Safety Study of CAELYX in Patients With Metastatic Breast Cancer Previously Treated With Anthracyclines (Study P04057)(TERMINATED)

This study has been terminated.

Sponsor:
Merck Sharp & Dohme Corp.

Information provided by (Responsible Party):
Merck Sharp & Dohme Corp.

ClinicalTrials.gov Identifier:
NCT00779285

First received: October 23, 2008
Last updated: June 18, 2015
Last verified: June 2015
History of Changes

Full Text View | Tabular View | Study Results | Disclaimer | How to Read a Study Record

Purpose

The purpose of this study is to evaluate the cardiac safety of Caelyx in patients with metastatic breast cancer who have previously received chemotherapy with anthracyclines.

Condition	Intervention	Phase
Breast Neoplasm	Drug: Pegylated Liposomal Doxorubicin	Phase 4

Study Type: Interventional
Study Design: Endpoint Classification: Safety Study
Intervention Model: Single Group Assignment
Masking: Open Label
Primary Purpose: Treatment

Official Title: Cardiac Safety Profile of Caelyx Therapy in Anthracyclin Pretreated Metastatic Breast Cancer Patients.

Resource links provided by NLM:

Genetics Home Reference related topics: breast cancer

MedlinePlus related topics: Breast Cancer Cancer

Drug Information available for: Doxorubicin Doxorubicin hydrochloride

U.S. FDA Resources

Further study details as provided by Merck Sharp & Dohme Corp.:

Primary Outcome Measures:

- Cardiac Events [Time Frame: Every 4 weeks during 6 cycles.] [Designated as safety issue: Yes]

A cardiac event was defined as a decrease in left ventricular ejection fraction (LVEF) of >=20 points from baseline if the resting LVEF remained in the normal range, or a decrease of >=10 points if the LVEF became abnormal (lower than the institutional lower limit of normal).

Enrollment:	1
Study Start Date:	February 2006
Study Completion Date:	August 2006
Primary Completion Date:	August 2006 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Experimental: Single-arm Pegylated Lyposomal Doxorubicin (Caelyx) 50 mg/m2, given for 6 cycles	Drug: Pegylated Liposomal Doxorubicin Pegylated Liposomal Doxorubicin (Caelyx) IV, 50 mg/m2 once every 4 weeks for 6 cycles or until disease progression, whichever is earlier. Patients still receiving clinical benefit after a total of 6 cycles of Caelyx, may continue therapy at the discretion of the investigator. Other Name: SCH 200746

Eligibility

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

Criteria

Inclusion Criteria:

- Women with histologically or cytologically confirmed metastatic breast cancer (no prior chemotherapy for metastatic disease).
- Prior treatment with an anthracyclin-containing regimen in the adjuvant setting (cumulative dose >240mg/m^2 and <360mg/m^2 doxorubicin or >430mg/m^2 and <650mg/m^2 epirubicin).
- Women >18 years of age.
- Documented measurable and/or evaluable metastatic breast cancer by appropriate radiological imaging (computed tomography (CT) scan and/or magnetic resonance imaging (MRI)).
- Performance status of at least 60% (Karnofsky index) and a life expectancy of at least 12 weeks.
- Left ventricular ejection fraction >50%.
- Normal organ function, except if abnormal due to tumor involvement.
  - Adequate bone marrow function as indicated:
    - Platelets >100,000/mm^3
    - Hemoglobin >9 g/dL
    - Neutrophils >1,500/mm^3
  - Adequate renal function as indicated by:
    - Serum Creatinine <1.5 x the upper limit of normal
  - Adequate liver function, as indicated by:
    - Bilirubin and aspartate aminotransferase (AST) or alanine aminotransferase (ALT) <2 times upper limit of normal (<4 times upper limit of normal when related to primary disease)
- Subjects must be capable to demonstrate their willingness to participate in the study and comply with its procedures by signing a written informed consent.
- Women of childbearing potential (includes women who are less than 1 year postmenopausal and women who become sexually active) must be using an acceptable method of birth control (e.g., hormonal contraceptive, medically prescribed intrauterine device (IUD), condom in combination with spermicide) or be surgically sterilized (e.g., hysterectomy or tubal ligation).
- Subjects must understand and be able to adhere to the dosing and visit schedules.

Exclusion Criteria:

- Patient is pregnant or is breastfeeding.
- Patients with moderate or severe heart failure (New York Heart Association (NYHA) class III/IV).
- Hypersensitivity to anthracycline therapy or a history of severe hypersensitivity reactions to products containing Cremophor® EL (e.g.,

cyclosporin for injection concentrate and teniposide for injection concentrate).

- Prior chemotherapy for metastatic disease.
- Clinically significant hepatic disease (except liver metastases of primary disease).
- Uncontrolled bacterial, viral, or fungal infection.
- Radiotherapy in the last 4 weeks or prior radiation therapy to more than one-third of the hemopoietic sites.
- Any other currently known malignancy or pre-malignant lesions or any history of other malignancy within the past five years (except non-melanoma skin cancer and surgically cured cervical cancer).
- Symptomatic brain metastasis.
- Patients who are incapacitated, largely or wholly bedridden or confined to a wheelchair, and who have little or no ability for self-care.
- Current signs or symptoms of severe, progressive or uncontrolled renal, hepatic, hematologic, endocrine, pulmonary, cardiac, neurological or cerebral disease.
- Documented human immunodeficiency virus (HIV) infection.
- Any condition (medical, social, psychological) which would prevent adequate follow-up.

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.

No Contacts or Locations Provided

More Information

Responsible Party:	Merck Sharp & Dohme Corp.
ClinicalTrials.gov Identifier:	NCT00779285 History of Changes
Other Study ID Numbers:	P04057 EUDRACT NO. 2004-001177-25
Study First Received:	October 23, 2008
Results First Received:	February 11, 2010
Last Updated:	June 18, 2015
Health Authority:	Hungary: National Institute of Pharmacy

Additional relevant MeSH terms:

Breast Neoplasms	Antineoplastic Agents
Breast Diseases	Enzyme Inhibitors
Neoplasms	Molecular Mechanisms of Pharmacological Action
Neoplasms by Site	Pharmacologic Actions
Skin Diseases	Therapeutic Uses
Doxorubicin	Topoisomerase II Inhibitors
Liposomal doxorubicin	Topoisomerase Inhibitors
Antibiotics, Antineoplastic	

ClinicalTrials.gov processed this record on May 08, 2016

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Results First Received: February 11, 2010

Study Type:	Interventional
Study Design:	Endpoint Classification: Safety Study; Intervention Model: Single Group Assignment; Masking: Open Label; Primary Purpose: Treatment
Condition:	Breast Neoplasm
Intervention:	Drug: Pegylated Liposomal Doxorubicin

Participant Flow

Hide Participant Flow

Recruitment Details

Key information relevant to the recruitment process for the overall study, such as dates of the recruitment period and locations
No text entered.

Pre-Assignment Details

Significant events and approaches for the overall study following participant enrollment, but prior to group assignment
No text entered.

Reporting Groups

	Description
Caelyx	

	Pegylated Lyposomal Doxorubicin (Caelyx) 50 mg/m2, given for 6 cycles

Participant Flow: Overall Study

	Caelyx
STARTED	**1**
COMPLETED	**1**
NOT COMPLETED	**0**

Baseline Characteristics

Hide Baseline Characteristics

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
No text entered.

Reporting Groups

	Description
Caelyx	Pegylated Lyposomal Doxorubicin (Caelyx) 50 mg/m2, given for 6 cycles

Baseline Measures

	Caelyx
Number of Participants [units: participants]	**1**
Age, Customized [units: participants]	**1**
Gender [units: participants]	
Female	**1**
Male	**0**
Region of Enrollment [units: participants]	
Hungary	**1**

Outcome Measures

1. Primary: Cardiac Events [Time Frame: Every 4 weeks during 6 cycles.]

Hide Outcome Measure 1

Measure Type	Primary
Measure Title	Cardiac Events
Measure Description	A cardiac event was defined as a decrease in left ventricular ejection fraction (LVEF) of >=20 points from baseline if the resting LVEF remained in the normal range, or a decrease of >=10 points if the LVEF became abnormal (lower than the institutional lower limit of normal).
Time Frame	Every 4 weeks during 6 cycles.
Safety Issue	Yes

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
No text entered.

Reporting Groups

	Description
Caelyx	Pegylated Lyposomal Doxorubicin (Caelyx) 50 mg/m2, given for 6 cycles

Measured Values

	Caelyx
Number of Participants Analyzed [units: participants]	**1**
Cardiac Events [units: Cardiac Events]	**0**

No statistical analysis provided for Cardiac Events

Serious Adverse Events

Hide Serious Adverse Events

Time Frame	No text entered.
Additional Description	No text entered.

Reporting Groups

	Description
Caelyx	Pegylated Lyposomal Doxorubicin (Caelyx) 50 mg/m2, given for 6 cycles

Serious Adverse Events

	Caelyx
Total, serious adverse events	

# participants affected / at risk	**0/1 (0.00%)**

Other Adverse Events

Hide Other Adverse Events

Time Frame	No text entered.
Additional Description	No text entered.

Frequency Threshold

Threshold above which other adverse events are reported	5%

Reporting Groups

	Description
Caelyx	Pegylated Lyposomal Doxorubicin (Caelyx) 50 mg/m2, given for 6 cycles

Other Adverse Events

	Caelyx
Total, other (not including serious) adverse events	
# participants affected / at risk	**1/1 (100.00%)**
Skin and subcutaneous tissue disorders	
Maculopapulosus exanthema	
# participants affected / at risk	**1/1 (100.00%)**
# events	**1**

Limitations and Caveats

Hide Limitations and Caveats

Limitations of the study, such as early termination leading to small numbers of participants analyzed and technical problems with measurement leading to unreliable or uninterpretable data
No text entered.

More Information

Hide More Information

Certain Agreements:

Principal Investigators are **NOT** employed by the organization sponsoring the study.
There **IS** an agreement between Principal Investigators and the Sponsor (or its agents) that restricts the PI's rights to discuss or publish trial

results after the trial is completed.

The agreement is:

☐ The only disclosure restriction on the PI is that the sponsor can review results communications prior to public release and can embargo communications regarding trial results for a period that is **less than or equal to 60 days**. The sponsor cannot require changes to the communication and cannot extend the embargo.

☐ The only disclosure restriction on the PI is that the sponsor can review results communications prior to public release and can embargo communications regarding trial results for a period that is **more than 60 days but less than or equal to 180 days**. The sponsor cannot require changes to the communication and cannot extend the embargo.

Other disclosure agreement that restricts the right of the PI to discuss or publish trial results after the trial is completed.

Restriction Description:

☑ Principal investigator agrees not to publish/publicly present any

interim results without prior Sponsor written consent and agrees to provide 30 days written notice prior to submission to permit review of abstracts/manuscripts which report any results. Sponsor has the right to review/comment/edit to ensure confidentiality, information accuracy, and that the presentation is fairly balanced. If the parties disagree, the investigator agrees to meet with Sponsor to discuss/resolve any disagreement.

Results Point of Contact:

Name/Title: Senior Vice President, Global Clinical Development
Organization: Merck Sharp & Dohme Corp.
e-mail: ClinicalTrialsDisclosure@merck.com

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