E7080 in Combination With Carboplatin + Gemcitabine Versus Carboplatin + Gemcitabine Alone as Second Line Therapy in Patients With Platinum-Sensitive Recurrent Ovarian Cancer by CA125

This study has been terminated.
(poor accrual)

Sponsor:
Eisai Inc.

Collaborator:
PharmaBio Development Inc.

Information provided by (Responsible Party):
Eisai Inc.

ClinicalTrials.gov Identifier:
NCT01133756

First received: May 21, 2010
Last updated: October 11, 2016
Last verified: October 2016
History of Changes

Results First Received: February 16, 2016

Study Type:	Interventional
Study Design:	Allocation: Randomized; Endpoint Classification: Safety/Efficacy Study; Intervention Model: Parallel Assignment; Masking: Open Label; Primary Purpose: Treatment
Condition:	Ovarian Cancer
Interventions:	Drug: Lenvatinib Drug: Carboplatin Drug: Gemcitabine

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
Approximately, 100 participants were planned to be enrolled (10-20 in Phase 1b and 80 in Phase 2) but only 7 participants were enrolled.

Reporting Groups

	Description

Lenvatinib 16 mg (Day 1 to Day 21) + Carboplatin + Gemcitabine	Participants received carboplatin (area under the concentration-time curve [AUC] 4) + gemcitabine (1000 mg/m2) intravenous (IV) infusion over 30 minutes in combination with lenvatinib 16 mg on Day 1 of 21-day cycle and gemcitabine (1000 mg/m2) alone on Day 8 of the cycle.
Lenvatinib 16 mg (Day 2 to Day 21) + Carboplatin + Gemcitabine	Participants received carboplatin (AUC 4) + gemcitabine (1000 mg/m2) IV infusion over 30 minutes in combination with lenvatinib 16 mg on Day 2 of 21-day cycle and gemcitabine (1000 mg/m2) alone on Day 8 of the cycle.
Lenvatinib 8 mg (Day 2 to Day 21) + Carboplatin + Gemcitabine	Participants received carboplatin (AUC 4) + gemcitabine (1000 mg/m2) IV infusion over 30 minutes in combination with lenvatinib 8 mg on Day 2 of 21-day cycle and gemcitabine (1000 mg/m2) alone on Day 8 of the cycle.

Participant Flow: Overall Study

	Lenvatinib 16 mg (Day 1 to Day 21) + Carboplatin + Gemcitabine	Lenvatinib 16 mg (Day 2 to Day 21) + Carboplatin + Gemcitabine	Lenvatinib 8 mg (Day 2 to Day 21) + Carboplatin + Gemcitabine
STARTED	2	3	2
Completed 6 Cycles	1 [1]	0	0
COMPLETED	0	0	0
NOT COMPLETED	2	3	2
Adverse Event	1	2	1
Investigator Decision	1	0	0
Withdrawal by Subject	0	1	0
Progression of Disease	0	0	1

[1] One participant completed 6 cycles and remained in the study until 18 Sep 2012.

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
Lenvatinib 16 mg (Day 1 to Day 21) + Carboplatin + Gemcitabine	Participants received carboplatin (AUC 4) + gemcitabine (1000 mg/m2) IV infusion over 30 minutes in combination with lenvatinib 16 mg on Day 1 of 21-day cycle and gemcitabine (1000 mg/m2) alone on Day 8 of the cycle.
Lenvatinib 16 mg (Day 2 to Day 21) + Carboplatin + Gemcitabine	Participants received carboplatin (AUC 4) + gemcitabine (1000 mg/m2) IV infusion over 30 minutes in combination with lenvatinib 16 mg on Day 2 of 21-day cycle and gemcitabine (1000 mg/m2) alone on Day 8 of the cycle.
Lenvatinib 8 mg (Day 2 to Day 21) + Carboplatin + Gemcitabine	Participants received carboplatin (AUC 4) + gemcitabine (1000 mg/m2) IV infusion over 30 minutes in combination with lenvatinib 8 mg on Day 2 of 21-

	day cycle and gemcitabine (1000 mg/m2) alone on Day 8 of the cycle.
Total	Total of all reporting groups

Baseline Measures

	Lenvatinib 16 mg (Day 1 to Day 21) + Carboplatin + Gemcitabine	Lenvatinib 16 mg (Day 2 to Day 21) + Carboplatin + Gemcitabine	Lenvatinib 8 mg (Day 2 to Day 21) + Carboplatin + Gemcitabine	Total
Overall Participants Analyzed [Units: Participants]	**2**	**3**	**2**	**7**
Age [Units: Participants]				
<=18 years	**0**	**0**	**0**	**0**
Between 18 and 65 years	**0**	**0**	**0**	**0**
>=65 years	**2**	**3**	**2**	**7**
Gender [Units: Participants]				
Female	**2**	**3**	**2**	**7**
Male	**0**	**0**	**0**	**0**

Outcome Measures

Hide All Outcome Measures

1. Primary: Number of Participants With Dose Limiting Toxicity (DLT) [Time Frame: Cycle 1 (21 days)]

Measure Type	Primary
Measure Title	Number of Participants With Dose Limiting Toxicity (DLT)
Measure Description	DLTs were defined as clinically significant adverse events occurring less than or equal to 21 days after commencing study treatment and considered to be possibly or probably related to study treatment by the Investigator. If 1 DLT occurred at any dose level, the cohort was to be expanded to include a maximum of six evaluable subjects. If 2 DLTs occurred at any dose level, the maximum tolerated dose (MTD) was to be either defined as the preceding dose, or an intermediate dose. To evaluate an intermediate dose, an additional dose cohort could be added to more accurately define the MTD.
Time Frame	Cycle 1 (21 days)
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.
Safety analysis was evaluated based on Safety Population, defined as all subjects enrolled into the Phase 1b portion of this study, except for those who (i) dropped out of the study prior to receiving any study drug, or (ii) were without any safety assessments following the first dose of study drug.

Reporting Groups

	Description
Lenvatinib 16 mg (Day 1 to Day 21) + Carboplatin + Gemcitabine	Participants received carboplatin (AUC 4) + gemcitabine (1000 mg/m2) IV infusion over 30 minutes in combination with lenvatinib 16 mg on Day 1 of 21-

	day cycle and gemcitabine (1000 mg/m2) alone on Day 8 of the cycle.
Lenvatinib 16 mg (Day 2 to Day 21) + Carboplatin + Gemcitabine	Participants received carboplatin (AUC 4) + gemcitabine (1000 mg/m2) IV infusion over 30 minutes in combination with lenvatinib 16 mg on Day 2 of 21-day cycle and gemcitabine (1000 mg/m2) alone on Day 8 of the cycle.
Lenvatinib 8 mg (Day 2 to Day 21) + Carboplatin + Gemcitabine	Participants received carboplatin (AUC 4) + gemcitabine (1000 mg/m2) IV infusion over 30 minutes in combination with lenvatinib 8 mg on Day 2 of 21-day cycle and gemcitabine (1000 mg/m2) alone on Day 8 of the cycle.

Measured Values

	Lenvatinib 16 mg (Day 1 to Day 21) + Carboplatin + Gemcitabine	Lenvatinib 16 mg (Day 2 to Day 21) + Carboplatin + Gemcitabine	Lenvatinib 8 mg (Day 2 to Day 21) + Carboplatin + Gemcitabine
Participants Analyzed [Units: Participants]	**2**	**3**	**2**
Number of Participants With Dose Limiting Toxicity (DLT) [Units: Participants]			
Platelet count decreased	**1**	**0**	**0**
Thrombocytopenia	**0**	**2**	**0**

No statistical analysis provided for Number of Participants With Dose Limiting Toxicity (DLT)

2. Secondary: Biomarker CA125-based Overall Response Rate (B-ORR), Within Treatment Group [Time Frame: Day 1 of every cycle, at end of treatment visit and every 2 months during follow-up period for patients who complete study without progressive disease.]

Measure Type	Secondary
Measure Title	Biomarker CA125-based Overall Response Rate (B-ORR), Within Treatment Group
Measure Description	Due to the limited enrollment despite significant diligence to boost enrollment and the complex study design required to manage hematologic toxicity, the study was terminated before the initiation of Phase 2. Hence the analysis was not conducted.
Time Frame	Day 1 of every cycle, at end of treatment visit and every 2 months during follow-up period for patients who complete study without progressive disease.
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.
Due to the limited enrollment despite significant diligence to boost enrollment and the complex study design required to manage hematologic toxicity, the study was terminated before the initiation of Phase 2. Hence the analysis was not conducted.

Reporting Groups

	Description
Lenvatinib 16 mg (Day 1 to Day 21) + Carboplatin + Gemcitabine	Participants received carboplatin (AUC 4) + gemcitabine (1000 mg/m2) IV infusion over 30 minutes in combination with lenvatinib 16 mg on Day 1 of 21-day cycle and gemcitabine (1000 mg/m2) alone on Day 8 of the cycle.
Lenvatinib 16 mg (Day 2 to Day 21) + Carboplatin + Gemcitabine	Participants received carboplatin (AUC 4) + gemcitabine (1000 mg/m2) IV infusion over 30 minutes in combination with lenvatinib 16 mg on Day 2 of 21-day cycle and gemcitabine (1000 mg/m2) alone on Day 8 of the cycle.

Lenvatinib 8 mg (Day 2 to Day 21) + Carboplatin + Gemcitabine	Participants received carboplatin (AUC 4) + gemcitabine (1000 mg/m2) IV infusion over 30 minutes in combination with lenvatinib 8 mg on Day 2 of 21-day cycle and gemcitabine (1000 mg/m2) alone on Day 8 of the cycle.

Measured Values

	Lenvatinib 16 mg (Day 1 to Day 21) + Carboplatin + Gemcitabine	Lenvatinib 16 mg (Day 2 to Day 21) + Carboplatin + Gemcitabine	Lenvatinib 8 mg (Day 2 to Day 21) + Carboplatin + Gemcitabine
Participants Analyzed [Units: Participants]	**0**	**0**	**0**
Biomarker CA125-based Overall Response Rate (B-ORR), Within Treatment Group			

No statistical analysis provided for Biomarker CA125-based Overall Response Rate (B-ORR), Within Treatment Group

3. Secondary: Biomarker-based Proportion of Biomarker-Progression-Free Survival (B-PFS) at Week 12, Within Treatment Group [Time Frame: Week 12]

Measure Type	Secondary
Measure Title	Biomarker-based Proportion of Biomarker-Progression-Free Survival (B-PFS) at Week 12, Within Treatment Group
Measure Description	Due to the limited enrollment despite significant diligence to boost enrollment and the complex study design required to manage hematologic toxicity, the study was terminated before the initiation of Phase 2. Hence the analysis was not conducted.
Time Frame	Week 12
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.
Due to the limited enrollment despite significant diligence to boost enrollment and the complex study design required to manage hematologic toxicity, the study was terminated before the initiation of Phase 2. Hence the analysis was not conducted.

Reporting Groups

	Description
Lenvatinib 16 mg (Day 1 to Day 21) + Carboplatin + Gemcitabine	Participants received carboplatin (AUC 4) + gemcitabine (1000 mg/m2) IV infusion over 30 minutes in combination with lenvatinib 16 mg on Day 1 of 21-day cycle and gemcitabine (1000 mg/m2) alone on Day 8 of the cycle.
Lenvatinib 16 mg (Day 2 to Day 21) + Carboplatin + Gemcitabine	Participants received carboplatin (AUC 4) + gemcitabine (1000 mg/m2) IV infusion over 30 minutes in combination with lenvatinib 16 mg on Day 2 of 21-day cycle and gemcitabine (1000 mg/m2) alone on Day 8 of the cycle.
Lenvatinib 8 mg (Day 2 to Day 21) + Carboplatin + Gemcitabine	Participants received carboplatin (AUC 4) + gemcitabine (1000 mg/m2) IV infusion over 30 minutes in combination with lenvatinib 8 mg on Day 2 of 21-day cycle and gemcitabine (1000 mg/m2) alone on Day 8 of the cycle.

Measured Values

	Lenvatinib 16 mg (Day 1 to Day 21) + Carboplatin +	Lenvatinib 16 mg (Day 2 to Day 21) + Carboplatin +	Lenvatinib 8 mg (Day 2 to Day 21) + Carboplatin +

	Gemcitabine	Gemcitabine	Gemcitabine
Participants Analyzed [Units: Participants]	**0**	**0**	**0**
Biomarker-based Proportion of Biomarker-Progression-Free Survival (B-PFS) at Week 12, Within Treatment Group			

No statistical analysis provided for Biomarker-based Proportion of Biomarker-Progression-Free Survival (B-PFS) at Week 12, Within Treatment Group

Serious Adverse Events

Hide Serious Adverse Events

Time Frame	For each participant, from the first dose till 30 days after the last dose or up to 18 Sep 2012 or up to 2.5 years
Additional Description	Treatment emergent adverse events (defined as an adverse event (serious or non-serious) that started/increased in severity on/after the first dose of study medication up to 30 days after the final dose of study medication) are reported.

Reporting Groups

	Description
Lenvatinib 16 mg (Day 1 to Day 21) + Carboplatin + Gemcitabine	Participants received carboplatin (AUC 4) + gemcitabine (1000 mg/m2) IV infusion over 30 minutes in combination with lenvatinib 16 mg on Day 1 of 21-day cycle and gemcitabine (1000 mg/m2) alone on Day 8 of the cycle.
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Serious Adverse Events

	Lenvatinib 16 mg (Day 1 to Day 21) + Carboplatin + Gemcitabine	Lenvatinib 16 mg (Day 2 to Day 21) + Carboplatin + Gemcitabine	Lenvatinib 8 mg (Day 2 to Day 21) + Carboplatin + Gemcitabine
Total, serious adverse events			
# participants affected / at risk	**0/2 (0.00%)**	**0/3 (0.00%)**	**0/2 (0.00%)**

Other Adverse Events

Hide Other Adverse Events

Time Frame	For each participant, from the first dose till 30 days after the last dose or up to 18 Sep 2012 or up to 2.5 years
Additional Description	Treatment emergent adverse events (defined as an adverse event (serious or non-serious) that started/increased in severity on/after the first dose of study medication up to 30 days after the final dose of study medication) are reported.

Frequency Threshold

Threshold above which other adverse events are reported	5

Reporting Groups

	Description
Lenvatinib 16 mg (Day 1 to Day 21) + Carboplatin + Gemcitabine	Participants received carboplatin (AUC 4) + gemcitabine (1000 mg/m2) IV infusion over 30 minutes in combination with lenvatinib 16 mg on Day 1 of 21-day cycle and gemcitabine (1000 mg/m2) alone on Day 8 of the cycle.
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Other Adverse Events

	Lenvatinib 16 mg (Day 1 to Day 21) + Carboplatin + Gemcitabine	Lenvatinib 16 mg (Day 2 to Day 21) + Carboplatin + Gemcitabine	Lenvatinib 8 mg (Day 2 to Day 21) + Carboplatin + Gemcitabine
Total, other (not including serious) adverse events			
# participants affected / at risk	**2/2 (100.00%)**	**2/3 (66.67%)**	**1/2 (50.00%)**
Blood and lymphatic system disorders			
ANAEMIA † 1			
# participants affected / at risk	**1/2 (50.00%)**	**2/3 (66.67%)**	**1/2 (50.00%)**
NEUTROPENIA † 1			
# participants affected / at risk	**1/2 (50.00%)**	**2/3 (66.67%)**	**1/2 (50.00%)**
THROMBOCYTOPENIA † 1			
# participants affected / at risk	**1/2 (50.00%)**	**2/3 (66.67%)**	**1/2 (50.00%)**
Cardiac disorders			
BRADYCARDIA † 1			
# participants affected / at risk	**0/2 (0.00%)**	**1/3 (33.33%)**	**0/2 (0.00%)**
Gastrointestinal disorders			
ABDOMINAL DISCOMFORT † 1			
# participants affected / at risk	**0/2 (0.00%)**	**0/3 (0.00%)**	**1/2 (50.00%)**
ABDOMINAL DISTENSION † 1			
# participants affected / at risk	**0/2 (0.00%)**	**0/3 (0.00%)**	**1/2 (50.00%)**
ABDOMINAL PAIN † 1			
# participants affected / at risk	**0/2 (0.00%)**	**0/3 (0.00%)**	**1/2 (50.00%)**

ABDOMINAL PAIN UPPER † 1			
# participants affected / at risk	1/2 (50.00%)	0/3 (0.00%)	0/2 (0.00%)
CONSTIPATION † 1			
# participants affected / at risk	1/2 (50.00%)	1/3 (33.33%)	1/2 (50.00%)
DIARRHOEA † 1			
# participants affected / at risk	1/2 (50.00%)	0/3 (0.00%)	1/2 (50.00%)
DRY MOUTH † 1			
# participants affected / at risk	0/2 (0.00%)	0/3 (0.00%)	1/2 (50.00%)
FLATULENCE † 1			
# participants affected / at risk	1/2 (50.00%)	0/3 (0.00%)	0/2 (0.00%)
LIP SWELLING † 1			
# participants affected / at risk	0/2 (0.00%)	1/3 (33.33%)	0/2 (0.00%)
NAUSEA † 1			
# participants affected / at risk	1/2 (50.00%)	1/3 (33.33%)	0/2 (0.00%)
ORAL DISORDER † 1			
# participants affected / at risk	0/2 (0.00%)	1/3 (33.33%)	0/2 (0.00%)
STOMATITIS † 1			
# participants affected / at risk	0/2 (0.00%)	0/3 (0.00%)	1/2 (50.00%)
VOMITING † 1			
# participants affected / at risk	1/2 (50.00%)	0/3 (0.00%)	1/2 (50.00%)
General disorders			
CHEST PAIN † 1			
# participants affected / at risk	1/2 (50.00%)	0/3 (0.00%)	0/2 (0.00%)
FATIGUE † 1			
# participants affected / at risk	1/2 (50.00%)	2/3 (66.67%)	1/2 (50.00%)
OEDEMA PERIPHERAL † 1			
# participants affected / at risk	1/2 (50.00%)	0/3 (0.00%)	0/2 (0.00%)
Hepatobiliary disorders			
HYPERBILIRUBINAEMIA † 1			
# participants affected / at risk	1/2 (50.00%)	0/3 (0.00%)	0/2 (0.00%)
Immune system disorders			
SEASONAL ALLERGY † 1			
# participants affected / at risk	0/2 (0.00%)	0/3 (0.00%)	1/2 (50.00%)
Infections and infestations			

ABSCESS NECK † 1			
# participants affected / at risk	1/2 (50.00%)	0/3 (0.00%)	0/2 (0.00%)
GASTROENTERITIS VIRAL † 1			
# participants affected / at risk	0/2 (0.00%)	1/3 (33.33%)	0/2 (0.00%)
LOCALISED INFECTION † 1			
# participants affected / at risk	1/2 (50.00%)	0/3 (0.00%)	0/2 (0.00%)
NASOPHARYNGITIS † 1			
# participants affected / at risk	1/2 (50.00%)	0/3 (0.00%)	0/2 (0.00%)
URINARY TRACT INFECTION † 1			
# participants affected / at risk	0/2 (0.00%)	0/3 (0.00%)	1/2 (50.00%)
Injury, poisoning and procedural complications			
INCISIONAL HERNIA † 1			
# participants affected / at risk	1/2 (50.00%)	0/3 (0.00%)	0/2 (0.00%)
Investigations			
BLOOD ALBUMIN DECREASED † 1			
# participants affected / at risk	1/2 (50.00%)	0/3 (0.00%)	0/2 (0.00%)
BLOOD MAGNESIUM DECREASED † 1			
# participants affected / at risk	1/2 (50.00%)	0/3 (0.00%)	0/2 (0.00%)
BLOOD PRESSURE INCREASED † 1			
# participants affected / at risk	1/2 (50.00%)	0/3 (0.00%)	0/2 (0.00%)
HAEMATOCRIT DECREASED † 1			
# participants affected / at risk	1/2 (50.00%)	0/3 (0.00%)	0/2 (0.00%)
LYMPHOCYTE COUNT DECREASED † 1			
# participants affected / at risk	0/2 (0.00%)	1/3 (33.33%)	0/2 (0.00%)
WHITE BLOOD CELL COUNT DECREASED † 1			
# participants affected / at risk	0/2 (0.00%)	1/3 (33.33%)	0/2 (0.00%)
Metabolism and nutrition disorders			
DECREASED APPETITE † 1			
# participants affected / at risk	0/2 (0.00%)	0/3 (0.00%)	1/2 (50.00%)

HYPOKALAEMIA † 1			
# participants affected / at risk	0/2 (0.00%)	0/3 (0.00%)	1/2 (50.00%)
HYPOMAGNESAEMIA † 1			
# participants affected / at risk	1/2 (50.00%)	0/3 (0.00%)	1/2 (50.00%)
Musculoskeletal and connective tissue disorders			
ARTHRALGIA † 1			
# participants affected / at risk	1/2 (50.00%)	0/3 (0.00%)	0/2 (0.00%)
Nervous system disorders			
DYSGEUSIA † 1			
# participants affected / at risk	1/2 (50.00%)	0/3 (0.00%)	0/2 (0.00%)
HEADACHE † 1			
# participants affected / at risk	1/2 (50.00%)	0/3 (0.00%)	0/2 (0.00%)
NEUROPATHY PERIPHERAL † 1			
# participants affected / at risk	1/2 (50.00%)	0/3 (0.00%)	0/2 (0.00%)
TREMOR † 1			
# participants affected / at risk	1/2 (50.00%)	0/3 (0.00%)	0/2 (0.00%)
Renal and urinary disorders			
PROTEINURIA † 1			
# participants affected / at risk	1/2 (50.00%)	1/3 (33.33%)	0/2 (0.00%)
Reproductive system and breast disorders			
BREAST MASS † 1			
# participants affected / at risk	1/2 (50.00%)	0/3 (0.00%)	0/2 (0.00%)
Respiratory, thoracic and mediastinal disorders			
COUGH † 1			
# participants affected / at risk	1/2 (50.00%)	1/3 (33.33%)	0/2 (0.00%)
DYSPNOEA † 1			
# participants affected / at risk	1/2 (50.00%)	1/3 (33.33%)	0/2 (0.00%)
HICCUPS † 1			
# participants affected / at risk	0/2 (0.00%)	0/3 (0.00%)	1/2 (50.00%)
OROPHARYNGEAL PAIN † 1			
# participants affected / at risk	0/2 (0.00%)	0/3 (0.00%)	1/2 (50.00%)
RHINORRHOEA † 1			

# participants affected / at risk	0/2 (0.00%)	0/3 (0.00%)	1/2 (50.00%)
Skin and subcutaneous tissue disorders			
DERMATITIS ACNEIFORM † 1			
# participants affected / at risk	1/2 (50.00%)	0/3 (0.00%)	0/2 (0.00%)
RASH † 1			
# participants affected / at risk	0/2 (0.00%)	1/3 (33.33%)	0/2 (0.00%)
SKIN ATROPHY † 1			
# participants affected / at risk	0/2 (0.00%)	1/3 (33.33%)	0/2 (0.00%)
SWELLING FACE † 1			
# participants affected / at risk	0/2 (0.00%)	1/3 (33.33%)	0/2 (0.00%)
Vascular disorders			
HYPERTENSION † 1			
# participants affected / at risk	0/2 (0.00%)	2/3 (66.67%)	0/2 (0.00%)
THROMBOSIS † 1			
# participants affected / at risk	1/2 (50.00%)	0/3 (0.00%)	0/2 (0.00%)

† Events were collected by systematic assessment
1 Term from vocabulary, CTCAE version 4.0.

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

Due to the limited enrollment despite significant diligence to boost enrollment and the complex study design required to manage hematologic toxicity, the study was terminated before the initiation of 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: 1-888-422-4743
e-mail: esi_medinfo@eisai.com

Responsible Party:	Eisai Inc.
ClinicalTrials.gov Identifier:	NCT01133756 History of Changes
Other Study ID Numbers:	E7080-701 2009-016050-41 (EudraCT Number)
Study First Received:	May 21, 2010
Results First Received:	February 16, 2016
Last Updated:	October 11, 2016
Health Authority:	France: Afssaps - Agence française de sécurité sanitaire des produits de santé (Saint-Denis) Italy: Ministry of Health Poland: Office for Registration of Medicinal Products, Medical Devices and Biocidal Products Russia: Ministry of Health of the Russian Federation Ukraine: State Pharmacological Center - Ministry of Health United States: Food and Drug Administration

TO TOP

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