A Phase II Study of E7389 in Patients With Breast Cancer, Previously Treated With Anthracycline, Taxane and Capecitabine

This study has been completed.

Sponsor:
Eisai Inc.

Collaborator:
Eisai Limited

Information provided by:
Eisai Inc.

ClinicalTrials.gov Identifier:
NCT00246090

First received: October 27, 2005
Last updated: June 30, 2014
Last verified: April 2012
History of Changes

Results First Received: December 22, 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 Cancer
Intervention:	Drug: E7389

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 42 centers in US and 36 centers in EU during the period of Oct 2005 to Sep 2007.

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
E7389 1.4 mg/m^2	E7389 1.4 mg/m^2 intravenous bolus given over 2-5 minutes on Days 1 and 8 every 21 days.

Participant Flow: Overall Study

	E7389 1.4 mg/m^2
STARTED	298
COMPLETED	3
NOT COMPLETED	295
Adverse Event	25
Withdrawal by Subject	7
Progressive Disease	212
Clinical Progression	30
Physician Decision	11
Not Otherwise Specified	10

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
E7389 1.4 mg/m^2	E7389 1.4 mg/m^2 intravenous bolus given over 2-5 minutes on Days 1 and 8 every 21 days.

Baseline Measures

	E7389 1.4 mg/m^2
Overall Participants Analyzed [Units: Participants]	291
Age [1] [Units: Years] Mean (Standard Deviation)	55.4 (10.8)
[1] Safety Population	
Gender [Units: Participants]	
Female	291
Male	0
Race/Ethnicity, Customized [Units: Participants]	
Asian/Pacific Islander	6
Black or African American	12
White	199
Other	8
Unknown or Not Reported	66

Outcome Measures

Hide All Outcome Measures

1. Primary: Objective Response Rate [Time Frame: Every two cycles]

Measure Type	Primary
Measure Title	Objective Response Rate
Measure Description	Based on Response Evaluation Criteria in Solid Tumors (RECIST), consisting of complete response (CR) plus partial response (PR). 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	Every two cycles
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.
Eligible Population

Reporting Groups

	Description
E7389 1.4 mg/m^2	E7389 1.4 mg/m^2 intravenous bolus given over 2-5 minutes on Days 1 and 8 every 21 days.

Measured Values

	E7389 1.4 mg/m^2
Participants Analyzed [Units: Participants]	**269**
Objective Response Rate [Units: Percentage of Participants]	**14.1**

No statistical analysis provided for Objective Response Rate

2. Secondary: Duration of Response [Time Frame: From first documented complete or partial response until disease progression or death]

Measure Type	Secondary
Measure Title	Duration of Response
Measure Description	Complete response (CR) is defined as the disappearance of all lesions. Partial response (PR) is defined as 30% decrease in lesion diameter.
Time Frame	From first documented complete or partial response 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.
Eligible Population

Reporting Groups

	Description
E7389 1.4 mg/m^2	E7389 1.4 mg/m^2 intravenous bolus given over 2-5 minutes on Days 1 and 8 every 21 days.

Measured Values

	E7389 1.4 mg/m^2
Participants Analyzed [Units: Participants]	**38**
Duration of Response [Units: Days] Median (Full Range)	**176 (29 to 258)**

No statistical analysis provided for Duration of Response

Serious Adverse Events

Hide Serious Adverse Events

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

Reporting Groups

	Description
E7389 1.4 mg/m^2	E7389 1.4 mg/m^2 intravenous bolus given over 2-5 minutes on Days 1 and 8 every 21 days.

Serious Adverse Events

	E7389 1.4 mg/m^2
Total, serious adverse events	
# participants affected / at risk	**88/291 (30.24%)**
Blood and lymphatic system disorders	
Anemia	
# participants affected / at risk	**3/291 (1.03%)**
Febrile Neutropenia	
# participants affected / at risk	**11/291 (3.78%)**
Leukopenia	
# participants affected / at risk	**1/291 (0.34%)**
Neutropenia	
# participants affected / at risk	**7/291 (2.41%)**
Thrombocytopenia	
# participants affected / at risk	**2/291 (0.69%)**
Cardiac disorders	

Cardiac Arrest	
# participants affected / at risk	1/291 (0.34%)
Pericardial Effusion	
# participants affected / at risk	1/291 (0.34%)
Pericarditis	
# participants affected / at risk	1/291 (0.34%)
Tachycardia	
# participants affected / at risk	2/291 (0.69%)
Eye disorders	
Diplopia	
# participants affected / at risk	1/291 (0.34%)
Macular Hole	
# participants affected / at risk	1/291 (0.34%)
Gastrointestinal disorders	
Abdominal Pain	
# participants affected / at risk	3/291 (1.03%)
Ascites	
# participants affected / at risk	1/291 (0.34%)
Dysphagia	
# participants affected / at risk	1/291 (0.34%)
Intestinal Obstruction	
# participants affected / at risk	1/291 (0.34%)
Nausea	
# participants affected / at risk	3/291 (1.03%)
Vomiting	
# participants affected / at risk	4/291 (1.37%)
General disorders	
Asthenia	
# participants affected / at risk	2/291 (0.69%)
Chest Pain	
# participants affected / at risk	1/291 (0.34%)
Death	
# participants affected / at risk	1/291 (0.34%)
Fatigue	
# participants affected / at risk	1/291 (0.34%)
Pain	
# participants affected / at risk	4/291 (1.37%)
Pyrexia	
# participants affected / at risk	11/291 (3.78%)
Hepatobiliary disorders	
Biliary Dilatation	
# participants affected / at risk	1/291 (0.34%)
Infections and infestations	
Bacteremia	
# participants affected / at risk	1/291 (0.34%)
Bacterial Sepsis	
# participants affected / at risk	1/291 (0.34%)
Clostridium Difficile Colitis	
# participants affected / at risk	1/291 (0.34%)

Endocarditis	
# participants affected / at risk	1/291 (0.34%)
Gastroenteritis	
# participants affected / at risk	1/291 (0.34%)
Lymphangitis	
# participants affected / at risk	1/291 (0.34%)
Neutropenic Infection	
# participants affected / at risk	1/291 (0.34%)
Neutropenic Sepsis	
# participants affected / at risk	1/291 (0.34%)
Pneumonia	
# participants affected / at risk	2/291 (0.69%)
Pyelonephritis	
# participants affected / at risk	1/291 (0.34%)
Respiratory Tract Infection	
# participants affected / at risk	1/291 (0.34%)
Sepsis	
# participants affected / at risk	2/291 (0.69%)
Septic Shock	
# participants affected / at risk	1/291 (0.34%)
Urinary Tract Infection	
# participants affected / at risk	2/291 (0.69%)
Injury, poisoning and procedural complications	
Fall	
# participants affected / at risk	1/291 (0.34%)
Hip Fracture	
# participants affected / at risk	2/291 (0.69%)
Metabolism and nutrition disorders	
Anorexia	
# participants affected / at risk	1/291 (0.34%)
Dehydration	
# participants affected / at risk	1/291 (0.34%)
Hypokalemia	
# participants affected / at risk	1/291 (0.34%)
Hypovolemia	
# participants affected / at risk	1/291 (0.34%)
Musculoskeletal and connective tissue disorders	
Arthralgia	
# participants affected / at risk	1/291 (0.34%)
Back Pain	
# participants affected / at risk	4/291 (1.37%)
Bone Pain	
# participants affected / at risk	1/291 (0.34%)
Muscular Weakness	
# participants affected / at risk	2/291 (0.69%)
Musculoskeletal Chest Pain	
# participants affected / at risk	1/291 (0.34%)
Neck Pain	
# participants affected / at risk	1/291 (0.34%)

Pain in Extremity	
# participants affected / at risk	1/291 (0.34%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	
Lymphangiosis Carcinomatosa	
# participants affected / at risk	1/291 (0.34%)
Malignant Neoplasm Progression	
# participants affected / at risk	4/291 (1.37%)
Malignant Pleural Effusion	
# participants affected / at risk	1/291 (0.34%)
Metastases to Central Nervous	
# participants affected / at risk	3/291 (1.03%)
Metastases to Liver	
# participants affected / at risk	2/291 (0.69%)
Metastases to Meninges	
# participants affected / at risk	2/291 (0.69%)
Metastases to Retroperitoneum	
# participants affected / at risk	1/291 (0.34%)
Nervous system disorders	
Aphasia	
# participants affected / at risk	1/291 (0.34%)
Cerebrovascular Accident	
# participants affected / at risk	1/291 (0.34%)
Convulsion	
# participants affected / at risk	1/291 (0.34%)
Peripheral Sensorimotor Neuropathy	
# participants affected / at risk	1/291 (0.34%)
Spinal Cord Compression	
# participants affected / at risk	2/291 (0.69%)
Syncope	
# participants affected / at risk	1/291 (0.34%)
Psychiatric disorders	
Confusional State	
# participants affected / at risk	2/291 (0.69%)
Depression	
# participants affected / at risk	1/291 (0.34%)
Mental Status Changes	
# participants affected / at risk	1/291 (0.34%)
Renal and urinary disorders	
Hydronephrosis	
# participants affected / at risk	1/291 (0.34%)
Nephrolithiasis	
# participants affected / at risk	1/291 (0.34%)
Renal Failure	
# participants affected / at risk	1/291 (0.34%)
Urinary Retention	
# participants affected / at risk	1/291 (0.34%)
Respiratory, thoracic and mediastinal disorders	
Dyspnea	

# participants affected / at risk	7/291 (2.41%)
Lung Disorder	
# participants affected / at risk	1/291 (0.34%)
Pleural Effusion	
# participants affected / at risk	7/291 (2.41%)
Pleurisy	
# participants affected / at risk	1/291 (0.34%)
Respiratory Failure	
# participants affected / at risk	2/291 (0.69%)
Vascular disorders	
Deep Vein Thrombosis	
# participants affected / at risk	1/291 (0.34%)

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
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Other Adverse Events

	E7389 1.4 mg/m^2
Total, other (not including serious) adverse events	
# participants affected / at risk	290/291 (99.66%)
Blood and lymphatic system disorders	
Anemia	
# participants affected / at risk	86/291 (29.55%)
Febrile Neutropenia	
# participants affected / at risk	16/291 (5.50%)
Leukopenia	
# participants affected / at risk	64/291 (21.99%)
Neutropenia	
# participants affected / at risk	174/291 (59.79%)
Eye disorders	
Lacrimation Increased	
# participants affected / at risk	31/291 (10.65%)
Gastrointestinal disorders	
Abdominal Distention	
# participants affected / at risk	16/291 (5.50%)

Abdominal Pain	
# participants affected / at risk	38/291 (13.06%)
Abdominal Pain Upper	
# participants affected / at risk	26/291 (8.93%)
Constipation	
# participants affected / at risk	96/291 (32.99%)
Diarrhea	
# participants affected / at risk	65/291 (22.34%)
Dry Mouth	
# participants affected / at risk	25/291 (8.59%)
Dyspepsia	
# participants affected / at risk	27/291 (9.28%)
Nausea	
# participants affected / at risk	141/291 (48.45%)
Stomatitis	
# participants affected / at risk	32/291 (11.00%)
Vomiting	
# participants affected / at risk	72/291 (24.74%)
General disorders	
Asthenia	
# participants affected / at risk	112/291 (38.49%)
Chest Pain	
# participants affected / at risk	24/291 (8.25%)
Fatigue	
# participants affected / at risk	107/291 (36.77%)
Mucosal Inflammation	
# participants affected / at risk	44/291 (15.12%)
Peripheral Edema	
# participants affected / at risk	37/291 (12.71%)
Pain	
# participants affected / at risk	32/291 (11.00%)
Pyrexia	
# participants affected / at risk	88/291 (30.24%)
Infections and infestations	
Urinary Tract Infection	
# participants affected / at risk	35/291 (12.03%)
Investigations	
Weight Decreased	
# participants affected / at risk	29/291 (9.97%)
Metabolism and nutrition disorders	
Anorexia	
# participants affected / at risk	74/291 (25.43%)
Hypokalemia	
# participants affected / at risk	26/291 (8.93%)
Musculoskeletal and connective tissue disorders	
Arthralgia	
# participants affected / at risk	48/291 (16.49%)
Back Pain	
# participants affected / at risk	46/291 (15.81%)

Bone Pain	
# participants affected / at risk	30/291 (10.31%)
Muscle Spasms	
# participants affected / at risk	17/291 (5.84%)
Muscular Weakness	
# participants affected / at risk	16/291 (5.50%)
Musculoskeletal Chest Pain	
# participants affected / at risk	20/291 (6.87%)
Musculoskeletal Pain	
# participants affected / at risk	30/291 (10.31%)
Myalgia	
# participants affected / at risk	42/291 (14.43%)
Neck Pain	
# participants affected / at risk	17/291 (5.84%)
Pain in Extremity	
# participants affected / at risk	38/291 (13.06%)
Nervous system disorders	
Dizziness	
# participants affected / at risk	28/291 (9.62%)
Dysgeusia	
# participants affected / at risk	40/291 (13.75%)
Headache	
# participants affected / at risk	61/291 (20.96%)
Neuropathy	
# participants affected / at risk	24/291 (8.25%)
Neuropathy Peripheral	
# participants affected / at risk	30/291 (10.31%)
Paraesthesia	
# participants affected / at risk	33/291 (11.34%)
Peripheral Sensory Neuropathy	
# participants affected / at risk	28/291 (9.62%)
Psychiatric disorders	
Anxiety	
# participants affected / at risk	27/291 (9.28%)
Depression	
# participants affected / at risk	26/291 (8.93%)
Insomnia	
# participants affected / at risk	33/291 (11.34%)
Respiratory, thoracic and mediastinal disorders	
Cough	
# participants affected / at risk	57/291 (19.59%)
Dyspnea	
# participants affected / at risk	57/291 (19.59%)
Pharyngolarygeal Pain	
# participants affected / at risk	20/291 (6.87%)
Skin and subcutaneous tissue disorders	
Alopecia	
# participants affected / at risk	179/291 (61.51%)

Rash	
# participants affected / at risk	16/291 (5.50%)

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:

Name/Title: Eisai Inc.
Organization: Eisai Call Center
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.

Responsible Party:	Eisai Medical Services, Eisai Inc.
ClinicalTrials.gov Identifier:	NCT00246090 History of Changes
Other Study ID Numbers:	E7389-G000-211 2005-003656-35 (EudraCT Number)
Study First Received:	October 27, 2005
Results First Received:	December 22, 2011
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Health Authority:	United States: Food and Drug Administration Europe: European Agency for the Evaluation of Medicinal Products

TO TOP

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

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