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

Trial Description

Title

A Phase II, Double-Blind, Placebo Controlled, Randomized Study of GDC-0941 or GDC-0980 With Fulvestrant Versus Fulvestrant in Advanced or Metastatic Breast Cancer in Patients Resistant to Aromatase Inhibitor Therapy

Trial Acronym

[---]*

URL of the trial

[---]*

Brief Summary in Lay Language

This is a multicenter, international, randomized, double-blinded, placebo-controlled, Phase II trial. Patients with advanced or Metastatic Breast Cancer (MBC) who have previously received treatment with an aromatase inhibitor. Patients will receive treatment with GDC-0941 + fulvestrant or GDC-0980 + fulvestrant or placebo + fulvestrant.

Brief Summary in Scientific Language

[---]*

Organizational Data

- DRKS-ID: **DRKS00005397**
- Date of Registration in DRKS: **2013/10/25**
- Date of Registration in Partner Registry or other Primary Registry: **2011/09/08**
- 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): **2010-023763-17**
- Primary Registry-ID: **NCT01437566 (ClinicalTrials.gov)**
- Sponsor-ID: **GDC4950g (Genentech)**
- Other Secondary-ID: **GO00769**

Health condition or Problem studied

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

Interventions/Observational Groups

- Arm 1: **Drug: fulvestrant**
- Arm 2: **Drug: GDC-0941**
- Arm 3: **Drug: GDC-0980**
- Arm 4: **Drug: placebo**
- Arm 5: **Drug: GDC-0941**
- Arm 6: **Drug: placebo**

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Randomized controlled trial**
- Blinding: **[---]***
- Who is blinded: **[---]***
- Control: **Placebo**
- Purpose: **Treatment**
- Assignment: **Parallel**
- Phase: **II**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **[---]***

Primary Outcome

- Progression-free survival (PFS) as assessed by the investigator per modified RECIST version 1.1; time frame: until disease progression, up to 1 year
- Safety: incidence of adverse events; time frame: until disease progression, up to 1 year

Secondary Outcome

- Objective tumor response as assessed by the investigator per modified RECIST v1.1; time frame: until disease progression, up to 1 year
- Clinical benefit defined as partial response (PR), complete response (CR), or stable disease (SD) per modified RECIST v1.1; time frame: until disease progression, up to 1 year
- Duration of confirmed objective response as assessed by the investigator per modified RECIST v1.1; time frame: until disease progression, up to 1 year
- Proportion of patients with PIK3CA mutant tumors; time frame: until disease progression, up to 1 year
- Pharmacokinetic parameters of GDC-0941 and GDC-0980: time to maximum concentration; time frame: Cycle 1, Day 15/16; Cycle 2, Day 15; Cycle, 6 Day 1
- Pharmacokinetic parameters of GDC-0941 and GDC-0980: maximum concentration; time frame: Cycle 1, Day 15/16; Cycle 2, Day 15; Cycle, 6 Day 1
- Pharmacokinetic parameters of GDC-0941 and GDC-0980: Area under the concentration time curve; time frame: Cycle 1, Day 15/16; Cycle 2, Day 15; Cycle, 6 Day 1

Countries of recruitment

- US **United States**
- AR **Argentina**
- AU **Australia**
- BE **Belgium**
- CA **Canada**
- CL **Chile**
- CZ **Czech Republic**
- DK **Denmark**
- FR **France**
- DE **Germany**
- HK **Hong Kong**
- IL **Israel**
- IT **Italy**
- KR **Korea, Republic of**
- MY **Malaysia**
- MX **Mexico**
- NZ **New Zealand**
- PE **Peru**
- RU **Russian Federation**
-

SG **Singapore**

- ES **Spain**
- TH **Thailand**
- UK **United Kingdom**

Locations of Recruitment

- **Berlin**
- **Düsseldorf**
- **Freiburg**
- **Freiburg**
- **Hamburg**
- **Muenchen**
- **Muenchen**
- **München**
- **Trier**

Recruitment

- Planned/Actual: **[---]***
- (Anticipated or Actual) Date of First Enrollment: **2011/10/31**
- Target Sample Size: **270**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **International**

Inclusion Criteria

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

Additional Inclusion Criteria

- Patients with ER-positive locally advanced breast cancer or Metastatic Breast Cancer (MBC). Postmenopausal women with locally advanced breast cancer or Metastatic Breast Cancer whose disease has progressed during or after treatment with an aromatase inhibitor. Part II: Postmenopausal women with locally advanced PIK3CA-

mutant breast cancer or PIK3CA-mutant MBC that has progressed during or after treatment with an AI.

- Eastern Cooperative Oncology Group (ECOG) Performance Status of 0 or 1

- Patients must have measurable disease by RECIST v1.1 or bone-only disease

- Adequate hematologic and end-organ function

- Estrogen receptor-positive disease and HER2-negative disease

Exclusion criteria

- Prior treatment with fulvestrant, PI3K inhibitor, or mTOR inhibitor for advanced breast cancer or MBC

- Prior treatment with > one cytotoxic chemotherapy regimens or experienced recurrent or progressive disease on > two endocrine therapies for metastatic breast cancer

- History of malabsorption syndrome or other condition that would interfere with enteral absorption

- History of clinically significant cardiac or pulmonary dysfunction

- Clinically significant history of liver disease

- Active uncontrolled autoimmune disease or active inflammatory disease

- Immunocompromised status

- Symptomatic hypercalcemia

- Need for current chronic corticosteroid therapy

- Pregnancy, lactation, or breastfeeding

- Known untreated or active central nervous system (CNS) metastases Other protocol-defined inclusion/exclusion criteria may apply.

Addresses

■ **Primary Sponsor**

Genentech

Primary Sponsor

Genentech

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

- **Contact for Scientific Queries**

Genentech
Gallia Levy, M.D., Ph.D.

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

- **Contact for Public Queries**

Reference Study ID Number: GDC4950g
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: 5

- Last processed date by ClinicalTrials.gov: 2013/10/23

** 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.*