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

Trial Description

Title

A Multicenter Randomized Phase III Study to Compare the Combination Trastuzumab and Capecitabine, With or Without Pertuzumab in Patients With HER2-Positive Metastatic Breast Cancer That Have Progressed After One Line of Trastuzumab-Based Therapy in the Metastatic Setting (PHEREXA)

Trial Acronym

[---]*

URL of the trial

[---]*

Brief Summary in Lay Language

This randomized, two-arm study will evaluate the efficacy and safety of a combination of trastuzumab and capecitabine with or without pertuzumab in patients with HER2-positive metastatic breast cancer. The study population consists of female patients, whose disease has progressed during or following previous trastuzumab therapy for metastatic disease. All patients in Arm A and Arm B are to receive trastuzumab (8 mg/kg iv as loading dose and then 6 mg/kg iv every 3 weeks thereafter). Patients in Arm A and Arm B are to receive capecitabine oral twice daily for 14 days every 3 weeks (1250 mg/m2 twice daily in Arm A and 1000 mg/m2 twice daily in Arm B). In addition, patients in Arm B will receive pertuzumab (840 mg iv as loading dose and then 420 mg iv thereafter) every 3 weeks. Study treatment is to continue until disease progression or unacceptable toxicity.

Brief Summary in Scientific Language

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Organizational Data

- DRKS-ID: **DRKS00007744**
- Date of Registration in DRKS: **2015/02/18**
- Date of Registration in Partner Registry or other Primary Registry: **2009/11/27**
- 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): **2008-006801-17**
- Primary Registry-ID: **NCT01026142 (ClinicalTrials.gov)**
- Sponsor-ID: **MO22324 (Hoffmann-La Roche)**
- Other Secondary-ID: **2008-006801-17**

Health condition or Problem studied

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

Interventions/Observational Groups

- Arm 1: **Drug: capecitabine [Xeloda]**
- Arm 2: **Drug: capecitabine [Xeloda]**
- Arm 3: **Drug: pertuzumab**
- Arm 4: **Drug: trastuzumab [Herceptin]**

Characteristics

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

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Assignment: **Parallel**

Phase: **III**

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

Primary Outcome

- Progression free survival (Independent assessment); time frame: Tumour Assessment every 9 weeks until week 27, then every 12 weeks thereafter

Secondary Outcome

- Safety, Tolerability; AEs, laboratory parameters; time frame: AEs: from screening until 2 years after last dose of study drug. Laboratory assessments: every 3 weeks
- Duration of response; time frame: Tumour Assessment every 9 weeks until week 27, then every 12 weeks thereafter
- Overall Survival based on a 2-year truncated analysis; time frame: From randomization until death from any cause
- Progression free survival (investigator assessment); time frame: Tumour Assessment every 9 weeks until week 27, then every 12 weeks thereafter
- Time to progression; time frame: Tumour Assessment every 9 weeks until week 27, then every 12 weeks thereafter
- Time to treatment failure; time frame: Tumour Assessment every 9 weeks until week 27, then every 12 weeks thereafter
- Overall objective response; time frame: Tumour Assessment every 9 weeks until week 27, then every 12 weeks thereafter
- Clinical benefit rate; time frame: Tumour Assessment every 9 weeks until week 27, then every 12 weeks thereafter
- Overall Survival; time frame: From randomization until death from any cause

Countries of recruitment

- AR **Argentina**
- AT **Austria**
- BE **Belgium**
-

BR **Brazil**

- CA **Canada**
- HR **Croatia**
- CZ **Czech Republic**
- EE **Estonia**
- FR **France**
- DE **Germany**
- HK **Hong Kong**
- HU **Hungary**
- IT **Italy**
- KR **Korea, Republic of**
- MX **Mexico**
- NL **Netherlands**
- PE **Peru**
- PL **Poland**
- RO **Romania**
- RU **Russian Federation**
- ES **Spain**
- TH **Thailand**
- UK **United Kingdom**

Locations of Recruitment

- **Berlin**
- **Bremen**
- **Böblingen**
- **Darmstadt**
- **Dortmund**
- **Essen**
- **Frankfurt**
- **Fulda**
- **Hamburg**
- **Hamburg**
- **Hannover**

- **Hannover**
- **Karlsruhe**
- **Kiel**
- **Koblenz**
- **Koeln**
- **Lübeck**
- **Mainz**
- **München**
- **Münster**
- **Offenburg**
- **Recklinghausen**
- **Stendal**
- **Trier**
- **Weinheim**

Recruitment

- Planned/Actual: **[---]***
- (Anticipated or Actual) Date of First Enrollment: **2010/01/31**
- Target Sample Size: **452**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **International**

Inclusion Criteria

- Gender: **Female**
- Minimum Age: **18 Years**
- Maximum Age: **no maximum age**

Additional Inclusion Criteria

- Adult female patients >/=18 years of age

- Metastatic HER2 positive breast cancer

- ECOG performance status 0 or 1

- Disease progression during or following trastuzumab-based therapy for 1st line metastatic breast cancer (trastuzumab must have been part of the last prior treatment

regimen)

- Prior treatment with taxane-containing regimen

- LVEF >/=50 percent

- For women of childbearing potential agreement to use highly effective non-hormonal form of contraception or two effective forms of non-hormonal contraception by patient and/or partner. Contraception must continue for duration of study treatment and for at least 6 months after last dose of study drug treatment

Exclusion criteria

- Prior treatment with pertuzumab or capecitabine

- Concurrent treatment with other experimental drug

- Concurrent immunotherapy or anticancer hormonal therapy

- Serious concurrent disease (e.g. active infection, uncontrolled hypertension, cardiovascular disease)

- CNS metastases, which are not well controlled

- History of exposure to anthracycline cumulative dose equivalent to 360mg/m2

- History of congestive heart failure of any New York Heart Association criteria, or serious cardiac arrhythmia requiring treatment

- History of myocardial infarction within 6 months prior to randomization

- History of LVEF decline to below 50% during or after prior trastuzumab therapy or other cardiac toxicity during previous trastuzumab treatment that necessitated discontinuation of trastuzumab

- History of another cancer which could affect compliance or result interpretation

- Inadequate organ function

- Pregnant or breastfeeding women

- life expectancy < 12 weeks

Addresses

- **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**

  Hoffmann-La Roche
  Clinical Trials

  Telephone: **[---]***
  Fax: **[---]***
  E-mail: **[---]***
  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 complete, follow-up continuing**
- 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: 3
- Last processed date by ClinicalTrials.gov: 2015/01/22

** 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.*