***PLEASE NOTE:*** *This study has been imported from ClinicalTrials.gov without additional data checks.*

## Trial Description

### Title

**A PHASE III PROSPECTIVE, TWO-COHORT NON-RANDOMIZED, MULTI-CENTRE, MULTINATIONAL, OPEN LABEL STUDY TO ASSESS THE SAFETY OF ASSISTED- AND SELF-ADMINISTERED SUBCUTANEOUS TRASTUZUMAB AS THERAPY IN PATIENTS WITH OPERABLE HER2-POSITIVE EARLY BREAST CANCER [SafeHer Study]**

### Trial Acronym

**[---]***

### URL of the trial

**[---]***

### Brief Summary in Lay Language

**This multicenter, two-cohort, non-randomized, open-label study will evaluate the safety and tolerability of assisted- and self-administered subcutaneous Herceptin (trastuzumab) as adjuvant therapy in patients with early HER2-positive breast cancer whose tumour has been excised. Patients will receive Herceptin 600 mg subcutaneously every 3 weeks for 18 cycles, either by an assisted administration using a conventional syringe and needle (vial formulation, Cohort A) or with assisted- and self-administration using a single-use injection device (SID) in selected patients (Cohort B). Anticipated time on study treatment is up to 1 year.**

### Brief Summary in Scientific Language

**[---]***

## Organizational Data

- DRKS-ID: **DRKS00004499**
- Date of Registration in DRKS: **2012/11/30**
- Date of Registration in Partner Registry or other Primary Registry: **2012/03/22**

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- Investigator Sponsored/Initiated Trial (IST/IIT): **no**
- Ethics Approval/Approval of the Ethics Committee: **[---]***
- (leading) Ethics Committee Nr.: **[---]***

## Secondary IDs

- EudraCT-No.
  (for studies acc. to Drug Law): **2011-005328-17**
- Primary Registry-ID: **NCT01566721 (ClinicalTrials.gov)**
- Sponsor-ID: **MO28048 (Hoffmann-La Roche)**
- Other Secondary-ID: **2011-005328-17**

## Health condition or Problem studied

- Free text: **Breast Cancer**
- ICD10: **C50 - Malignant neoplasm of breast**

## Interventions/Observational Groups

- Arm 1: **Drug: trastuzumab [Herceptin]**
- Arm 2: **Drug: trastuzumab [Herceptin]**

## Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Non-randomized controlled trial**
- Blinding: **[---]***
- Who is blinded: **[---]***
- Control: **[---]***
- Purpose: **Treatment**
- Assignment: **Parallel**
-

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Blinding: **[---]***

Who is blinded: **[---]***

Control: **[---]***

Purpose: **Treatment**

Assignment: **Parallel**

Phase: **III**

- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **[---]***

### Primary Outcome

**- Safety: Incidence of adverse events; time frame: approximately 8 years**

### Secondary Outcome

**- Disease-free survival; time frame: approximately 8 years**
**- Overall survival; time frame: approximately 8 years**
**- Patient satisfaction with trastuzumab SC using the single-use injection device (SID): SID satisfaction questionnaire (patients in cohort B who went on to self-administration of the study drug); time frame: approximately 3 years**

## Countries of recruitment

- AL **Albania**
- DZ **Algeria**
- AR **Argentina**
- AU **Australia**
- BA **Bosnia and Herzegovina**
- BR **Brazil**
- BG **Bulgaria**
- CA **Canada**
- CL **Chile**
- CO **Colombia**
- HR **Croatia**

- CZ **Czech Republic**
- DO **Dominican Republic**
- EC **Ecuador**
- EG **Egypt**
- SV **El Salvador**
- FI **Finland**
- FR **France**
- DE **Germany**
- GR **Greece**
- GT **Guatemala**
- HK **Hong Kong**
- HU **Hungary**
- IN **India**
- ID **Indonesia**
- IE **Ireland**
- IT **Italy**
- KR **Korea, Republic of**
- LT **Lithuania**
- MY **Malaysia**
- MX **Mexico**
- MA **Morocco**
- NL **Netherlands**
- NZ **New Zealand**
- NO **Norway**
- PK **Pakistan**
- PA **Panama**
- PE **Peru**
- PH **Philippines**
- PL **Poland**
- PT **Portugal**
- RO **Romania**
- RU **Russian Federation**

- SA **Saudi Arabia**
- RS **Serbia**
- SG **Singapore**
- SK **Slovakia**
- SI **Slovenia**
- ZA **South Africa**
- ES **Spain**
- SE **Sweden**
- CH **Switzerland**
- TW **Taiwan, Province of China**
- TH **Thailand**
- TR **Turkey**
- UA **Ukraine**
- AE **United Arab Emirates**
- UK **United Kingdom**
- UY **Uruguay**
- VE **Venezuela, Bolivarian Republic of**
- VN **Viet Nam**

## Locations of Recruitment

- **Augsburg**
- **Bad Soden**
- **Berlin**
- **Berlin**
- **Bielefeld**
- **Bochum**
- **Bremerhaven**
- **Deggendorf**
- **Dresden**
- **Düsseldorf**
- **Essen**
- **Essen**
- **Freiburg**

- **Georgsmarienhütte**
- **Gera**
- **Halle**
- **Hamburg**
- **Hamburg**
- **Hannover**
- **Hannover**
- **Heidelberg**
- **Jena**
- **Kassel**
- **Koeln**
- **Kulmbach**
- **Köln**
- **Köln**
- **Langen**
- **Leverkusen**
- **Ludwigsburg**
- **Lübeck**
- **Magedburg**
- **Mainz**
- **Marburg**
- **Meiningen**
- **Memmingen**
- **Minden**
- **Muenchen**
- **Mühlhausen**
- **München**
- **München**
- **München**
- **Münster**
- **Neuruppin**
- **Nuernberg**

- **Offenbach**
- **Ostfildern**
- **Paderborn**
- **Recklinghausen**
- **Rotenburg-wuemme**
- **Saarbruecken**
- **Schweinfurt**
- **Schwerin**
- **Stendal**
- **Stuttgart**
- **Torgau**
- **Tübingen**
- **Unna**
- **Weiden**
- **Weinheim**
- **Weißenfels**
- **Wetzlar**
- **Wuerselen**

## Recruitment

- Planned/Actual: **[---]***
- (Anticipated or Actual) Date of First Enrollment: **2012/05/31**
- Target Sample Size: **2500**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **International**

### Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
- Maximum Age: **no maximum age**

### Additional Inclusion Criteria

**- Adult male or female patients, >/= 18 years of age**

**- Histologically confirmed early invasive HER2-positive carcinoma of the breast with no**

**evidence of residual, locally recurrent or metastatic disease and defined as clinical stage I to IIIC that is eligible for adjuvant treatment with trastuzumab**

**- Eastern Cooperative Oncology Group (ECOG) performance status 0 or 1**

**- Screening left ventricular ejection fraction (LVEF) >/= 55%**

**Exclusion criteria**

**- Previous neoadjuvant or adjuvant breast cancer treatment with an approved or investigational anti-HER2 agent**

**- History of other malignancy, except for curatively treated carcinoma in situ of the cervix or basal cell carcinoma and patients with other curatively treated malignancies, other than breast cancer, who have been disease-free for at least 5 years**

**- Past history of ductal carcinoma in situ that has been treated with any systemic therapy or with radiation therapy to the ipsilateral breast where the invasive cancer subsequently develops**

**- Metastatic disease**

**- Inadequate bone marrow, hepatic or renal function**

**- Serious cardiac or cardiovascular disease**

**- Uncontrolled hypertension, or history of hypertensive crisis or hypertensive encephalopathy**

**- History of severe allergic or immunological reactions, e.g. difficult to control asthma**

**- Pregnant or lactating women**

## Addresses

■ **Primary Sponsor**

**Hoffmann-La Roche**

**Primary Sponsor**

**Hoffmann-La Roche**

Telephone: **[---]***
Fax: **[---]***
E-mail: **[---]***
URL: **[---]***

- **Contact for Scientific Queries**

**Hoffmann-La Roche**
**Clinical Trials**

Telephone: **[---]***
Fax: **[---]***
E-mail: **[---]***
URL: **[---]***

- **Contact for Public Queries**

**Reference Study ID Number: MO28048**
**www.roche.com/about_roche/roche_worldwide.htm**

Telephone: **888-662-6728 (U.S. Only)**
Fax: **[---]***
E-mail: **global.rochegenentechtrials at roche.com**
URL: **[---]***

## Sources of Monetary or Material Support

- **[---]***

**Bitte wenden Sie sich an den Sponsor / Please refer to primary sponsor**

Telephone: **[---]***
Fax: **[---]***
E-mail: **[---]***
URL: **[---]***

## Status

- Recruitment Status: **Recruiting ongoing**
- Study Closing (LPLV): **[---]***

## Trial Publications, Results and other documents

*The parameters in ClinicalTrials.gov and DRKS are not identical. Therefore the data import from ClinicalTrials.gov required adjustments. For full details please see the DRKS FAQs.*

*- Translation on version: 4*

*- Last processed date by ClinicalTrials.gov: 2013/10/30*

** This entry means the parameter is not applicable or has not been set.*

**** This entry means that data is not displayed due to insufficient data privacy clearing.*