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

Trial Description

Title

An Open-label Study to Evaluate the Safety and Effect on Disease Progression and Overall Survival of Avastin Plus Taxane-based Chemotherapy in Patients With Locally Recurrent or Metastatic Breast Cancer

Trial Acronym

[---]*

URL of the trial

[---]*

Brief Summary in Lay Language

This single arm study will assess the safety and efficacy of a regimen of Avastin plus a taxane, with or without additional chemotherapy, as first-line treatment in patients with locally recurrent or metastatic breast cancer. All patients will receive Avastin (10mg/kg iv every 2 weeks, or 15 mg/kg iv every 3 weeks) plus taxane-based chemotherapy. If taxanes are contraindicated, alternative chemotherapy (other than anthracyclines or pegylated liposomal doxorubicin) may be used. The anticipated time on study treatment is until disease progression, and the target sample size is 500+ individuals.

Brief Summary in Scientific Language

[---]*

Do you plan to share individual participant data with other researchers?

[---]*

Description IPD sharing plan

[---]*

Organizational Data

- DRKS-ID: **DRKS00003642**
- Date of Registration in DRKS: **2012/05/08**
- Date of Registration in Partner Registry or other Primary Registry: **2007/03/16**
- Investigator Sponsored/Initiated Trial (IST/IIT): **no**
- Ethics Approval/Approval of the Ethics Committee: **[---]***
- (leading) Ethics Committee Nr.: **[---]***

Secondary IDs

- Primary Registry-ID: **NCT00448591 (ClinicalTrials.gov)**
- Sponsor-ID: **MO19391 (Hoffmann-La Roche)**

Health condition or Problem studied

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

Interventions/Observational Groups

- Arm 1: **Drug: bevacizumab [Avastin]**
- Arm 2: **Drug: Taxane-based chemotherapy**

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Single arm study**
- Blinding: **[---]***
- Who is blinded: **[---]***
- Control: **Uncontrolled/Single arm**
- Purpose: **Treatment**
- Assignment: **Single (group)**
- Phase: **III**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **[---]***

Primary Outcome

- Incidence of AEs, and SAEs related to Avastin; time frame: Throughout study

Secondary Outcome

- Duration of survival, time to disease progression; time frame: Event driven

Countries of recruitment

- AR **Argentina**
- AU **Australia**
- AT **Austria**
- BR **Brazil**
- BG **Bulgaria**
- CA **Canada**
- CN **China**
- CO **Colombia**
- CZ **Czech Republic**
- EC **Ecuador**
- EG **Egypt**
- EE **Estonia**
- FI **Finland**
- FR **France**
- DE **Germany**
- HK **Hong Kong**
- HU **Hungary**
- IL **Israel**
- IT **Italy**
- LV **Latvia**
- LB **Lebanon**
- LT **Lithuania**
- MY **Malaysia**
- MX **Mexico**
- MA **Morocco**

- NL **Netherlands**
- PL **Poland**
- PT **Portugal**
- RU **Russian Federation**
- SA **Saudi Arabia**
- SK **Slovakia**
- SI **Slovenia**
- ES **Spain**
- SE **Sweden**
- CH **Switzerland**
- TR **Turkey**
- UK **United Kingdom**

Locations of Recruitment

- **Augsburg**
- **Bad Saarow**
- **Berlin**
- **Berlin**
- **Berlin**
- **Bielefeld**
- **Bochum**
- **Böblingen**
- **Chemnitz**
- **Cottbus**
- **Deggendorf**
- **Dresden**
- **Duisburg**
- **Düsseldorf**
- **Erfurt**
- **Essen**
- **Frankfurt Am Main**
- **Freiburg**
- **Halle**

- **Hamburg**
- **Hamburg**
- **Hannover**
- **Hannover**
- **Kassel**
- **Kiel**
- **Leipzig**
- **Lübeck**
- **Magdeburg**
- **Magdeburg**
- **Mainz**
- **Mannheim**
- **München**
- **Regensburg**
- **Rostock**
- **Saarbrücken**
- **Stralsund**
- **Stuttgart**
- **Stuttgart**
- **Troisdorf**
- **ULM**
- **Unna**
- **Wiesbaden**
- **Wuppertal**
- **Würselen**

Recruitment

- Planned/Actual: **[---]***
- (Anticipated or Actual) Date of First Enrollment: **2006/09/30**
- Target Sample Size: **2300**
- 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

- patients, >=18 years of age;

- HER-2 negative adenocarcinoma of the breast, with locally recurrent or metastatic disease; (HER-2 positive patients only if previously treated with Herceptin in the adjuvant setting;

- candidates for chemotherapy.

Exclusion criteria

- previous chemotherapy for metastatic or locally recurrent breast cancer;

- concomitant hormonal therapy for metastatic or locally recurrent disease;

- concomitant Herceptin therapy for treatment of metastatic or locally recurrent HER-2 positive disease;

- previous radiotherapy for treatment of metastatic disease;

- evidence of CNS metastases.

Addresses

- **Primary Sponsor**

  Hoffmann-La Roche

  Telephone: **[---]***
  Fax: **[---]***
  E-mail: **[---]***
  URL: **[---]***
- **Contact for Scientific Queries**

  Hoffmann-La Roche
  Clinical Trials

Contact for Scientific Queries

Hoffmann-La Roche
Clinical Trials

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

- **Contact for Public Queries**

Please reference Study ID Number: MO19391

Telephone: **888-662-6728 (U.S. Only)**
Fax: **[---]***
E-mail: **genentechclinicaltrials at druginfo.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.*