absolute points from pre-chemotherapy</li><li>- 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</li><li>- Documentation of hepatitis B virus and hepatitis C virus serology is required</li></ul>
<b>Ausschlusskriterien</b>	<ul style="list-style-type: none"><li>- Stage IV (metastatic) breast cancer</li><li>- History of any prior (ipsi- or contralateral) breast cancer except lobular carcinoma in situ</li><li>- Evidence of clinically evident gross residual or recurrent disease following preoperative therapy and surgery</li><li>- Progressive disease during preoperative therapy Treatment with any anti-cancer investigational drug within 28 days prior to commencing study treatment</li><li>- 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</li><li>- Patients for whom radiotherapy would be recommended for breast cancer treatment but for whom it is contraindicated because of medical reasons</li><li>- Current NCI CTCAE (Version 4.0) Grade <math>\geq</math> 2 peripheral neuropathy</li></ul>

## **KURZPROTOKOLL** **Katherine (TDM-1)**

- History of exposure to the following cumulative doses of anthracyclines: Doxorubicin > 240 mg/m<sup>2</sup> Epirubicin > 480 mg/m<sup>2</sup> For other anthracyclines, exposure equivalent to doxorubicin > 240 mg/m<sup>2</sup>
- 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

<b>Alter</b>	18 Jahre und älter
<b>Molekularer Marker</b>	HER2/neu pos.
<b>Prüfzentren</b>	<b>Frauenheilkunde und Geburtshilfe (Nachbeobachtung)</b> Theodor-Stern-Kai 7 60590 Frankfurt am Main Lena Schütz Tel: 069 6301-84497 Fax: 069 6301-83655 <a href="mailto:lana.schuetz@kgu.de">lana.schuetz@kgu.de</a> <b>Sana Klinikum Offenbach (Geschlossen)</b> Ambulantes Onkologisches Zentrum Starkenburgring 66 63069 Offenbach n.a. Melanie Moschitz Tel: 069 8405 5815 Fax: 069 8405 4486 <a href="mailto:Melanie.Moschitz@sana.de">Melanie.Moschitz@sana.de</a> <b>Universitätsklinikum Frankfurt (Nachbeobachtung)</b> Klinik für Frauenheilkunde und Geburtshilfe Theodor-Stern-Kai 7 60590 Frankfurt am Main Lena Schütz Tel: 069 6301-84497 Fax: 069 6301-83655 <a href="mailto:lana.schuetz@kgu.de">lana.schuetz@kgu.de</a>
<b>Sponsor</b>	Roche Pharma AG
<b>Förderer</b>	Roche Pharma AG
<b>Registrierung in anderen Studienregistern</b>	ClinicalTrials.gov NCT01772472 EudraCT 2012-002018-37
<b>Therapie</b>	Trastuzumab und Pertuzumab versus Trastuzumab und Placebo