E7389 Versus Treatment of Physician's Choice in Patients With Locally Recurrent or Metastatic Breast Cancer

This study has been completed.

Sponsor:
Eisai Inc.

Collaborator:
Eisai Limited

Information provided by (Responsible Party):
Eisai Inc.

ClinicalTrials.gov Identifier:
NCT00388726

First received: October 13, 2006
Last updated: July 25, 2014
Last verified: July 2014
History of Changes

Results First Received: December 22, 2011

Study Type:	Interventional
Study Design:	Allocation: Randomized; Endpoint Classification: Safety/Efficacy Study; Intervention Model: Parallel Assignment; Masking: Open Label; Primary Purpose: Treatment
Condition:	Breast Cancer
Interventions:	Drug: E7389 Drug: Physician's Choice

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
This study was recruited at 135 centers in 19 countries during the period of Nov 2006 to May 2009.

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
Eribulin Mesylate 1.4 mg/kg^2	Eribulin Mesylate 1.4 mg/kg^2 on Days 1 and 8

Treatment of Physician's Choice	Treatment of Physician's Choice

Participant Flow: Overall Study

	Eribulin Mesylate 1.4 mg/kg^2	Treatment of Physician's Choice
STARTED	508	254
COMPLETED	24	10
NOT COMPLETED	484	244
Adverse Event	50	24
Progressive Disease	336	153
Clinical Progression	61	36
Withdrawal by Subject	10	7
Administrative	6	9
Physician Decision	18	13
Death	3	2

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
Eribulin Mesylate 1.4 mg/kg^2	Eribulin Mesylate 1.4 mg/kg^2 on Days 1 and 8
Treatment of Physician's Choice	Treatment of Physician's Choice
Total	Total of all reporting groups

Baseline Measures

	Eribulin Mesylate 1.4 mg/kg^2	Treatment of Physician's Choice	Total
Overall Participants Analyzed [Units: Participants]	508	254	762
Age [Units: Years] Mean (Standard Deviation)	54.8 (10.34)	55.9 (10.43)	55.2 (10.37)
Gender [Units: Participants]			
Female	508	254	762
Male	0	0	0
Race (NIH/OMB) [Units: Participants]			
American Indian or Alaska Native	0	0	0
Asian	3	2	5

Native Hawaiian or Other Pacific Islander	**0**	**0**	**0**
Black or African American	**20**	**14**	**34**
White	**470**	**233**	**703**
More than one race	**0**	**0**	**0**
Unknown or Not Reported	**15**	**5**	**20**

Outcome Measures

Hide All Outcome Measures

1. Primary: Overall Survival [Time Frame: From date of randomization until death from any cause]

Measure Type	Primary
Measure Title	Overall Survival
Measure Description	Defined as the time from the date of randomization until the date of death from any cause.
Time Frame	From date of randomization until death from any cause
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.
Intent to Treat

Reporting Groups

	Description
Eribulin Mesylate 1.4 mg/kg^2	Eribulin Mesylate 1.4 mg/kg^2 on Days 1 and 8
Treatment of Physician's Choice	Treatment of Physician's Choice

Measured Values

	Eribulin Mesylate 1.4 mg/kg^2	**Treatment of Physician's Choice**
Participants Analyzed [Units: Participants]	**508**	**254**
Overall Survival [Units: Days] Median (Full Range)	**399 (360 to 434)**	**324 (282 to 380)**

No statistical analysis provided for Overall Survival

2. Secondary: Progression-Free Survival. [Time Frame: Until disease progression or death.]

Measure Type	Secondary
Measure Title	Progression-Free Survival.
Measure Description	Measured using Response Evaluation Criteria in Solid Tumors (RECIST) and defined as the time from the date of randomization until progressive disease or death from any cause in the absence of of progressive disease.
Time Frame	Until disease progression or death.

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.
Intent to Treat

Reporting Groups

	Description
Eribulin Mesylate 1.4 mg/kg^2	Eribulin Mesylate 1.4 mg/kg^2 on Days 1 and 8
Treatment of Physician's Choice	Treatment of Physician's Choice

Measured Values

	Eribulin Mesylate 1.4 mg/kg^2	**Treatment of Physician's Choice**
Participants Analyzed [Units: Participants]	**508**	**254**
Progression-Free Survival. [Units: Days] Median (Full Range)	**113 (101 to 118)**	**68 (63 to 103)**

No statistical analysis provided for Progression-Free Survival.

3. Secondary: Best Overall Response [Time Frame: Until Day 30 or every 3 months during Follow-up period for patients who complete study without PD.]

Measure Type	Secondary
Measure Title	Best Overall Response
Measure Description	Measured by RECIST criteria and defined as the best response from the start of treatment until disease progression or recurrence. Lesions measured by computed tomography (CT) scan and magnetic resonance imaging (MRI). Objective response rate: complete response (CR-disappearance of all lesions)+ partial response (PR-30% decrease in lesion diameter), Progressive Disease (PD-20% increase in lesion diameter), stable disease (SD-neither shrinkage nor increase of lesions).
Time Frame	Until Day 30 or every 3 months during Follow-up period for patients who complete study without PD.
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.
Response Evaluable Population

Reporting Groups

	Description
Eribulin Mesylate 1.4 mg/kg^2	Eribulin Mesylate 1.4 mg/kg^2 on Days 1 and 8
Treatment of Physician's Choice	Treatment of Physician's Choice

Measured Values

	Eribulin Mesylate 1.4 mg/kg^2	Treatment of Physician's Choice
Participants Analyzed [Units: Participants]	**468**	**214**
Best Overall Response [Units: Percent of Participants]		
Objective Response Rate (CR+PR)	**12.2**	**4.7**
Complete Response	**0.6**	**0**
Partial Response	**11.5**	**4.7**
Stable Disease	**44.4**	**44.9**
Progressive Disease	**40.6**	**49.1**
Not Evaluable	**2.6**	**1.4**
Unknown	**0.2**	**0**

No statistical analysis provided for Best Overall Response

4. Secondary: Duration of Response. [Time Frame: From first documented CR or PR until disease progression or death.]

Measure Type	Secondary
Measure Title	Duration of Response.
Measure Description	As measured by RECIST criteria and defined as the time from the first documented CR or PR until disease progression or death from any cause.
Time Frame	From first documented CR or PR until disease progression or death.
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.
Response Evaluable Population

Reporting Groups

	Description
Eribulin Mesylate 1.4 mg/kg^2	Eribulin Mesylate 1.4 mg/kg^2 on Days 1 and 8
Treatment of Physician's Choice	Treatment of Physician's Choice

Measured Values

	Eribulin Mesylate 1.4 mg/kg^2	Treatment of Physician's Choice
Participants Analyzed [Units: Participants]	**468**	**214**
Duration of Response. [Units: Days] Median (Full Range)	**128 (116 to 152)**	**205 (205 to 212)**

No statistical analysis provided for Duration of Response.

5. Secondary: Safety Parameters: Adverse Events (AEs), Laboratory Parameters, Concomitant Medication, Electrocardiograms (ECGs), and Study Drug Exposure. [Time Frame: AEs and conmeds – until study termination; lab tests – Day 1 and weekly until study termination; ECGs - Day 1 and at study termination.]

Results not yet reported. **Anticipated Reporting Date:** No text entered. **Safety Issue:** Yes

Serious Adverse Events

Hide Serious Adverse Events

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

Reporting Groups

	Description
Eribulin Mesylate 1.4 mg/kg^2	Eribulin Mesylate 1.4 mg/kg^2 on Days 1 and 8
Treatment of Physician's Choice	Treatment of Physician's Choice

Serious Adverse Events

	Eribulin Mesylate 1.4 mg/kg^2	Treatment of Physician's Choice
Total, serious adverse events		
# participants affected / at risk	**126/503 (25.05%)**	**64/247 (25.91%)**
Blood and lymphatic system disorders		
Febrile Neutropenia		
# participants affected / at risk	**21/503 (4.17%)**	**3/247 (1.21%)**
Neutropenia		
# participants affected / at risk	**9/503 (1.79%)**	**0/247 (0.00%)**
Anemia		
# participants affected / at risk	**1/503 (0.20%)**	**2/247 (0.81%)**
Pancytopenia		
# participants affected / at risk	**1/503 (0.20%)**	**0/247 (0.00%)**
Cardiac disorders		
Pericardial Effusion		
# participants affected / at risk	**2/503 (0.40%)**	**0/247 (0.00%)**
Cardiac Failure		
# participants affected / at risk	**1/503 (0.20%)**	**0/247 (0.00%)**
Extrasystoles		
# participants affected / at risk	**0/503 (0.00%)**	**1/247 (0.40%)**
Gastrointestinal disorders		
Nausea		
# participants affected / at risk	**7/503 (1.39%)**	**2/247 (0.81%)**
Vomiting		
# participants affected / at risk	**5/503 (0.99%)**	**1/247 (0.40%)**
Diarrhea		
# participants affected / at risk	**1/503 (0.20%)**	**4/247 (1.62%)**
Abdominal Pain		
# participants affected / at risk	**1/503 (0.20%)**	**3/247 (1.21%)**

Ascites		
# participants affected / at risk	1/503 (0.20%)	2/247 (0.81%)
Constipation		
# participants affected / at risk	1/503 (0.20%)	1/247 (0.40%)
Stomatitis		
# participants affected / at risk	2/503 (0.40%)	0/247 (0.00%)
Abdominal Distention		
# participants affected / at risk	0/503 (0.00%)	1/247 (0.40%)
Abdominal Pain Upper		
# participants affected / at risk	0/503 (0.00%)	1/247 (0.40%)
Colonic Obstruction		
# participants affected / at risk	1/503 (0.20%)	0/247 (0.00%)
Intestinal Obstruction		
# participants affected / at risk	1/503 (0.20%)	0/247 (0.00%)
Melena		
# participants affected / at risk	0/503 (0.00%)	1/247 (0.40%)
Mouth Hemorrhage		
# participants affected / at risk	1/503 (0.20%)	0/247 (0.00%)
Esophageal Stenosis		
# participants affected / at risk	1/503 (0.20%)	0/247 (0.00%)
Esophageal Varices Hemorrhage		
# participants affected / at risk	1/503 (0.20%)	0/247 (0.00%)
Pancreatitis		
# participants affected / at risk	1/503 (0.20%)	0/247 (0.00%)
Rectal Hemorrhage		
# participants affected / at risk	1/503 (0.20%)	0/247 (0.00%)
General disorders		
Asthenia/Fatigue		
# participants affected / at risk	7/503 (1.39%)	6/247 (2.43%)
Asthenia		
# participants affected / at risk	6/503 (1.19%)	5/247 (2.02%)
Pyrexia		
# participants affected / at risk	7/503 (1.39%)	2/247 (0.81%)
General Physical Health Deterioration		
# participants affected / at risk	6/503 (1.19%)	2/247 (0.81%)
Pain		
# participants affected / at risk	1/503 (0.20%)	2/247 (0.81%)
Performance Status Decreased		
# participants affected / at risk	0/503 (0.00%)	3/247 (1.21%)
Fatigue		
# participants affected / at risk	1/503 (0.20%)	1/247 (0.40%)
Mucosal Inflammation		
# participants affected / at risk	1/503 (0.20%)	1/247 (0.40%)
Chills		
# participants affected / at risk	1/503 (0.20%)	0/247 (0.00%)
Non-Cardiac Chest Pain		
# participants affected / at risk	1/503 (0.20%)	0/247 (0.00%)
Hepatobiliary disorders		
Bile Duct Obstruction		
# participants affected / at risk	1/503 (0.20%)	0/247 (0.00%)

Cytolytic Hepatitis		
# participants affected / at risk	1/503 (0.20%)	0/247 (0.00%)
Hepatic Failure		
# participants affected / at risk	0/503 (0.00%)	1/247 (0.40%)
Hyperbilirubinemia		
# participants affected / at risk	0/503 (0.00%)	1/247 (0.40%)
Infections and infestations		
Pneumonia		
# participants affected / at risk	4/503 (0.80%)	1/247 (0.40%)
Erisipelas		
# participants affected / at risk	2/503 (0.40%)	1/247 (0.40%)
Catheter Related Infection		
# participants affected / at risk	2/503 (0.40%)	0/247 (0.00%)
Cellulitis		
# participants affected / at risk	1/503 (0.20%)	1/247 (0.40%)
Lung Infection		
# participants affected / at risk	2/503 (0.40%)	0/247 (0.00%)
Urinary Tract Infection		
# participants affected / at risk	2/503 (0.40%)	0/247 (0.00%)
Aspergillosis		
# participants affected / at risk	0/503 (0.00%)	1/247 (0.40%)
Breast Cellulitis		
# participants affected / at risk	1/503 (0.20%)	0/247 (0.00%)
Bronchopneumonia		
# participants affected / at risk	1/503 (0.20%)	0/247 (0.00%)
Catheter Site Infection		
# participants affected / at risk	1/503 (0.20%)	0/247 (0.00%)
Central Line Infection		
# participants affected / at risk	1/503 (0.20%)	0/247 (0.00%)
Clostridium Difficile Colitis		
# participants affected / at risk	1/503 (0.20%)	0/247 (0.00%)
Herpes Zoster		
# participants affected / at risk	1/503 (0.20%)	0/247 (0.00%)
Lower Respiratory Tract Infection		
# participants affected / at risk	0/503 (0.00%)	1/247 (0.40%)
Neutropenic Sepsis		
# participants affected / at risk	1/503 (0.20%)	0/247 (0.00%)
Parotitis		
# participants affected / at risk	1/503 (0.20%)	0/247 (0.00%)
Respiratory Tract Infection		
# participants affected / at risk	0/503 (0.00%)	1/247 (0.40%)
Sepsis		
# participants affected / at risk	1/503 (0.20%)	0/247 (0.00%)
Septic Shock		
# participants affected / at risk	1/503 (0.20%)	0/247 (0.00%)
Staphylococcal Sepsis		
# participants affected / at risk	0/503 (0.00%)	1/247 (0.40%)
Viral Infection		
# participants affected / at risk	1/503 (0.20%)	0/247 (0.00%)
Injury, poisoning and procedural complications		

Hip Fracture		
# participants affected / at risk	1/503 (0.20%)	1/247 (0.40%)
Humerus Fracture		
# participants affected / at risk	1/503 (0.20%)	1/247 (0.40%)
Compression Fracture		
# participants affected / at risk	0/503 (0.00%)	1/247 (0.40%)
Fall		
# participants affected / at risk	1/503 (0.20%)	0/247 (0.00%)
Femur Fracture		
# participants affected / at risk	1/503 (0.20%)	0/247 (0.00%)
Investigations		
Body Temperature Increased		
# participants affected / at risk	2/503 (0.40%)	1/247 (0.40%)
Blood Creatinine Increased		
# participants affected / at risk	1/503 (0.20%)	0/247 (0.00%)
Metabolism and nutrition disorders		
Hypercalcemia		
# participants affected / at risk	7/503 (1.39%)	2/247 (0.81%)
Dehydration		
# participants affected / at risk	3/503 (0.60%)	2/247 (0.81%)
Anorexia		
# participants affected / at risk	0/503 (0.00%)	1/247 (0.40%)
Diabetic Ketoacidosis		
# participants affected / at risk	1/503 (0.20%)	0/247 (0.00%)
Hyperglycemia		
# participants affected / at risk	1/503 (0.20%)	0/247 (0.00%)
Hypoglycemia		
# participants affected / at risk	0/503 (0.00%)	0/247 (0.00%)
Hypovolemia		
# participants affected / at risk	1/503 (0.20%)	0/247 (0.00%)
Musculoskeletal and connective tissue disorders		
Back Pain		
# participants affected / at risk	4/503 (0.80%)	3/247 (1.21%)
Bone Pain		
# participants affected / at risk	3/503 (0.60%)	0/247 (0.00%)
Muscular Weakness		
# participants affected / at risk	2/503 (0.40%)	0/247 (0.00%)
Musculoskeletal Pain		
# participants affected / at risk	2/503 (0.40%)	0/247 (0.00%)
Arthralgia		
# participants affected / at risk	0/503 (0.00%)	1/247 (0.40%)
Arthralgia/Myalgia		
# participants affected / at risk	0/503 (0.00%)	1/247 (0.40%)
Fistula		
# participants affected / at risk	1/503 (0.20%)	0/247 (0.00%)
Osteonecrosis		
# participants affected / at risk	1/503 (0.20%)	0/247 (0.00%)
Pain in Extremity		

# participants affected / at risk	0/503 (0.00%)	1/247 (0.40%)
Pathological Fracture		
# participants affected / at risk	1/503 (0.20%)	0/247 (0.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		
Malignant Neoplasm Progression		
# participants affected / at risk	4/503 (0.80%)	2/247 (0.81%)
Metastases to Meninges		
# participants affected / at risk	3/503 (0.60%)	0/247 (0.00%)
Cancer Pain		
# participants affected / at risk	0/503 (0.00%)	2/247 (0.81%)
Brain Cancer		
# participants affected / at risk	0/503 (0.00%)	1/247 (0.40%)
Metastatic Hepatic Neoplasm		
# participants affected / at risk	0/503 (0.00%)	1/247 (0.40%)
Metastases to Bone		
# participants affected / at risk	1/503 (0.20%)	0/247 (0.00%)
Ovarian Neoplasm		
# participants affected / at risk	1/503 (0.20%)	0/247 (0.00%)
Nervous system disorders		
Peripheral Neuropathy		
# participants affected / at risk	3/503 (0.60%)	2/247 (0.81%)
Headache		
# participants affected / at risk	1/503 (0.20%)	2/247 (0.81%)
Dizziness		
# participants affected / at risk	1/503 (0.20%)	1/247 (0.40%)
Epilepsy		
# participants affected / at risk	2/503 (0.40%)	0/247 (0.00%)
Lethargy		
# participants affected / at risk	2/503 (0.40%)	0/247 (0.00%)
Neuropathy Peripheral		
# participants affected / at risk	1/503 (0.20%)	1/247 (0.40%)
Peripheral Motor Neuropathy		
# participants affected / at risk	1/503 (0.20%)	1/247 (0.40%)
Convulsion		
# participants affected / at risk	1/503 (0.20%)	0/247 (0.00%)
Epiduritis		
# participants affected / at risk	1/503 (0.20%)	0/247 (0.00%)
Memory Impairment		
# participants affected / at risk	1/503 (0.20%)	0/247 (0.00%)
Paraesthesia		
# participants affected / at risk	1/503 (0.20%)	0/247 (0.00%)
Paraparesis		
# participants affected / at risk	1/503 (0.20%)	0/247 (0.00%)
Vocal Cord Paralysis		
# participants affected / at risk	0/503 (0.00%)	1/247 (0.40%)
Psychiatric disorders		
Confusional State		
# participants affected / at risk	2/503 (0.40%)	1/247 (0.40%)
Anxiety		

# participants affected / at risk	1/503 (0.20%)	0/247 (0.00%)
Mental Status Changes		
# participants affected / at risk	1/503 (0.20%)	0/247 (0.00%)
Renal and urinary disorders		
Renal Failure Acute		
# participants affected / at risk	1/503 (0.20%)	2/247 (0.81%)
Hematuria		
# participants affected / at risk	0/503 (0.00%)	1/247 (0.40%)
Obstructive Uropathy		
# participants affected / at risk	1/503 (0.20%)	0/247 (0.00%)
Reproductive system and breast disorders		
Ovarian Mass		
# participants affected / at risk	1/503 (0.20%)	0/247 (0.00%)
Respiratory, thoracic and mediastinal disorders		
Dyspnea		
# participants affected / at risk	7/503 (1.39%)	9/247 (3.64%)
Pleural Effusion		
# participants affected / at risk	6/503 (1.19%)	4/247 (1.62%)
Pulmonary Embolism		
# participants affected / at risk	7/503 (1.39%)	3/247 (1.21%)
Respiratory Failure		
# participants affected / at risk	1/503 (0.20%)	2/247 (0.81%)
Atelectasis		
# participants affected / at risk	0/503 (0.00%)	1/247 (0.40%)
Cough		
# participants affected / at risk	1/503 (0.20%)	0/247 (0.00%)
Interstitial Lung Disease		
# participants affected / at risk	0/503 (0.00%)	1/247 (0.40%)
Pharyngolaryngeal Pain		
# participants affected / at risk	1/503 (0.20%)	0/247 (0.00%)
Pneumonitis		
# participants affected / at risk	0/503 (0.00%)	1/247 (0.40%)
Productive Cough		
# participants affected / at risk	1/503 (0.20%)	0/247 (0.00%)
Pulmonary Artery Thrombosis		
# participants affected / at risk	1/503 (0.20%)	0/247 (0.00%)
Skin and subcutaneous tissue disorders		
Palmar-Plantar Erythrodysaethesia Syndrome		
# participants affected / at risk	1/503 (0.20%)	1/247 (0.40%)
Rash		
# participants affected / at risk	1/503 (0.20%)	1/247 (0.40%)
Angioedema		
# participants affected / at risk	1/503 (0.20%)	0/247 (0.00%)
Vascular disorders		
Deep Vein Thrombosis		
# participants affected / at risk	2/503 (0.40%)	2/247 (0.81%)
Cardiovascular Insufficiency		
# participants affected / at risk	1/503 (0.20%)	1/247 (0.40%)

Embolism		
# participants affected / at risk	1/503 (0.20%)	1/247 (0.40%)
Hypotension		
# participants affected / at risk	1/503 (0.20%)	0/247 (0.00%)
Venous Thrombosis		
# participants affected / at risk	1/503 (0.20%)	0/247 (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
Eribulin Mesylate 1.4 mg/kg^2	Eribulin Mesylate 1.4 mg/kg^2 on Days 1 and 8
Treatment of Physician's Choice	Treatment of Physician's Choice

Other Adverse Events

	Eribulin Mesylate 1.4 mg/kg^2	Treatment of Physician's Choice
Total, other (not including serious) adverse events		
# participants affected / at risk	497/503 (98.81%)	230/247 (93.12%)
Blood and lymphatic system disorders		
Neutropenia		
# participants affected / at risk	264/503 (52.49%)	74/247 (29.96%)
Anemia		
# participants affected / at risk	97/503 (19.28%)	56/247 (22.67%)
Leukopenia		
# participants affected / at risk	118/503 (23.46%)	28/247 (11.34%)
Eye disorders		
Lacrimation Decreased		
# participants affected / at risk	35/503 (6.96%)	8/247 (3.24%)
Gastrointestinal disorders		
Nausea		
# participants affected / at risk	175/503 (34.79%)	70/247 (28.34%)
Constipation		
# participants affected / at risk	124/503 (24.65%)	51/247 (20.65%)
Diarrhea		
# participants affected / at risk	96/503 (19.09%)	45/247 (18.22%)
Vomiting		
# participants affected / at risk	94/503 (18.69%)	44/247 (17.81%)
Abdominal Pain Upper		

# participants affected / at risk	46/503 (9.15%)	15/247 (6.07%)
Abdominal Pain		
# participants affected / at risk	39/503 (7.75%)	20/247 (8.10%)
Dyspepsia		
# participants affected / at risk	42/503 (8.35%)	8/247 (3.24%)
Stomatitis		
# participants affected / at risk	38/503 (7.55%)	12/247 (4.86%)
Dry Mouth		
# participants affected / at risk	29/503 (5.77%)	3/247 (1.21%)
General disorders		
Asthenia/Fatigue		
# participants affected / at risk	273/503 (54.27%)	99/247 (40.08%)
Asthenia		
# participants affected / at risk	138/503 (27.44%)	59/247 (23.89%)
Fatigue		
# participants affected / at risk	148/503 (29.42%)	47/247 (19.03%)
Pyrexia		
# participants affected / at risk	107/503 (21.27%)	31/247 (12.55%)
Mucosal Inflammation		
# participants affected / at risk	44/503 (8.75%)	25/247 (10.12%)
Peripheral Edema		
# participants affected / at risk	46/503 (9.15%)	21/247 (8.50%)
Pain		
# participants affected / at risk	24/503 (4.77%)	16/247 (6.48%)
Infections and infestations		
Urinary Tract Infection		
# participants affected / at risk	49/503 (9.74%)	13/247 (5.26%)
Upper Respiratory Tract Infection		
# participants affected / at risk	27/503 (5.37%)	5/247 (2.02%)
Investigations		
Weight Decreased		
# participants affected / at risk	107/503 (21.27%)	36/247 (14.57%)
Alanine Aminotransferase Increased		
# participants affected / at risk	27/503 (5.37%)	6/247 (2.43%)
Metabolism and nutrition disorders		
Anorexia		
# participants affected / at risk	101/503 (20.08%)	32/247 (12.96%)
Hypokalemia		
# participants affected / at risk	36/503 (7.16%)	5/247 (2.02%)
Musculoskeletal and connective tissue disorders		
Arthralgia/Myalgia		
# participants affected / at risk	112/503 (22.27%)	29/247 (11.74%)
Back Pain		
# participants affected / at risk	81/503 (16.10%)	18/247 (7.29%)
Arthralgia		
# participants affected / at risk	73/503 (14.51%)	13/247 (5.26%)
Bone Pain		
# participants affected / at risk	61/503 (12.13%)	23/247 (9.31%)

Pain in Extremity		
# participants affected / at risk	58/503 (11.53%)	25/247 (10.12%)
Myalgia		
# participants affected / at risk	54/503 (10.74%)	17/247 (6.88%)
Musculoskeletal Chest Pain		
# participants affected / at risk	37/503 (7.36%)	15/247 (6.07%)
Musculoskeletal Pain		
# participants affected / at risk	38/503 (7.55%)	11/247 (4.45%)
Muscle Spasms		
# participants affected / at risk	38/503 (7.55%)	10/247 (4.05%)
Muscular Weakness		
# participants affected / at risk	27/503 (5.37%)	3/247 (1.21%)
Nervous system disorders		
Peripheral Neuropathy		
# participants affected / at risk	174/503 (34.59%)	40/247 (16.19%)
Headache		
# participants affected / at risk	98/503 (19.48%)	29/247 (11.74%)
Paresthesia		
# participants affected / at risk	56/503 (11.13%)	16/247 (6.48%)
Peripheral Sensory Neuropathy		
# participants affected / at risk	62/503 (12.33%)	10/247 (4.05%)
Dizziness		
# participants affected / at risk	38/503 (7.55%)	14/247 (5.67%)
Neuropathy Peripheral		
# participants affected / at risk	39/503 (7.75%)	9/247 (3.64%)
Dysgeusia		
# participants affected / at risk	40/503 (7.95%)	5/247 (2.02%)
Psychiatric disorders		
Insomnia		
# participants affected / at risk	38/503 (7.55%)	10/247 (4.05%)
Anxiety		
# participants affected / at risk	27/503 (5.37%)	11/247 (4.45%)
Depression		
# participants affected / at risk	27/503 (5.37%)	3/247 (1.21%)
Respiratory, thoracic and mediastinal disorders		
Dyspnea		
# participants affected / at risk	79/503 (15.71%)	31/247 (12.55%)
Cough		
# participants affected / at risk	74/503 (14.71%)	21/247 (8.50%)
Pharyngolaryngeal Pain		
# participants affected / at risk	36/503 (7.16%)	3/247 (1.21%)
Epistaxis		
# participants affected / at risk	12/503 (2.39%)	13/247 (5.26%)
Skin and subcutaneous tissue disorders		
Alopecia		
# participants affected / at risk	225/503 (44.73%)	24/247 (9.72%)
Rash		
# participants affected / at risk	32/503 (6.36%)	15/247 (6.07%)
Palmar-Plantar Erythrodysaesthesia Syndrome		

# participants affected / at risk	7/503 (1.39%)	34/247 (13.77%)

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 **NOT** 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.

Results Point of Contact:

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Organization: Eisai
phone: 888-422-4743

Publications automatically indexed to this study by ClinicalTrials.gov Identifier (NCT Number):

Muss H, Cortes J, Vahdat LT, Cardoso F, Twelves C, Wanders J, Dutcus CE, Yang J, Seegobin S, O'Shaughnessy J. Eribulin monotherapy in patients aged 70 years and older with metastatic breast cancer. Oncologist. 2014 Apr;19(4):318-27. doi: 10.1634/theoncologist.2013-0282.

Cortes J, O'Shaughnessy J, Loesch D, Blum JL, Vahdat LT, Petrakova K, Chollet P, Manikas A, Diéras V, Delozier T, Vladimirov V, Cardoso F, Koh H, Bougnoux P, Dutcus CE, Seegobin S, Mir D, Meneses N, Wanders J, Twelves C; EMBRACE (Eisai Metastatic Breast Cancer Study Assessing Physician's Choice Versus E7389) investigators.. Eribulin monotherapy versus treatment of physician's choice in patients with metastatic breast cancer (EMBRACE): a phase 3 open-label randomised study. Lancet. 2011 Mar 12;377(9769):914-23. doi: 10.1016/S0140-6736(11)60070-6.

Twelves C, Cortes J, Vahdat LT, Wanders J, Akerele C, Kaufman PA. Phase III trials of eribulin mesylate (E7389) in extensively pretreated patients with locally recurrent or metastatic breast cancer. Clin Breast Cancer. 2010 Apr;10(2):160-3. doi: 10.3816/CBC.2010.n.023.

Responsible Party:	Eisai Inc.
ClinicalTrials.gov Identifier:	NCT00388726 History of Changes
Other Study ID Numbers:	E7389-G000-305 2006-001949-34 (EudraCT Number)
Study First Received:	October 13, 2006
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Health Authority:	United States: Food and Drug Administration European Union: European Medicines Agency

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