Pegylated Liposomal Doxorubicin (Caelyx(R)) as Monotherapy in Elderly Patients With Locally Advanced and/or Metastatic Breast Cancer (Study P05059)

This study has been terminated.

Sponsor:
Merck Sharp & Dohme Corp.

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

ClinicalTrials.gov Identifier:
NCT00604968

First received: January 21, 2008
Last updated: April 29, 2015
Last verified: April 2015
History of Changes

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Purpose

The purpose of this study is to evaluate the safety and efficacy of pegylated liposomal doxorubicin (Caelyx) in elderly patients who are to receive first-line chemotherapy for metastatic or locally advanced breast cancer, not amenable to surgery.

Condition	Intervention	Phase
Breast Neoplasms	Drug: Caelyx (pegylated liposomal doxorubicin; SCH 200746)	Phase 4

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

Official Title: Caelyx(R) in Breast Cancer in the Elderly. Pegylated Liposomal Doxorubicin (Caelyx(R)) as Monotherapy in Elderly Patients With Locally Advanced and/or Metastatic Breast Cancer.

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:

- Time to Treatment Failure (Defined as Progression of Disease [According to the Response Evaluation Criteria in Solid Tumors (RECIST) or World Health Organization (WHO) Criteria] or Unacceptable Toxicity Leading to Discontinuation of Treatment or Death). [Time Frame: Time of treatment until progression of disease or unacceptable toxicity leading to discontinuation of treatment or death, assessed every 12th week until end of treatment (study planned to continue until all participants ended treatment).] [Designated as safety issue: No]

  Treatment failure was defined as progression of disease (according to the RECIST or WHO criteria) or unacceptable toxicity leading to discontinuation of treatment or death. Progressive Disease according to RECIST response criteria: >=20% increase in the sum of the Longest Diameter of target lesions or unequivocal progression of non-target lesions. Appearance of new lesions will also constitute progressive disease. Progressive Disease according to WHO response criteria: Increase in size of existing lesions or appearance of new lesions.

Secondary Outcome Measures:

- Number of Patients With Stable Disease (SD) as Best Response [Time Frame: Time of treatment until treatment discontinuation, assessed every 12th week until end of treatment (study planned to continue until all participants ended treatment).] [Designated as safety issue: No]

  Response was calculated according to RECIST criteria except for bone metastasis where WHO criteria was used. For patients with skeletal disease only, WHO criteria was used. For patients with measurable disease according to RECIST as well as bone metastasis, both RECIST & WHO were used.

  RECIST response criteria for SD required steady state of response of at least 9 weeks duration. There may be no appearance of new lesions.

  WHO response criteria for SD required no significant change for at least 8 weeks.

- Number of Patients With Partial Response (PR) as Best Response [Time Frame: Time of treatment until treatment discontinuation, assessed every 12th week until end of treatment (study planned to continue until all participants ended treatment).] [Designated as safety issue: No]

  Response was calculated according to RECIST criteria except for bone metastasis where WHO criteria was used. For patients with skeletal disease only, WHO criteria was used. For patients with measurable disease according to RECIST as well as bone metastasis, both RECIST & WHO were used.

  RECIST PR criteria required >=30% decrease in certain target lesions & no increase in size of non-target lesions or appearance of new lesions

  WHO PR criteria required partial decrease in size of lytic lesions, recalcification of lytic lesions, or decreased density of blastic lesions for >=4 wks

- Number of Patients With Progressive Disease (PD) as Best Response [Time Frame: Time of treatment until treatment discontinuation, assessed every 12th week until end of treatment (study planned to continue until all participants ended treatment).] [Designated as safety issue: No]

  Response was calculated according to RECIST criteria except for bone metastasis where WHO criteria was used. For patients with skeletal disease only, WHO criteria was used. For patients with measurable disease according to RECIST as well as bone metastasis, both RECIST & WHO were used.

  RECIST PD criteria required >=20% increase in certain target lesions OR progression of non-target lesions, or appearance of new lesions

  WHO PD criteria required increase in size of existing lesions or appearance of new lesions.

- Number of Patients Requiring Dose Reduction [Time Frame: Time of treatment until treatment discontinuation (study planned to continue until all participants ended treatment).] [Designated as safety issue: Yes]

  The protocol contains instructions to reduce the Caelyx dose according to specific schedules, in cases necessary due to reasons such as hematological toxicity, non-hematological toxicity, cardiotoxicity, or other toxic side-effects of treatment reducing quality of life etc.

- Time to Response [Time Frame: Time of treatment until response, assessed every 12th week until end of treatment (study planned to continue until all participants ended treatment).] [Designated as safety issue: No]

  Response can be partial (>=30% decrease in the sum of Longest Diameter of target lesions, determined by two observations not less than 4 weeks apart; no unequivocal increase in the size of non-target lesions or the appearance of new lesions may occur) or complete (disappearance of all clinical evidence of tumor determined by 2 observations not less than 4 weeks apart), whichever status is recorded first.

- Duration of Response [Time Frame: Time of treatment until treatment discontinuation, assessed every 12th week until end of treatment (study planned to continue until all participants ended treatment).] [Designated as safety issue: No]

  Duration of response is defined as the time span from the first evaluation that shows response until the first evaluation that shows progression. Where patients did not show progress, duration of response was measured from the first evaluation that showed response until they discontinued the study.

  Response can be partial or complete (as previously defined), whichever status is recorded first.

- Time to Progression [Time Frame: Time of treatment until progression, assessed every 12th week until end of treatment (study planned to continue until all participants ended treatment).] [Designated as safety issue: No]

  Progression is defined as the first evaluation that shows progression (either by RECIST or WHO criteria):

  Progressive Disease according to RECIST response criteria: >=20% increase in the sum of the Longest Diameter of target lesions or unequivocal progression of non-target lesions. Appearance of new lesions will also constitute progressive disease.

  Progressive Disease according to WHO response criteria: Increase in size of existing lesions or appearance of new lesions.

- Duration of Overall Survival [Time Frame: Time of treatment until death, up to the time that all participants ended treatment] [Designated as safety issue: No]

  Patients were followed with regards to survival even after they left the trial (ie after End of Treatment visit). Deaths that occurred after patient participation ended were collected all the way through to the overall end of the trial which took place on Oct 31, 2009. These deaths were used to calculate overall survival.

- Number of Days the Patients Were Hospitalized for Cancer-related Symptoms or Toxicity of Treatment [Time Frame: Time of treatment until treatment discontinuation (study planned to continue until all participants ended treatment).] [Designated as safety issue: No]

  The cumulative sum of hospitalization days during the study, per patient. Some patients had multiple hospitalizations.

Enrollment:	25
Study Start Date:	February 2007
Study Completion Date:	October 2009
Primary Completion Date:	October 2009 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Experimental: Caelyx	Drug: Caelyx (pegylated liposomal doxorubicin; SCH 200746) Caelyx will be administered intravenously at a dose of 40 mg/m^2 on day one every 4 weeks until progression, or unacceptable toxicity, or other reason to discontinue the study treatment. The drug is diluted in 250 ml glucose 5% (500 ml for doses >=90 mg).

Eligibility

Ages Eligible for Study:	65 Years and older
Genders Eligible for Study:	Female
Accepts Healthy Volunteers:	No

Criteria

Inclusion Criteria:

- Patients meeting the following criteria will be eligible for enrollment.
  - Female patients with histologic or cytologic diagnosis of breast cancer that is locally advanced or metastatic, and not amenable to surgery.
  - Age >= 65 years.
  - World Health Organization (WHO) Performance Status 0 - 2
  - Measurable disease in accordance with Response Evaluation Criteria in Solid Tumors (RECIST) criteria. Patients with bone metastasis can also be included but will be evaluated according to WHO criteria. Patients with non-measurable disease can also be included.
  - Left ventricular ejection fraction (LVEF) >= 50% verified by ultrasound cardiography (UCG); no clinical signs of heart disease.
  - Normal organ function, except due to disease involvement, however maximum deviation:
    - S-creatinine <= 1.5 x upper normal limit;
    - Bilirubin <= 2 x upper normal limit;
    - Alanine aminotransferase (ALAT) and/or aspartate aminotransferase (ASAT) <= 3 x upper normal limit. In case of liver metastases, ALAT and/or ASAT <= 5 x upper normal limit.
  - Adequate bone marrow function, ie:
    - Platelets >= 100 x 10^9/L;

        - Neutrophils >= 1.5 x 10^9/L;
        - White Blood Cell (WBC) >= 3.0 x 10^9/L;
        - Hemoglobin > 90 g/L.
    - Life expectancy >= 12 weeks.
    - Patients having received oral and written information and having provided written informed consent.

Exclusion Criteria:

- Patients will not be enrolled if any of the following conditions apply.
    - Previous chemotherapy for metastatic disease. (The patient may have received previous endocrine therapy or single-drug Herceptin. Intrapleural or intrapericardial Novantrone is allowed.)
    - Recurrence <= 12 months after adjuvant anthracycline-containing treatment and/or prior doxorubicin > 300 mg/m^2 or epirubicin > 540 mg/m^2.
    - Myocardial infarction within 6 months of planned inclusion.
    - Symptomatic brain metastases.
    - Human Epidermal growth factor Receptor 2 (HER-2) positivity eligible for treatment with trastuzumab, or estrogen receptor (ER) positivity eligible for hormonal therapy.
    - Allergy to anthracyclines.
    - Uncontrolled infection.
    - Other not radically treated malignancy.
    - Other disease or condition contraindicating treatment or not allowing 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

Publications:

Green H, Stål O, Bachmeier K, Bäcklund LM, Carlsson L, Hansen J, Lagerlund M, Norberg B, Franzén Å, Åleskog A, Malmström A. Pegylated liposomal doxorubicin as first-line monotherapy in elderly women with locally advanced or metastatic breast cancer: novel treatment predictive factors identified. Cancer Lett. 2011 Dec 27;313(2):145-53. doi: 10.1016/j.canlet.2011.07.017. Epub 2011 Aug 31.

Responsible Party:	Merck Sharp & Dohme Corp.
ClinicalTrials.gov Identifier:	NCT00604968 History of Changes
Other Study ID Numbers:	P05059
Study First Received:	January 21, 2008
Results First Received:	January 27, 2011
Last Updated:	April 29, 2015
Health Authority:	Sweden: Medical Products Agency

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: January 27, 2011

Study Type:	Interventional
Study Design:	Allocation: Non-Randomized; Endpoint Classification: Safety/Efficacy Study; Intervention Model: Single Group Assignment; Masking: Open Label; Primary Purpose: Treatment
Condition:	Breast Neoplasms
Intervention:	Drug: Caelyx (pegylated liposomal doxorubicin; SCH 200746)

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
28 patients were screened and 25 were enrolled. All 25 patients enrolled received >=1 cycle of treatment with Caelyx. Per protocol, treatment was to continue until progression, unacceptable toxicity, or other reason for discontinuation of treatment - all subjects eventually discontinued treatment but were considered to have completed the study.

Reporting Groups

	Description
Caelyx	Caelyx was administered intravenously at a dose of 40 mg/m^2 on day one every 4 weeks until progression, or unacceptable toxicity, or other reason to discontinue the study treatment. The drug was diluted in 250 ml glucose 5% (500 ml for doses >=90 mg).

Participant Flow: Overall Study

	Caelyx
STARTED	**25**
COMPLETED	**25** [1]
NOT COMPLETED	**0**

[1] Due to the nature of study, all subjects receiving drug were considered to have completed.

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	Caelyx was administered intravenously at a dose of 40 mg/m^2 on day one every 4 weeks until progression, or unacceptable toxicity, or other reason to discontinue the study treatment. The drug was diluted in 250 ml glucose 5% (500 ml for doses >=90 mg).

Baseline Measures

	Caelyx
Number of Participants [units: participants]	**25**
Age [units: participants]	
<=18 years	**0**
Between 18 and 65 years	**0**
>=65 years	**25**
Age [units: years] Mean (Standard Deviation)	**72.3 (5.0)**
Gender [units: participants]	
Female	**25**
Male	**0**

Outcome Measures

Hide All Outcome Measures

1. Primary: Time to Treatment Failure (Defined as Progression of Disease [According to the Response Evaluation Criteria in Solid Tumors (RECIST) or World Health Organization (WHO) Criteria] or Unacceptable Toxicity Leading to Discontinuation of Treatment or Death). [Time Frame: Time of treatment until progression of disease or unacceptable toxicity leading to discontinuation of treatment or death, assessed every 12th week until end of treatment (study planned to continue until all participants ended treatment).]

Measure Type	Primary
Measure Title	Time to Treatment Failure (Defined as Progression of Disease [According to the Response Evaluation Criteria in Solid Tumors (RECIST) or World Health Organization (WHO) Criteria] or Unacceptable Toxicity Leading to Discontinuation of Treatment or Death).
Measure Description	Treatment failure was defined as progression of disease (according to the RECIST or WHO criteria) or unacceptable toxicity leading to discontinuation of treatment or death. Progressive Disease according to RECIST response criteria: >=20% increase in the sum of the Longest Diameter of target lesions or unequivocal progression of non-target lesions. Appearance of new lesions will also constitute progressive disease. Progressive Disease according to WHO response criteria: Increase in size of existing lesions or appearance of new lesions.
Time Frame	Time of treatment until progression of disease or unacceptable toxicity leading to discontinuation of treatment or death, assessed every 12th week until end of treatment (study planned to continue until all participants ended treatment).
Safety Issue	No

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	Caelyx was administered intravenously at a dose of 40 mg/m^2 on day one every 4 weeks until progression, or unacceptable toxicity, or other reason to discontinue the study treatment. The drug was diluted in 250 ml glucose 5% (500 ml for doses >=90 mg).

Measured Values

	Caelyx
Number of Participants Analyzed [units: participants]	**25**
Time to Treatment Failure (Defined as Progression of Disease [According to the Response Evaluation Criteria in Solid Tumors (RECIST) or World Health Organization (WHO) Criteria] or Unacceptable Toxicity Leading to Discontinuation of Treatment or Death). [units: Months] Median (95% Confidence Interval)	**5.52 (3.67 to 8.52)**

No statistical analysis provided for Time to Treatment Failure (Defined as Progression of Disease [According to the Response Evaluation Criteria in Solid Tumors (RECIST) or World Health Organization (WHO) Criteria] or Unacceptable Toxicity Leading to Discontinuation of Treatment or Death).

2. Secondary: Number of Patients With Stable Disease (SD) as Best Response [Time Frame: Time of treatment until treatment discontinuation, assessed every 12th week until end of treatment (study planned to continue until all participants ended treatment).]

Measure Type	Secondary

Measure Title	Number of Patients With Stable Disease (SD) as Best Response
Measure Description	Response was calculated according to RECIST criteria except for bone metastasis where WHO criteria was used. For patients with skeletal disease only, WHO criteria was used. For patients with measurable disease according to RECIST as well as bone metastasis, both RECIST & WHO were used. RECIST response criteria for SD required steady state of response of at least 9 weeks duration. There may be no appearance of new lesions. WHO response criteria for SD required no significant change for at least 8 weeks.
Time Frame	Time of treatment until treatment discontinuation, assessed every 12th week until end of treatment (study planned to continue until all participants ended treatment).
Safety Issue	No

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.
10 patients were followed by RECIST, 4 patients were followed by WHO Response criteria, and 8 patients by both RECIST and WHO Response criteria (n=22). 3 patients had non-measurable disease and could not be included in the analysis.

Reporting Groups

	Description
Caelyx	Caelyx was administered intravenously at a dose of 40 mg/m^2 on day one every 4 weeks until progression, or unacceptable toxicity, or other reason to discontinue the study treatment. The drug was diluted in 250 ml glucose 5% (500 ml for doses >=90 mg).

Measured Values

	Caelyx
Number of Participants Analyzed [units: participants]	**22**
Number of Patients With Stable Disease (SD) as Best Response [units: participants]	
Patients followed by RECIST only (n=10)	**5**
Patients followed by WHO only (n=4)	**4**
Patients followed by RECIST & WHO (n=8)	**4**

No statistical analysis provided for Number of Patients With Stable Disease (SD) as Best Response

3. Secondary: Number of Patients With Partial Response (PR) as Best Response [Time Frame: Time of treatment until treatment discontinuation, assessed every 12th week until end of treatment (study planned to continue until all participants ended treatment).]

Measure Type	Secondary
Measure Title	Number of Patients With Partial Response (PR) as Best Response
Measure Description	Response was calculated according to RECIST criteria except for bone metastasis where WHO criteria was used. For patients with skeletal disease only, WHO criteria was used. For patients with measurable disease according to RECIST as well as bone metastasis, both RECIST & WHO were used. RECIST PR criteria required >=30% decrease in certain target lesions & no increase in size of non-target lesions or appearance of new lesions

	WHO PR criteria required partial decrease in size of lytic lesions, recalcification of lytic lesions, or decreased density of blastic lesions for >=4 wks
Time Frame	Time of treatment until treatment discontinuation, assessed every 12th week until end of treatment (study planned to continue until all participants ended treatment).
Safety Issue	No

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.
10 patients were followed by RECIST, 4 patients were followed by WHO Response criteria, and 8 patients by both RECIST and WHO Response criteria (n=22). 3 patients had non-measurable disease and could not be included in the analysis.

Reporting Groups

	Description
Caelyx	Caelyx was administered intravenously at a dose of 40 mg/m^2 on day one every 4 weeks until progression, or unacceptable toxicity, or other reason to discontinue the study treatment. The drug was diluted in 250 ml glucose 5% (500 ml for doses >=90 mg).

Measured Values

	Caelyx
Number of Participants Analyzed [units: participants]	**22**
Number of Patients With Partial Response (PR) as Best Response [units: participants]	
Patients followed by RECIST only (n=10)	**1**
Patients followed by WHO only (n=4)	**0**
Patients followed by RECIST & WHO (n=8)	**2**

No statistical analysis provided for Number of Patients With Partial Response (PR) as Best Response

4. Secondary: Number of Patients With Progressive Disease (PD) as Best Response [Time Frame: Time of treatment until treatment discontinuation, assessed every 12th week until end of treatment (study planned to continue until all participants ended treatment).]

Measure Type	Secondary
Measure Title	Number of Patients With Progressive Disease (PD) as Best Response
Measure Description	Response was calculated according to RECIST criteria except for bone metastasis where WHO criteria was used. For patients with skeletal disease only, WHO criteria was used. For patients with measurable disease according to RECIST as well as bone metastasis, both RECIST & WHO were used. RECIST PD criteria required >=20% increase in certain target lesions OR progression of non-target lesions, or appearance of new lesions WHO PD criteria required increase in size of existing lesions or appearance of new lesions.
Time Frame	Time of treatment until treatment discontinuation, assessed every 12th week until end of treatment (study planned to continue until all participants ended treatment).
Safety Issue	No

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.
10 patients were followed by RECIST, 4 patients were followed by WHO Response criteria, and 8 patients by both RECIST and WHO Response criteria (n=22). 3 patients had non-measurable disease and could not be included in the analysis.

Reporting Groups

	Description
Caelyx	Caelyx was administered intravenously at a dose of 40 mg/m^2 on day one every 4 weeks until progression, or unacceptable toxicity, or other reason to discontinue the study treatment. The drug was diluted in 250 ml glucose 5% (500 ml for doses >=90 mg).

Measured Values

	Caelyx
Number of Participants Analyzed [units: participants]	**22**
Number of Patients With Progressive Disease (PD) as Best Response [units: participants]	
Patients followed by RECIST only (n=10)	**4**
Patients followed by WHO only (n=4)	**0**
Patients followed by RECIST & WHO (n=8)	**2**

No statistical analysis provided for Number of Patients With Progressive Disease (PD) as Best Response

5. Secondary: Number of Patients Requiring Dose Reduction [Time Frame: Time of treatment until treatment discontinuation (study planned to continue until all participants ended treatment).]

Measure Type	Secondary
Measure Title	Number of Patients Requiring Dose Reduction
Measure Description	The protocol contains instructions to reduce the Caelyx dose according to specific schedules, in cases necessary due to reasons such as hematological toxicity, non-hematological toxicity, cardiotoxicity, or other toxic side-effects of treatment reducing quality of life etc.
Time Frame	Time of treatment until treatment discontinuation (study planned to continue until all participants ended treatment).
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	Caelyx was administered intravenously at a dose of 40 mg/m^2 on day one every 4 weeks until progression, or unacceptable toxicity, or other reason to discontinue the study treatment. The drug was diluted in 250 ml glucose 5% (500 ml for doses >=90 mg).

Measured Values

	Caelyx
Number of Participants Analyzed [units: participants]	**25**
Number of Patients Requiring Dose Reduction [units: participants]	
Due to weight change	**6**
Due to toxicity/adverse event	**4**

No statistical analysis provided for Number of Patients Requiring Dose Reduction

6. Secondary: Time to Response [Time Frame: Time of treatment until response, assessed every 12th week until end of treatment (study planned to continue until all participants ended treatment).]

Measure Type	Secondary
Measure Title	Time to Response
Measure Description	Response can be partial (>=30% decrease in the sum of Longest Diameter of target lesions, determined by two observations not less than 4 weeks apart; no unequivocal increase in the size of non-target lesions or the appearance of new lesions may occur) or complete (disappearance of all clinical evidence of tumor determined by 2 observations not less than 4 weeks apart), whichever status is recorded first.
Time Frame	Time of treatment until response, assessed every 12th week until end of treatment (study planned to continue until all participants ended treatment).
Safety Issue	No

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.
Only 3 patients had measureable time to response

Reporting Groups

	Description
Caelyx	Caelyx was administered intravenously at a dose of 40 mg/m^2 on day one every 4 weeks until progression, or unacceptable toxicity, or other reason to discontinue the study treatment. The drug was diluted in 250 ml glucose 5% (500 ml for doses >=90 mg).

Measured Values

	Caelyx
Number of Participants Analyzed [units: participants]	**3**
Time to Response [units: Weeks] Median (Full Range)	
	12.2

Patient 1	**(12.2 to 12.2)**
Patient 2	**11.4 (11.4 to 11.4)**
Patient 3	**12.0 (12.0 to 12.0)**

No statistical analysis provided for Time to Response

7. Secondary: Duration of Response [Time Frame: Time of treatment until treatment discontinuation, assessed every 12th week until end of treatment (study planned to continue until all participants ended treatment).]

Measure Type	Secondary
Measure Title	Duration of Response
Measure Description	Duration of response is defined as the time span from the first evaluation that shows response until the first evaluation that shows progression. Where patients did not show progress, duration of response was measured from the first evaluation that showed response until they discontinued the study. Response can be partial or complete (as previously defined), whichever status is recorded first.
Time Frame	Time of treatment until treatment discontinuation, assessed every 12th week until end of treatment (study planned to continue until all participants ended treatment).
Safety Issue	No

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.
Three patients showed Partial Response according to RECIST criteria.

Reporting Groups

	Description
Caelyx	Caelyx was administered intravenously at a dose of 40 mg/m^2 on day one every 4 weeks until progression, or unacceptable toxicity, or other reason to discontinue the study treatment. The drug was diluted in 250 ml glucose 5% (500 ml for doses >=90 mg).

Measured Values

	Caelyx
Number of Participants Analyzed [units: participants]	**3**
Duration of Response [units: weeks] Median (Full Range)	
Patient 1	**11.8 (11.8 to 11.8)**
Patient 2	**48.6 (48.6 to 48.6)**

Patient 3	**17.8 (17.8 to 17.8)**

No statistical analysis provided for Duration of Response

8. Secondary: Time to Progression [Time Frame: Time of treatment until progression, assessed every 12th week until end of treatment (study planned to continue until all participants ended treatment).]

Measure Type	Secondary
Measure Title	Time to Progression
Measure Description	Progression is defined as the first evaluation that shows progression (either by RECIST or WHO criteria): Progressive Disease according to RECIST response criteria: >=20% increase in the sum of the Longest Diameter of target lesions or unequivocal progression of non-target lesions. Appearance of new lesions will also constitute progressive disease. Progressive Disease according to WHO response criteria: Increase in size of existing lesions or appearance of new lesions.
Time Frame	Time of treatment until progression, assessed every 12th week until end of treatment (study planned to continue until all participants ended treatment).
Safety Issue	No

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.
Of the 25 patients in the study 3 patients had non-measurable disease and could not be included in the progression analysis.

Reporting Groups

	Description
Caelyx	Caelyx was administered intravenously at a dose of 40 mg/m^2 on day one every 4 weeks until progression, or unacceptable toxicity, or other reason to discontinue the study treatment. The drug was diluted in 250 ml glucose 5% (500 ml for doses >=90 mg).

Measured Values

	Caelyx
Number of Participants Analyzed [units: participants]	**22**
Time to Progression [units: months] Median (95% Confidence Interval)	**5.69 (3.74 to 13.8)**

No statistical analysis provided for Time to Progression

9. Secondary: Duration of Overall Survival [Time Frame: Time of treatment until death, up to the time that all participants ended treatment]

Measure Type	Secondary
Measure Title	Duration of Overall Survival

Measure Description	Patients were followed with regards to survival even after they left the trial (ie after End of Treatment visit). Deaths that occurred after patient participation ended were collected all the way through to the overall end of the trial which took place on Oct 31, 2009. These deaths were used to calculate overall survival.
Time Frame	Time of treatment until death, up to the time that all participants ended treatment
Safety Issue	No

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	Caelyx was administered intravenously at a dose of 40 mg/m^2 on day one every 4 weeks until progression, or unacceptable toxicity, or other reason to discontinue the study treatment. The drug was diluted in 250 ml glucose 5% (500 ml for doses >=90 mg).

Measured Values

	Caelyx
Number of Participants Analyzed [units: participants]	**25**
Duration of Overall Survival [units: months] Median (95% Confidence Interval)	**20.6 (6.58 to 25.6)**

No statistical analysis provided for Duration of Overall Survival

10. Secondary: Number of Days the Patients Were Hospitalized for Cancer-related Symptoms or Toxicity of Treatment [Time Frame: Time of treatment until treatment discontinuation (study planned to continue until all participants ended treatment).]

Measure Type	Secondary
Measure Title	Number of Days the Patients Were Hospitalized for Cancer-related Symptoms or Toxicity of Treatment
Measure Description	The cumulative sum of hospitalization days during the study, per patient. Some patients had multiple hospitalizations.
Time Frame	Time of treatment until treatment discontinuation (study planned to continue until all participants ended treatment).
Safety Issue	No

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.
Of the 25 total patients, 12 were hospitalized during the study.

Reporting Groups

	Description
Caelyx	Caelyx was administered intravenously at a dose of 40 mg/m^2 on day one every 4 weeks until progression, or unacceptable toxicity,

	or other reason to discontinue the study treatment. The drug was diluted in 250 ml glucose 5% (500 ml for doses >=90 mg).

Measured Values

	Caelyx
Number of Participants Analyzed [units: participants]	**12**
Number of Days the Patients Were Hospitalized for Cancer-related Symptoms or Toxicity of Treatment [units: days]	
Patient 1	**1**
Patient 2	**1**
Patient 3	**6**
Patient 4	**4**
Patient 5	**5**
Patient 6	**71**
Patient 7	**16**
Patient 8	**1**
Patient 9	**1**
Patient 10	**3**
Patient 11	**33**
Patient 12	**20**

No statistical analysis provided for Number of Days the Patients Were Hospitalized for Cancer-related Symptoms or Toxicity of Treatment

Serious Adverse Events

Hide Serious Adverse Events

Time Frame	Time of treatment until treatment discontinuation (study planned to continue until all participants ended treatment).
Additional Description	No text entered.

Reporting Groups

	Description
Caelyx	Caelyx was administered intravenously at a dose of 40 mg/m^2 on day one every 4 weeks until progression, or unacceptable toxicity, or other reason to discontinue the study treatment. The drug was diluted in 250 ml glucose 5% (500 ml for doses >=90 mg).

Serious Adverse Events

	Caelyx
Total, serious adverse events	
# participants affected / at risk	**9/25 (36.00%)**

Cardiac disorders	
MYOCARDIAL INFARCTION † 1	
# participants affected / at risk	**1/25 (4.00%)**
# events	**1**
Gastrointestinal disorders	
ABDOMINAL PAIN † 1	
# participants affected / at risk	**1/25 (4.00%)**
# events	**1**
DYSPEPSIA † 1	
# participants affected / at risk	**1/25 (4.00%)**
# events	**1**
VOMITING † 1	
# participants affected / at risk	**1/25 (4.00%)**
# events	**1**
General disorders	
PYREXIA † 1	
# participants affected / at risk	**2/25 (8.00%)**
# events	**2**
Infections and infestations	
CENTRAL LINE INFECTION † 1	
# participants affected / at risk	**1/25 (4.00%)**
# events	**1**
CLOSTRIDIAL INFECTION † 1	
# participants affected / at risk	**1/25 (4.00%)**
# events	**1**
CYSTITIS † 1	
# participants affected / at risk	**1/25 (4.00%)**
# events	**1**
PNEUMONIA † 1	
# participants affected / at risk	**1/25 (4.00%)**
# events	**1**
URINARY TRACT INFECTION † 1	
# participants affected / at risk	**2/25 (8.00%)**
# events	**2**
Metabolism and nutrition disorders	
HYPOGLYCAEMIA † 1	
# participants affected / at risk	**1/25 (4.00%)**
# events	**1**
Respiratory, thoracic and mediastinal disorders	
PULMONARY EMBOLISM † 1	
# participants affected / at risk	**1/25 (4.00%)**
# events	**1**

† Events were collected by systematic assessment

1 Term from vocabulary, MedDRA 12.1

Other Adverse Events

Hide Other Adverse Events

Time Frame	Time of treatment until treatment discontinuation (study planned to continue until all participants ended treatment).
Additional Description	No text entered.

Frequency Threshold

Threshold above which other adverse events are reported	5%

Reporting Groups

	Description
Caelyx	Caelyx was administered intravenously at a dose of 40 mg/m^2 on day one every 4 weeks until progression, or unacceptable toxicity, or other reason to discontinue the study treatment. The drug was diluted in 250 ml glucose 5% (500 ml for doses >=90 mg).

Other Adverse Events

	Caelyx
Total, other (not including serious) adverse events	
# participants affected / at risk	**25/25 (100.00%)**
Blood and lymphatic system disorders	
ANAEMIA † 1	
# participants affected / at risk	**4/25 (16.00%)**
# events	**5**
NEUTROPENIA † 1	
# participants affected / at risk	**4/25 (16.00%)**
# events	**7**
Eye disorders	
DRY EYE † 1	
# participants affected / at risk	**2/25 (8.00%)**
# events	**2**
LACRIMATION INCREASED † 1	
# participants affected / at risk	**2/25 (8.00%)**
# events	**2**
Gastrointestinal disorders	
ABDOMINAL PAIN † 1	
# participants affected / at risk	**3/25 (12.00%)**
# events	**6**
CONSTIPATION † 1	
# participants affected / at risk	**6/25 (24.00%)**
# events	**7**
DIARRHOEA † 1	

# participants affected / at risk	6/25 (24.00%)
# events	9
FLATULENCE † 1	
# participants affected / at risk	2/25 (8.00%)
# events	2
GASTRITIS † 1	
# participants affected / at risk	2/25 (8.00%)
# events	2
NAUSEA † 1	
# participants affected / at risk	16/25 (64.00%)
# events	31
STOMATITIS † 1	
# participants affected / at risk	6/25 (24.00%)
# events	15
VOMITING † 1	
# participants affected / at risk	7/25 (28.00%)
# events	12
General disorders	
CHEST PAIN † 1	
# participants affected / at risk	3/25 (12.00%)
# events	4
FATIGUE † 1	
# participants affected / at risk	17/25 (68.00%)
# events	21
OEDEMA PERIPHERAL † 1	
# participants affected / at risk	4/25 (16.00%)
# events	5
PYREXIA † 1	
# participants affected / at risk	6/25 (24.00%)
# events	11
Investigations	
BLOOD ALKALINE PHOSPHATASE INCREASED † 1	
# participants affected / at risk	2/25 (8.00%)
# events	2
BLOOD LACTATE DEHYDROGENASE INCREASED † 1	
# participants affected / at risk	3/25 (12.00%)
# events	3
C-REACTIVE PROTEIN INCREASED † 1	
# participants affected / at risk	2/25 (8.00%)
# events	4
HAEMOGLOBIN DECREASED † 1	
# participants affected / at risk	2/25 (8.00%)
# events	2
WEIGHT DECREASED † 1	
# participants affected / at risk	3/25 (12.00%)

# events	3
Metabolism and nutrition disorders	
DECREASED APPETITE † 1	
# participants affected / at risk	9/25 (36.00%)
# events	9
Musculoskeletal and connective tissue disorders	
ARTHRALGIA † 1	
# participants affected / at risk	2/25 (8.00%)
# events	2
BACK PAIN † 1	
# participants affected / at risk	6/25 (24.00%)
# events	9
MUSCULOSKELETAL PAIN † 1	
# participants affected / at risk	4/25 (16.00%)
# events	4
Nervous system disorders	
DIZZINESS † 1	
# participants affected / at risk	2/25 (8.00%)
# events	2
HEADACHE † 1	
# participants affected / at risk	4/25 (16.00%)
# events	4
Respiratory, thoracic and mediastinal disorders	
COUGH † 1	
# participants affected / at risk	3/25 (12.00%)
# events	4
Skin and subcutaneous tissue disorders	
ALOPECIA † 1	
# participants affected / at risk	6/25 (24.00%)
# events	6
BLISTER † 1	
# participants affected / at risk	4/25 (16.00%)
# events	4
DRY SKIN † 1	
# participants affected / at risk	2/25 (8.00%)
# events	2
ERYTHEMA † 1	
# participants affected / at risk	2/25 (8.00%)
# events	3
PALMAR-PLANTAR ERYTHRODYSAESTHESIA SYNDROME † 1	
# participants affected / at risk	13/25 (52.00%)
# events	18
RASH † 1	

# participants affected / at risk	**4/25 (16.00%)**
# events	**8**

† Events were collected by systematic assessment
1 Term from vocabulary, MedDRA 12.1

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:** If an investigator wishes to publish data from the study, a copy must be provided to the sponsor for review at least 60 days before submission for publication. If requested by the sponsor in writing, the investigator will withhold such publication for up to an additional 60 days. If issues arise regarding scientific integrity or regulatory compliance, the sponsor will review these issues with the investigator. The sponsor will not change scientific content or suppress information.

Results Point of Contact:

Name/Title: Senior Vice President, Global Clinical Development
Organization: Merck Sharp & Dohme Corp.
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Publications of Results:

Green H, Stål O, Bachmeier K, Bäcklund LM, Carlsson L, Hansen J, Lagerlund M, Norberg B, Franzén Å, Åleskog A, Malmström A. Pegylated liposomal doxorubicin as first-line monotherapy in elderly women with locally advanced or metastatic breast cancer: novel treatment predictive factors identified. Cancer Lett. 2011 Dec 27;313(2):145-53. doi: 10.1016/j.canlet.2011.07.017. Epub 2011 Aug 31.

Responsible Party: Merck Sharp & Dohme Corp.
ClinicalTrials.gov Identifier: NCT00604968 History of Changes
Other Study ID Numbers: P05059
Study First Received: January 21, 2008

Results First Received:	January 27, 2011
Last Updated:	April 29, 2015
Health Authority:	Sweden: Medical Products Agency

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For Patients and Families | **For Researchers** | **For Study Record Managers**

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