E7050 in Combination With Cisplatin and Capecitabine Versus Cisplatin and Capecitabine Alone in Patients With Advanced or Metastatic Solid Tumors and Previously Untreated Gastric Cancer

This study has been terminated.

(Sites not recruiting)

Sponsor:
Eisai Inc.

Collaborator:
Quintiles, Inc.

Information provided by (Responsible Party):
Eisai Inc.

ClinicalTrials.gov Identifier:
NCT01355302

First received: May 16, 2011
Last updated: April 7, 2017
Last verified: March 2017
History of Changes

Results First Received: January 19, 2017

Study Type:	Interventional
Study Design:	Allocation: Randomized; Intervention Model: Parallel Assignment; Masking: None (Open Label); Primary Purpose: Treatment
Conditions:	Advanced or Metastatic Solid Tumors Previously Untreated Gastric Cancer
Interventions:	Drug: E7050 Drug: cisplatin Drug: capecitabine

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
Subjects were to only participate in either the Phase 1b or Phase 2 portion of the study.

Reporting Groups

	Description
Phase 1b: Golvatinib+Capecitabine+Cisplatin	Oral golvatinib (200 mg) was taken at about the same time each day of every 21-day treatment cycle, with or without food. Oral capecitabine (1000 mg/m^2 tablet) was taken twice a day (2000 mg/m^2 total daily) with food at about the same time (after golvatinib), on Days 1 through 14 of each 21-day cycle. At least 2 hours after capecitabine was taken, cisplatin (80 mg/m^2) was administered by intravenous (IV) infusion over 60 minutes (after appropriate hydration or according to the institutional guidelines), on Day 1 of each 21-day cycle. Pretreatment hydration included 1 liter of normal saline by IV infusion over 120 minutes. Posttreatment hydration included 500 mL normal saline over 60 minutes. The dose level of golvatinib was to be escalated (to 300 and 400 mg) for additional cohorts after 3 participants enrolled into a given cohort unless there was a dose-limiting toxicity (DLT) in the first 3 participants.
Phase 2: Golvatinib+Capecitabine+Cisplatin	The dose of golvatinib was to be the maximum tolerated dose (MTD) as determined during the Phase 1b portion of the study in combination with capecitabine and cisplatin as described for Phase 1b. The study was terminated prior to Phase 2.
Phase 2: Capecitabine + Cisplatin	Oral capecitabine (1000 mg/m^2 tablet) was taken twice a day (2000 mg/m^2 total daily) with food at about the same time (after golvatinib), on Days 1 through 14 of each 21-day cycle. At least 2 hours after capecitabine was taken, cisplatin (80 mg/m^2) was administered by intravenous (IV) infusion over 60 minutes (after appropriate hydration or according to the institutional guidelines), on Day 1 of each 21-day cycle. Pretreatment hydration included 1 liter of normal saline by IV infusion over 120 minutes. Posttreatment hydration included 500 mL normal saline over 60 minutes.

Participant Flow for 2 periods

Period 1: Phase 1b

	Phase 1b: Golvatinib+Capecitabine+Cisplatin	Phase 2: Golvatinib+Capecitabine+Cisplatin	Phase 2: Capecitabine + Cisplatin
STARTED	7 [1]	0	0
COMPLETED	1 [2]	0	0
NOT COMPLETED	6	0	0
Death	4	0	0
Study terminated by sponsor	2	0	0

[1] Replaced 1 subject; who discontinued study drug in first cycle
[2] The subject who completed 6 cycles was withdrawn by sponsor request.

Period 2: Phase 2

	Phase 1b: Golvatinib+Capecitabine+Cisplatin	Phase 2: Golvatinib+Capecitabine+Cisplatin	Phase 2: Capecitabine + Cisplatin
STARTED	0 [1]	0 [2]	0 [2]
COMPLETED	0	0	0
NOT COMPLETED	0	0	0

[1] Treatment arm not designated for phase 2.
[2] The study was terminated prior to enrollment

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
Phase 1b: Golvatinib+Capecitabine+Cisplatin	Oral golvatinib (200 mg) was taken at about the same time each day of every 21-day treatment cycle, with or without food. Oral

	capecitabine (1000 mg/m^2 tablet) was taken twice a day (2000 mg/m^2 total daily) with food at about the same time (after golvatinib), on Days 1 through 14 of each 21-day cycle. At least 2 hours after capecitabine was taken, cisplatin (80 mg/m^2) was administered by intravenous (IV) infusion over 60 minutes (after appropriate hydration or according to the institutional guidelines), on Day 1 of each 21-day cycle. Pretreatment hydration included 1 liter of normal saline by IV infusion over 120 minutes. Posttreatment hydration included 500 mL normal saline over 60 minutes. The dose level of golvatinib was to be escalated (to 300 and 400 mg) for additional cohorts after 3 participants enrolled into a given cohort unless there was a dose-limiting toxicity (DLT) in the first 3 participants.

Baseline Measures

	Phase 1b: Golvatinib+Capecitabine+Cisplatin
Overall Participants Analyzed [Units: Participants]	**7**
Age, Customized [Units: Participants]	
Age range 47 to 80 years	**7**
Sex: Female, Male [Units: Participants] Count of Participants	
Female	**4** 57.1%
Male	**3** 42.9%

Outcome Measures

Hide All Outcome Measures

1. Primary: Area Under The Concentration-Time Curve (AUC) From 0 to 24 Hours of Golvatinib [Time Frame: Cycle 1 (Day -2); predose, 30 minutes, 1, 2, 3, 4, 8, 12 (if feasible), 24, and 48 hours after study treatment. Cycle 2 (Day 1); predose, 30 minutes, 1, 2, 3, 4, 8, 12 (if feasible), and 24 hours after study treatment.]

Measure Type	Primary
Measure Title	Area Under The Concentration-Time Curve (AUC) From 0 to 24 Hours of Golvatinib
Measure Description	On days when pharmacokinetic (PK) samples were to be drawn, a predose blood sample was obtained prior to administration of golvatinib and capecitabine. After administration of study drugs, a second postdose blood sample was taken. The amount of golvatinib in the participant's blood was analyzed and the AUC was calculated. The AUC reflects the actual body exposure to drug after administration of a dose of the drug and is dependent on the rate of elimination of the drug from the body and the dose administered. Predose samples

	that were below the limit of quantitation (BLQ) or missing were assigned a numerical value of zero for the calculation of AUC. Any other BLQ concentrations were assigned a value of zero. Results were expressed in nanograms·hour/milliter (ng·h/mL).
Time Frame	Cycle 1 (Day -2); predose, 30 minutes, 1, 2, 3, 4, 8, 12 (if feasible), 24, and 48 hours after study treatment. Cycle 2 (Day 1); predose, 30 minutes, 1, 2, 3, 4, 8, 12 (if feasible), and 24 hours after study treatment.

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.
Pharmacokinetic (PK) population: All participants in the Safety Population who had sufficient concentration data to derive one or more of the PK parameters. Participants with partial data were evaluated on a case-by-case basis to determine if sufficient data were available for meaningful PK analysis.

Reporting Groups

	Description
Phase 1b: Golvatinib+Capecitabine+Cisplatin	Oral golvatinib (200 mg) was taken at about the same time each day of every 21-day treatment cycle, with or without food. Oral capecitabine (1000 mg/m^2 tablet) was taken twice a day (2000 mg/m^2 total daily) with food at about the same time (after golvatinib), on Days 1 through 14 of each 21-day cycle. At least 2 hours after capecitabine was taken, cisplatin (80 mg/m^2) was administered by intravenous (IV) infusion over 60 minutes (after appropriate hydration or according to the institutional guidelines), on Day 1 of each 21-day cycle. Pretreatment hydration included 1 liter of normal saline by IV infusion over 120 minutes. Posttreatment hydration included 500 mL normal saline over 60 minutes. The dose level of golvatinib was to be escalated (to 300 and 400 mg) for additional cohorts after 3 participants enrolled into a given cohort unless there was a dose-limiting toxicity (DLT) in the first 3 participants.

Measured Values

	Phase 1b: Golvatinib+Capecitabine+Cisplatin
Participants Analyzed [Units: Participants]	**7**
Area Under The Concentration-Time Curve (AUC) From 0 to 24 Hours of Golvatinib [Units: ng·h/mL] Median (Full Range)	
Cycle 1, Day -2	**23400** **(5000 to 56100)**

Cycle 2, Day 1	**26300 (17400 to 62400)**

No statistical analysis provided for Area Under The Concentration-Time Curve (AUC) From 0 to 24 Hours of Golvatinib

2. Primary: Maximum Concentration (Cmax) of Golvatinib [Time Frame: Cycle 1 (Day -2); predose, 30 minutes, 1, 2, 3, 4, 8, 12 (if feasible), 24, and 48 hours after study treatment. Cycle 2 (Day 1); predose, 30 minutes, 1, 2, 3, 4, 8, 12 (if feasible), and 24 hours after study treatment.]

Measure Type	Primary
Measure Title	Maximum Concentration (Cmax) of Golvatinib
Measure Description	Blood samples were drawn to analyze the amount of golvatinib in the participant's serum. Maximum concentration refers to the maximum (or peak) serum concentration of study drug in the participant's system after administration of the study drug and prior to the administration of a second dose of the study drug. Results were expressed in nanograms/milliliter (ng/mL).
Time Frame	Cycle 1 (Day -2); predose, 30 minutes, 1, 2, 3, 4, 8, 12 (if feasible), 24, and 48 hours after study treatment. Cycle 2 (Day 1); predose, 30 minutes, 1, 2, 3, 4, 8, 12 (if feasible), and 24 hours after study treatment.

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.
Pharmacokinetic (PK) population: All participants in the Safety Population who had sufficient concentration data to derive one or more of the PK parameters. Participants with partial data were evaluated on a case-by-case basis to determine if sufficient data were available for meaningful PK analysis.

Reporting Groups

	Description
Phase 1b: Golvatinib+Capecitabine+Cisplatin	Oral golvatinib (200 mg) was taken at about the same time each day of every 21-day treatment cycle, with or without food. Oral capecitabine (1000 mg/m^2 tablet) was taken twice a day (2000 mg/m^2 total daily) with food at about the same time (after golvatinib), on Days 1 through 14 of each 21-day cycle. At least 2 hours after capecitabine was taken, cisplatin (80 mg/m^2) was administered by IV infusion over 60 minutes (after appropriate hydration or according to the institutional guidelines), on Day 1 of each 21-day cycle. Pretreatment hydration included 1 liter of normal saline by IV infusion over 120 minutes. Posttreatment hydration included 500 mL normal saline over 60 minutes. The dose level of golvatinib was to be escalated (to 300 and 400 mg) for additional cohorts after 3 participants enrolled into a given cohort unless there

	was a DLT in the first 3 participants.

Measured Values

	Phase 1b: Golvatinib+Capecitabine+Cisplatin
Participants Analyzed [Units: Participants]	**7**
Maximum Concentration (Cmax) of Golvatinib [Units: ng/mL] Median (Full Range)	
Cycle 1, Day -2	**1680** **(268 to 3890)**
Cycle 2, Day 1	**1620** **(834 to 3430)**

No statistical analysis provided for Maximum Concentration (Cmax) of Golvatinib

3. Primary: Number of Participants With a Treatment-Emergent Adverse Event (TEAE) [Time Frame: From date of first dose up to 30 days after the last dose of study treatment, up to approximately 1 year 1 month.]

Measure Type	Primary
Measure Title	Number of Participants With a Treatment-Emergent Adverse Event (TEAE)
Measure Description	Safety assessments consisted of monitoring and recording all adverse events (AEs) and serious AEs; regular monitoring of hematology, blood chemistry, and urine values; periodic measurement of vital signs and electrocardiograms (ECGs); and performance of physical examinations. A TEAE was defined as an adverse event (AE) that had an onset date, or a worsening in severity from Baseline (pretreatment), on or after the first dose of study drug up to 30 days after the date of last study treatment.
Time Frame	From date of first dose up to 30 days after the last dose of study treatment, up to approximately 1 year 1 month.

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.
Safety Population included all participants who received at least one dose of study drug and who had at least one safety assessment after the first dose of study drug.

Reporting Groups

	Description
Phase 1b: Golvatinib+Capecitabine+Cisplatin	Oral golvatinib (200 mg) was taken at about the same time each day

	of every 21-day treatment cycle, with or without food. Oral capecitabine (1000 mg/m^2 tablet) was taken twice a day (2000 mg/m^2 total daily) with food at about the same time (after golvatinib), on Days 1 through 14 of each 21-day cycle. At least 2 hours after capecitabine was taken, cisplatin (80 mg/m^2) was administered by IV infusion over 60 minutes (after appropriate hydration or according to the institutional guidelines), on Day 1 of each 21-day cycle. Pretreatment hydration included 1 liter of normal saline by IV infusion over 120 minutes. Posttreatment hydration included 500 mL normal saline over 60 minutes. The dose level of golvatinib was to be escalated (to 300 and 400 mg) for additional cohorts after 3 participants enrolled into a given cohort unless there was a DLT in the first 3 participants.

Measured Values

	Phase 1b: Golvatinib+Capecitabine+Cisplatin
Participants Analyzed [Units: Participants]	**7**
Number of Participants With a Treatment-Emergent Adverse Event (TEAE) [Units: Participants]	**7**

No statistical analysis provided for Number of Participants With a Treatment-Emergent Adverse Event (TEAE)

4. Primary: Time to Maximum Concentration (Tmax) of Golvatinib [Time Frame: Cycle 1 (Day -2); predose, 30 minutes, 1, 2, 3, 4, 8, 12 (if feasible), 24, and 48 hours after study treatment. Cycle 2 (Day 1); predose, 30 minutes, 1, 2, 3, 4, 8, 12 (if feasible), and 24 hours after study treatment.]

Measure Type	Primary
Measure Title	Time to Maximum Concentration (Tmax) of Golvatinib
Measure Description	Tmax was defined as the time at which Cmax was observed for golvatinib in combination with cisplatin and capecitabine.
Time Frame	Cycle 1 (Day -2); predose, 30 minutes, 1, 2, 3, 4, 8, 12 (if feasible), 24, and 48 hours after study treatment. Cycle 2 (Day 1); predose, 30 minutes, 1, 2, 3, 4, 8, 12 (if feasible), and 24 hours after study treatment.

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.
Pharmacokinetic (PK) population: All participants in the Safety Population who had sufficient concentration data to

derive one or more of the PK parameters. Participants with partial data were evaluated on a case-by-case basis to determine if sufficient data were available for meaningful PK analysis.

Reporting Groups

	Description
Phase 1b: Golvatinib+Capecitabine+Cisplatin	Oral golvatinib (200 mg) was taken at about the same time each day of every 21-day treatment cycle, with or without food. Oral capecitabine (1000 mg/m^2 tablet) was taken twice a day (2000 mg/m^2 total daily) with food at about the same time (after golvatinib), on Days 1 through 14 of each 21-day cycle. At least 2 hours after capecitabine was taken, cisplatin (80 mg/m^2) was administered by IV infusion over 60 minutes (after appropriate hydration or according to the institutional guidelines), on Day 1 of each 21-day cycle. Pretreatment hydration included 1 liter of normal saline by IV infusion over 120 minutes. Posttreatment hydration included 500 mL normal saline over 60 minutes. The dose level of golvatinib was to be escalated (to 300 and 400 mg) for additional cohorts after 3 participants enrolled into a given cohort unless there was a DLT in the first 3 participants.

Measured Values

	Phase 1b: Golvatinib+Capecitabine+Cisplatin
Participants Analyzed [Units: Participants]	**7**
Time to Maximum Concentration (Tmax) of Golvatinib [Units: Hours] Median (Full Range)	
Cycle 1, Day -2	**3.00** **(1.00 to 7.78)**
Cycle 2, Day 1	**6.07** **(3.00 to 12.82)**

No statistical analysis provided for Time to Maximum Concentration (Tmax) of Golvatinib

5. Secondary: Overall Response Rate (ORR) [Time Frame: Until disease progression or death for 3 years]

Measure Type	Secondary
Measure Title	Overall Response Rate (ORR)
Measure Description	The study was terminated prior to enrollment in Phase 2 so this outcome measure was not conducted.
Time Frame	Until disease progression or death for 3 years

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.
The study was terminated prior to enrollment in Phase 2 so this outcome measure was not conducted.

Reporting Groups

	Description
Phase 2: Golvatinib+Capecitabine+Cisplatin	The dose of golvatinib was to be the maximum tolerated dose (MTD) as determined during the Phase 1b portion of the study in combination with capecitabine and cisplatin as described for Phase 1b. The study was terminated prior to Phase 2.
Phase 2: Capecitabine + Cisplatin	The dose of golvatinib was to be the MTD as determined during the Phase 1b portion of the study in combination with capecitabine and cisplatin as described for Phase 1b. The study was terminated prior to Phase 2.

Measured Values

	Phase 2: Golvatinib+Capecitabine+Cisplatin	**Phase 2: Capecitabine + Cisplatin**
Participants Analyzed [Units: Participants]	**0**	**0**
Overall Response Rate (ORR)		

No statistical analysis provided for Overall Response Rate (ORR)

6. Secondary: Time to Progression (TTP) [Time Frame: Until disease progression or death for 3 years]

Measure Type	Secondary
Measure Title	Time to Progression (TTP)
Measure Description	The study was terminated prior to enrollment in Phase 2 so this outcome measure was not conducted.
Time Frame	Until disease progression or death for 3 years

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.
The study was terminated prior to enrollment in Phase 2 so this outcome measure was not conducted.

Reporting Groups

	Description
Phase 2: Golvatinib+Capecitabine+Cisplatin	The dose of golvatinib was to be the MTD as determined during the Phase 1b portion of the study in combination with capecitabine and cisplatin as described for Phase 1b. The study was terminated prior to Phase 2.
Phase 2: Capecitabine + Cisplatin	The dose of golvatinib was to be the MTD as determined during the Phase 1b portion of the study in combination with capecitabine and cisplatin as described for Phase 1b. The study was terminated prior to Phase 2.

Measured Values

	Phase 2: Golvatinib+Capecitabine+Cisplatin	Phase 2: Capecitabine + Cisplatin
Participants Analyzed [Units: Participants]	**0**	**0**
Time to Progression (TTP)		

No statistical analysis provided for Time to Progression (TTP)

Serious Adverse Events

Hide Serious Adverse Events

Time Frame	From date of first dose up to 30 days after the last dose of study treatment, up to approximately 1 year 1 month.
Additional Description	Safety population included all participants enrolled in Phase 1b of this study, except for those who (a) dropped out prior to receiving study drug, or (b) were without any safety assessments after the first dose of study drug. Treatment-emergent AEs, (onset date or worsening in severity from baseline after first dose of study drug), were reported.

Reporting Groups

	Description
Phase 1b: Golvatinib+Capecitabine+Cisplatin	Oral golvatinib (200 mg) was taken at about the same time each day of every 21-day treatment cycle, with or without food. Oral capecitabine (1000 mg/m^2 tablet) was taken twice a day (2000

	mg/m^2 total daily) with food at about the same time (after golvatinib), on Days 1 through 14 of each 21-day cycle. At least 2 hours after capecitabine was taken, cisplatin (80 mg/m^2) was administered by intravenous (IV) infusion over 60 minutes (after appropriate hydration or according to the institutional guidelines), on Day 1 of each 21-day cycle. Pretreatment hydration included 1 liter of normal saline by IV infusion over 120 minutes. Posttreatment hydration included 500 mL normal saline over 60 minutes. The dose level of golvatinib was to be escalated (to 300 and 400 mg) for additional cohorts after 3 participants enrolled into a given cohort unless there was a dose-limiting toxicity (DLT) in the first 3 participants.

Serious Adverse Events

	Phase 1b: Golvatinib+Capecitabine+Cisplatin
Total, Serious Adverse Events	
# participants affected / at risk	**5/7 (71.43%)**
Cardiac disorders	
Supraventricular tachycardia † 1	
# participants affected / at risk	**1/7 (14.29%)**
Gastrointestinal disorders	
Nausea † 1	
# participants affected / at risk	**1/7 (14.29%)**
Vomiting † 1	
# participants affected / at risk	**1/7 (14.29%)**
Stomatitis † 1	
# participants affected / at risk	**1/7 (14.29%)**
Infections and infestations	
Psoas abscess † 1	
# participants affected / at risk	**1/7 (14.29%)**
Pneumonia † 1	
# participants affected / at risk	**1/7 (14.29%)**
Metabolism and nutrition disorders	
Dehydration † 1	
# participants affected / at risk	**1/7 (14.29%)**
Electrolyte imbalance † 1	
# participants affected / at risk	**1/7 (14.29%)**
Musculoskeletal and connective tissue disorders	
Arthralgia † 1	
# participants affected / at risk	**1/7 (14.29%)**
Nervous system disorders	

Convulsion † 1	
# participants affected / at risk	**1/7 (14.29%)**
Vascular disorders	
Pulmonary embolism † 1	
# participants affected / at risk	**1/7 (14.29%)**

† Events were collected by systematic assessment
1 Term from vocabulary, MedDRA Version 15.0

Other Adverse Events

Hide Other Adverse Events

Time Frame	From date of first dose up to 30 days after the last dose of study treatment, up to approximately 1 year 1 month.
Additional Description	Safety population included all participants enrolled in Phase 1b of this study, except for those who (a) dropped out prior to receiving study drug, or (b) were without any safety assessments after the first dose of study drug. Treatment-emergent AEs, (onset date or worsening in severity from baseline after first dose of study drug), were reported.

Frequency Threshold

Threshold above which other adverse events are reported	5%

Reporting Groups

	Description
Phase 1b: Golvatinib+Capecitabine+Cisplatin	Oral golvatinib (200 mg) was taken at about the same time each day of every 21-day treatment cycle, with or without food. Oral capecitabine (1000 mg/m^2 tablet) was taken twice a day (2000 mg/m^2 total daily) with food at about the same time (after golvatinib), on Days 1 through 14 of each 21-day cycle. At least 2 hours after capecitabine was taken, cisplatin (80 mg/m^2) was administered by intravenous (IV) infusion over 60 minutes (after appropriate hydration or according to the institutional guidelines), on Day 1 of each 21-day cycle. Pretreatment hydration included 1 liter of normal saline by IV infusion over 120 minutes. Posttreatment hydration included 500 mL normal saline over 60 minutes. The dose level of golvatinib was to be escalated (to 300 and 400 mg) for additional cohorts after 3 participants enrolled into a given cohort unless there was a dose-limiting toxicity (DLT) in the first 3 participants.

Other Adverse Events

	Phase 1b: Golvatinib+Capecitabine+Cisplatin

Total, Other (not including serious) Adverse Events	
# participants affected / at risk	7/7 (100.00%)
Blood and lymphatic system disorders	
Anaemia † 1	
# participants affected / at risk	3/7 (42.86%)
Leukopenia † 1	
# participants affected / at risk	3/7 (42.86%)
Neutropenia † 1	
# participants affected / at risk	3/7 (42.86%)
Thrombocytopenia † 1	
# participants affected / at risk	2/7 (28.57%)
Leukocytosis † 1	
# participants affected / at risk	1/7 (14.29%)
Cardiac disorders	
Arteriosclerosis coronary artery † 1	
# participants affected / at risk	1/7 (14.29%)
Palpitations † 1	
# participants affected / at risk	1/7 (14.29%)
Supraventricular tachycardia † 1	
# participants affected / at risk	1/7 (14.29%)
Eye disorders	
Eye discharge † 1	
# participants affected / at risk	1/7 (14.29%)
Lacrimation increased † 1	
# participants affected / at risk	1/7 (14.29%)
Vision blurred † 1	
# participants affected / at risk	1/7 (14.29%)
Gastrointestinal disorders	
Nausea † 1	
# participants affected / at risk	7/7 (100.00%)
Vomiting † 1	
# participants affected / at risk	5/7 (71.43%)
Constipation † 1	
# participants affected / at risk	3/7 (42.86%)
Diarrhoea † 1	
# participants affected / at risk	3/7 (42.86%)
Abdominal discomfort † 1	
# participants affected / at risk	1/7 (14.29%)
Abdominal distension † 1	
# participants affected / at risk	1/7 (14.29%)

Abdominal pain † 1	
# participants affected / at risk	1/7 (14.29%)
Abdominal pain upper † 1	
# participants affected / at risk	1/7 (14.29%)
Abdominal tenderness † 1	
# participants affected / at risk	1/7 (14.29%)
Dry mouth † 1	
# participants affected / at risk	1/7 (14.29%)
Dyspepsia † 1	
# participants affected / at risk	1/7 (14.29%)
Dysphagia † 1	
# participants affected / at risk	1/7 (14.29%)
Enteritis † 1	
# participants affected / at risk	1/7 (14.29%)
Glossodynia † 1	
# participants affected / at risk	1/7 (14.29%)
Oral pain † 1	
# participants affected / at risk	1/7 (14.29%)
Proctalgia † 1	
# participants affected / at risk	1/7 (14.29%)
Stomatitis † 1	
# participants affected / at risk	1/7 (14.29%)
General disorders	
Fatigue † 1	
# participants affected / at risk	5/7 (71.43%)
Asthenia † 1	
# participants affected / at risk	2/7 (28.57%)
Chest pain † 1	
# participants affected / at risk	2/7 (28.57%)
Chills † 1	
# participants affected / at risk	2/7 (28.57%)
Pyrexia † 1	
# participants affected / at risk	2/7 (28.57%)
Cold sweat † 1	
# participants affected / at risk	1/7 (14.29%)
Feeling cold † 1	
# participants affected / at risk	1/7 (14.29%)
Feeling hot † 1	
# participants affected / at risk	1/7 (14.29%)
Malaise † 1	
# participants affected / at risk	1/7 (14.29%)

Mucosal inflammation † 1	
# participants affected / at risk	1/7 (14.29%)
Oedema peripheral † 1	
# participants affected / at risk	1/7 (14.29%)
Pain † 1	
# participants affected / at risk	1/7 (14.29%)
Pallor † 1	
# participants affected / at risk	1/7 (14.29%)
Infections and infestations	
Nasopharyngitis † 1	
# participants affected / at risk	1/7 (14.29%)
Oropharyngeal candidiasis † 1	
# participants affected / at risk	1/7 (14.29%)
Pneumonia † 1	
# participants affected / at risk	1/7 (14.29%)
Streptococcal bacteraemia † 1	
# participants affected / at risk	1/7 (14.29%)
Urinary tract infection † 1	
# participants affected / at risk	1/7 (14.29%)
Injury, poisoning and procedural complications	
Contusion † 1	
# participants affected / at risk	2/7 (28.57%)
Investigations	
Weight decreased † 1	
# participants affected / at risk	2/7 (28.57%)
Blood alkaline phosphatase increased † 1	
# participants affected / at risk	1/7 (14.29%)
Breath sounds abnormal † 1	
# participants affected / at risk	1/7 (14.29%)
Electrocardiogram st segment elevation † 1	
# participants affected / at risk	1/7 (14.29%)
Metabolism and nutrition disorders	
Dehydration † 1	
# participants affected / at risk	5/7 (71.43%)
Decreased appetite † 1	
# participants affected / at risk	4/7 (57.14%)
Hypocalcaemia † 1	
# participants affected / at risk	3/7 (42.86%)
Dizziness † 1	
# participants affected / at risk	2/7 (28.57%)

Hypoalbuminaemia † 1	
# participants affected / at risk	2/7 (28.57%)
Hypokalaemia † 1	
# participants affected / at risk	2/7 (28.57%)
Hypomagnesaemia † 1	
# participants affected / at risk	2/7 (28.57%)
Hyponatraemia † 1	
# participants affected / at risk	2/7 (28.57%)
Electrolyte imbalance † 1	
# participants affected / at risk	1/7 (14.29%)
Hyperglycaemia † 1	
# participants affected / at risk	1/7 (14.29%)
Hypoglycaemia † 1	
# participants affected / at risk	1/7 (14.29%)
Hypophosphataemia † 1	
# participants affected / at risk	1/7 (14.29%)
Musculoskeletal and connective tissue disorders	
Pain in extremity † 1	
# participants affected / at risk	2/7 (28.57%)
Arthralgia † 1	
# participants affected / at risk	1/7 (14.29%)
Back pain † 1	
# participants affected / at risk	1/7 (14.29%)
Muscle spasms † 1	
# participants affected / at risk	1/7 (14.29%)
Musculoskeletal pain † 1	
# participants affected / at risk	1/7 (14.29%)
Psoas abscess † 1	
# participants affected / at risk	1/7 (14.29%)
Scoliosis † 1	
# participants affected / at risk	1/7 (14.29%)
Spinal osteoarthritis † 1	
# participants affected / at risk	1/7 (14.29%)
Nervous system disorders	
Headache † 1	
# participants affected / at risk	3/7 (42.86%)
Ageusia † 1	
# participants affected / at risk	1/7 (14.29%)
Amnesia † 1	
# participants affected / at risk	1/7 (14.29%)

Balance disorder † [1]	
# participants affected / at risk	1/7 (14.29%)
Convulsion † [1]	
# participants affected / at risk	1/7 (14.29%)
Hypoaesthesia † [1]	
# participants affected / at risk	1/7 (14.29%)
Neuralgia † [1]	
# participants affected / at risk	1/7 (14.29%)
Neuropathy peripheral † [1]	
# participants affected / at risk	1/7 (14.29%)
Paraesthesia † [1]	
# participants affected / at risk	1/7 (14.29%)
Peripheral sensory neuropathy † [1]	
# participants affected / at risk	1/7 (14.29%)
Trigeminal neuralgia † [1]	
# participants affected / at risk	1/7 (14.29%)
Psychiatric disorders	
Anxiety † [1]	
# participants affected / at risk	2/7 (28.57%)
Insomnia † [1]	
# participants affected / at risk	2/7 (28.57%)
Catatonia † [1]	
# participants affected / at risk	1/7 (14.29%)
Depression † [1]	
# participants affected / at risk	1/7 (14.29%)
Mood swings † [1]	
# participants affected / at risk	1/7 (14.29%)
Restlessness † [1]	
# participants affected / at risk	1/7 (14.29%)
Renal and urinary disorders	
Haematuria † [1]	
# participants affected / at risk	1/7 (14.29%)
Nocturia † [1]	
# participants affected / at risk	1/7 (14.29%)
Renal failure acute † [1]	
# participants affected / at risk	1/7 (14.29%)
Respiratory, thoracic and mediastinal disorders	
Cough † [1]	
# participants affected / at risk	1/7 (14.29%)
Diaphragmatic paralysis † [1]	

# participants affected / at risk	1/7 (14.29%)
Dyspnoea † 1	
# participants affected / at risk	1/7 (14.29%)
Epistaxis † 1	
# participants affected / at risk	1/7 (14.29%)
Hiccups † 1	
# participants affected / at risk	1/7 (14.29%)
Hypoxia † 1	
# participants affected / at risk	1/7 (14.29%)
Increased upper airway secretion † 1	
# participants affected / at risk	1/7 (14.29%)
Nasal dryness † 1	
# participants affected / at risk	1/7 (14.29%)
Oropharyngeal pain † 1	
# participants affected / at risk	1/7 (14.29%)
Paranasal sinus hypersecretion † 1	
# participants affected / at risk	1/7 (14.29%)
Tachypnoea † 1	
# participants affected / at risk	1/7 (14.29%)
Wheezing † 1	
# participants affected / at risk	1/7 (14.29%)
Skin and subcutaneous tissue disorders	
Palmar-Plantar erythrodysaesthesia Syndrome † 1	
# participants affected / at risk	4/7 (57.14%)
Rash † 1	
# participants affected / at risk	2/7 (28.57%)
Decubitus ulcer † 1	
# participants affected / at risk	1/7 (14.29%)
Dry skin † 1	
# participants affected / at risk	1/7 (14.29%)
Erythema † 1	
# participants affected / at risk	1/7 (14.29%)
Rash generalised † 1	
# participants affected / at risk	1/7 (14.29%)
Scab † 1	
# participants affected / at risk	1/7 (14.29%)
Vascular disorders	
Hypotension † 1	
# participants affected / at risk	1/7 (14.29%)
Pulmonary embolism † 1	
# participants affected / at risk	1/7 (14.29%)

† Events were collected by systematic assessment
1 Term from vocabulary, MedDRA Version 15.0

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

The study was terminated prior to enrollment in Phase 2.

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: No text entered.

Results Point of Contact:

Name/Title: Eisai Medical Services
Organization: Eisai Inc.
phone: 888-422-4743

Responsible Party: Eisai Inc.
ClinicalTrials.gov Identifier: NCT01355302 History of Changes
Other Study ID Numbers: E7050-703

	2011-000774-58 (EudraCT Number)
Study First Received:	May 16, 2011
Results First Received:	January 19, 2017
Last Updated:	April 7, 2017

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