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Trial record **7 of 8** for: larotaxel

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Breast Cancer Trial of RPR109881 Versus Capecitabine in Male or Female Patients With Advanced Breast Cancer

This study has been completed.

Sponsor:
Sanofi

Information provided by:
Sanofi

ClinicalTrials.gov Identifier:
NCT00081796

First received: April 20, 2004
Last updated: August 20, 2008
Last verified: August 2008
History of Changes

Full Text View | Tabular View | No Study Results Posted | Disclaimer | How to Read a Study Record

Purpose

The purpose of this clinical trial is to determine if RPR109881 is a better treatment than capecitabine (Xeloda) for advanced breast cancer in patients that no longer benefit from docetaxel and/or paclitaxel.

Condition	Intervention	Phase
Breast Cancer Metastases	Drug: **larotaxel** (RPR109881, **XRP9881**) Drug: capecitabine	Phase 3

Study Type: Interventional
Study Design: Allocation: Randomized
Endpoint Classification: Safety/Efficacy Study
Intervention Model: Parallel Assignment
Masking: Open Label
Primary Purpose: Treatment

Official Title: A Randomized, Open-Label, Phase III Study of RPR109881 IV Every 3 Weeks Versus Capecitabine (Xeloda) Tablets Twice Daily for 2 Weeks in 3-Week Cycles in Patients With Metastatic Breast Cancer Progressing After Taxanes and Anthracycline Therapy

Resource links provided by NLM:

Genetics Home Reference related topics: breast cancer

MedlinePlus related topics: Breast Cancer Cancer

Drug Information available for: Capecitabine

U.S. FDA Resources

Further study details as provided by Sanofi:

Primary Outcome Measures:

- Time to tumor progression.

Secondary Outcome Measures:

- Overall survival.

Enrollment: 438
Study Start Date: April 2004

Study Completion Date: September 2006
Primary Completion Date: September 2006 (Final data collection date for primary outcome measure)

Detailed Description:
All patients in this trial will receive either the investigational drug or capecitabine, a chemotherapy drug that is already approved to treat your disease. These drugs prevent tumor cells from dividing, so they may stop growing or die. The investigational drug in this clinical trial is a chemotherapy drug given through the vein once every three weeks. Patients who receive capecitabine will receive this drug by mouth for 14 days, every 21 days.

Eligibility

Ages Eligible for Study: 18 Years and older
Genders Eligible for Study: Both
Accepts Healthy Volunteers: No

Criteria

Eligibility Criteria

In order to be eligible for this trial you must:

- Have a diagnosis of breast cancer that is now metastatic (meaning the cancer has spread beyond its original location) or a recurrence of the cancer in its original location that cannot be removed by surgery.
- Have received previous treatment with anthracyclines (e.g., adriamycin, Doxorubicin) and taxanes (e.g., paclitaxel, docetaxel, Taxol®, Taxotere®) for your breast cancer and your doctor has determined that these treatment are no longer of benefit to you.
- Be at least 18 years of age.
- Not be taking other treatments for your cancer at the time you enter this trial.
- Not be pregnant.

Additionally, there are other criteria for study entry that a doctor participating in this study will need to review in detail with you and clinical assessments may need to be performed (e.g., lab tests, CT scans).

Contacts and Locations

Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the Contacts provided below. For general information, see Learn About Clinical Studies.

Please refer to this study by its ClinicalTrials.gov identifier: NCT00081796

Show 187 Study Locations

Sponsors and Collaborators

Sanofi

Investigators

Study Director: ICD CSD Sanofi

More Information

Responsible Party: ICD Study Director, sanofi-aventis
ClinicalTrials.gov Identifier: NCT00081796 History of Changes
Obsolete Identifiers: NCT00107406
Other Study ID Numbers: EFC6089 **XRP9881**B-3001
Study First Received: April 20, 2004
Last Updated: August 20, 2008
Health Authority: United States: Food and Drug Administration

Keywords provided by Sanofi:
Metastatic Breast Cancer

Additional relevant MeSH terms:

Breast Neoplasms	Capecitabine
Breast Diseases	Antimetabolites
Neoplasms	Antimetabolites, Antineoplastic

ClinicalTrials.gov processed this record on June 19, 2016