

**Clinical trial results:****An Open Label Extension Study of the Efficacy of MORAb-003 in Subjects with Platinum-Sensitive Epithelial Ovarian Cancer in First Relapse****Summary**

EudraCT number	2009-015825-36
Trial protocol	DE
Global end of trial date	05 March 2013

**Results information**

Result version number	v1
This version publication date	13 July 2016
First version publication date	15 August 2015

**Trial information****Trial identification**

Sponsor protocol code	MORAb-003-002A
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**Additional study identifiers**

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01018563
WHO universal trial number (UTN)	-

Notes:

**Sponsors**

Sponsor organisation name	Morphotek (subsidiary of Eisai)
Sponsor organisation address	210 Welsh Pool Road, Exton, United States, 19341
Public contact	Eisai Call Center, Eisai Inc., 888 422-4743,
Scientific contact	Eisai Call Center, Eisai Inc, 888 422-4743,

Notes:

**Paediatric regulatory details**

Is trial part of an agreed paediatric investigation plan (PIP)	No
Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	No
Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	No

Notes:

## Results analysis stage

Analysis stage	Final
Date of interim/final analysis	05 March 2013
Is this the analysis of the primary completion data?	No
Global end of trial reached?	Yes
Global end of trial date	05 March 2013
Was the trial ended prematurely?	Yes

Notes:

## General information about the trial

Main objective of the trial:

To provide MORAb-003 to subjects who are enrolled in the protocol MORAb-003-002 and appear to be deriving benefit

Protection of trial subjects:

This study was conducted in accordance with standard operating procedures (SOPs) of the Sponsor (or designee), which are designed to ensure adherence to Good Clinical Practice (GCP) guidelines as required by the following:

- Principles of the World Medical Association Declaration of Helsinki (World Medical Association, 2008)
- ICH E6 Guideline for GCP (CPMP/ICH/135/95) of the European Agency for the Evaluation of Medicinal Products, Committee for Proprietary Medicinal Products, International Conference on Harmonisation of Pharmaceuticals for Human Use (2002)
- Title 21 of the United States (US) Code of Federal Regulations (US 21 CFR) regarding clinical studies, including Part 50 and Part 56 concerning informed subject consent and Institutional Review Board (IRB) regulations and applicable sections of US 21 CFR Part 312 (2013)
- European Clinical Trial Directive 2005/28/EC and European Clinical Trial Directive 2001/20/EC for studies conducted within any European Union (EU) country. All suspected unexpected serious adverse reactions (SUSARs) were reported, as required, to the Competent Authorities of all involved EU member states.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	20 January 2010
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

## Population of trial subjects

### Subjects enrolled per country

Country: Number of subjects enrolled	United States: 2
Country: Number of subjects enrolled	Germany: 1
Worldwide total number of subjects	3
EEA total number of subjects	1

Notes:

### Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37 wk	0

Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	2
From 65 to 84 years	1
85 years and over	0

## Subject disposition

### Recruitment

Recruitment details:

Subjects must have participated in the MORAb-003-002 parent study, achieved normalization of cancer antigen 125 levels and/or tumor assessment of complete response, partial response, (or stable disease and an investigator's assessment of a clinical benefit) after receiving farletuzumab in combination with standard chemotherapy to enter this study.

### Pre-assignment

Screening details: -

### Pre-assignment period milestones

Number of subjects started	3
Intermediate milestone: Number of subjects	Eligible from MORAB-003-002: 3
Number of subjects completed	3

### Period 1

Period 1 title	Overall Study (overall period)
Is this the baseline period?	Yes
Allocation method	Not applicable
Blinding used	Not blinded

### Arms

Arm title	Farletuzumab
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Arm description:

Farletuzumab was initially administered by intravenous (IV) infusion once weekly at the same dose subjects were receiving in the MORAb-003-002 (NCT00318370) parent study (ie, 62.5 or 100 mg/m<sup>2</sup>). Dosage was changed per protocol amendment 12 May 2011 to 3 times the initial dosage (ie, 187.5 or 300 mg/m<sup>2</sup>) administered every 3 weeks (Q3W).

Arm type	Experimental
Investigational medicinal product name	Farletuzumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection/infusion
Routes of administration	Intravenous use

Dosage and administration details:

Farletuzumab was initially administered by IV infusion once weekly at the same dose subjects were receiving in the MORAb-003-002 parent study (ie, 62.5 or 100 mg/m<sup>2</sup>); dosage was changed per protocol amendment 12 May 2011 to 3 times the initial dosage (ie, 187.5 or 300 mg/m<sup>2</sup>) administered Q3W. Farletuzumab was continued as a single-agent maintenance therapy until relapse. If the second relapse was platinum-sensitive (platinum-free interval >6 months), the subject could receive carboplatin and taxane chemotherapy in combination with farletuzumab for an additional 6 cycles followed by single-agent farletuzumab maintenance therapy.

<b>Number of subjects in period 1</b>	Farletuzumab
Started	3
Completed	0
Not completed	3
Discontinuation of the study by sponsor	3

## Baseline characteristics

### Reporting groups

Reporting group title	Overall Study
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Reporting group description: -

Reporting group values	Overall Study	Total	
Number of subjects	3	3	
Age categorical Units: Subjects			
Adults (18-64 years)	2	2	
From 65-84 years	1	1	
Age continuous Units: years			
median	58		
full range (min-max)	38 to 74	-	
Gender categorical Units: Subjects			
Female	3	3	
Male	0	0	

## End points

### End points reporting groups

Reporting group title	Farletuzumab
Reporting group description: Farletuzumab was initially administered by intravenous (IV) infusion once weekly at the same dose subjects were receiving in the MORAb-003-002 (NCT00318370) parent study (ie, 62.5 or 100 mg/m <sup>2</sup> ). Dosage was changed per protocol amendment 12 May 2011 to 3 times the initial dosage (ie, 187.5 or 300 mg/m <sup>2</sup> ) administered every 3 weeks (Q3W).	
Subject analysis set title	Farletuzumab (per GCIG criteria)
Subject analysis set type	Intention-to-treat
Subject analysis set description: Maintenance infusions of farletuzumab in subjects with platinum-sensitive epithelial ovarian cancer in first relapse	
Subject analysis set title	Farletuzumab (CA125 criteria)
Subject analysis set type	Intention-to-treat
Subject analysis set description: Maintenance infusions of farletuzumab in subjects with platinum-sensitive epithelial ovarian cancer in first relapse	
Subject analysis set title	Farletuzumab (per RECIST)
Subject analysis set type	Intention-to-treat
Subject analysis set description: Maintenance infusions of farletuzumab in subjects with platinum-sensitive epithelial ovarian cancer in first relapse	
Subject analysis set title	Farletuzumab (62.5 mg/m <sup>2</sup> )
Subject analysis set type	Sub-group analysis
Subject analysis set description: Analysis set used for displaying duration of CA125 Response.	
Subject analysis set title	Farletuzumab (100 mg/m <sup>2</sup> )
Subject analysis set type	Sub-group analysis
Subject analysis set description: Analysis set used for displaying duration of CA125 Response.	

### Primary: Duration of ovarian tumor marker (CA125) response

End point title	Duration of ovarian tumor marker (CA125) response
End point description: The Duration of CA125 response, defined as the time from the date of the initial CA125 response (ie, prior to enrollment in the parent study) to the first documentation of progressive disease (PD) by either Gynecologic Cancer Inter Group (GCIG) criteria for CA125 level or Response Evaluation Criteria in Solid Tumors (RECIST) v.1.0 or by the date of death due to any cause, whichever occurred first. Disease progression as assessed by the investigator per RECIST v1.0 was defined as at least a 20% increase in sum of longest diameters (RECIST definition) compared to baseline (or lowest sum while on study if less than baseline), or any new lesions (measurable or nonmeasurable). Disease progression per CA125 was defined as the first of 2 consecutive CA125 values greater than twice the upper limit of normal. C= data censored at earlier non-PD assessment if PD did not occur.	
End point type	Primary
End point timeframe: From Baseline (Day 1) up to study completion i.e. approximately 3.2 years	

<b>End point values</b>	Farletuzumab	Farletuzumab (62.5 mg/m2)	Farletuzumab (100 mg/m2)	
Subject group type	Reporting group	Subject analysis set	Subject analysis set	
Number of subjects analysed	3	2	1	
Units: Months				
number (not applicable)				
Participant 003-1002 (dose group: 62.5 mg/m2)-C	77.2	77.2	0	
Participant 008-1004 (dose group: 62.5 mg/m2)-C	73.3	73.3	0	
Participant 028-1004 (dose group: 100 mg/m2)	18	0	18	

## Statistical analyses

<b>Statistical analysis title</b>	No analysis
Comparison groups	Farletuzumab (100 mg/m2) v Farletuzumab (62.5 mg/m2)
Number of subjects included in analysis	3
Analysis specification	Pre-specified
Analysis type	other <sup>[1]</sup>
Parameter estimate	Mean difference (final values)
Point estimate	57.25
Confidence interval	
level	95 %
sides	2-sided
lower limit	-999
upper limit	999

Notes:

[1] - No comparative analysis conducted. The study objective was to provide MORAb-003 to subjects who are enrolled in the protocol MORAb-003-002 and appear to be deriving benefit. A confidence interval cannot be calculated in this situation because the Dose Group 100 contains only 1 subject; no variability estimate can be derived and the pooled standard error of the treatment difference cannot be calculated.

## Secondary: Progression free survival (PFS) by Criteria Type

End point title	Progression free survival (PFS) by Criteria Type
End point description:	PFS was defined as the time from the date of first dose of study medication during the parent study to the date of disease progression (either by GCIG for CA125 criteria or RECIST v.1.0, whichever occurred first) or by the date of death due to any cause. Disease progression as assessed by the investigator per RECIST v1.0 was defined as at least a 20% increase in sum of longest diameters (RECIST definition) compared to baseline (or lowest sum while on study if less than baseline), or any new lesions (measurable or nonmeasurable). Disease progression per CA125 was defined as the first of 2 consecutive CA125 values greater than twice the upper limit of normal. C= data censored at earlier non-PD assessment if PD did not occur.
End point type	Secondary
End point timeframe:	From Baseline (Day 1) up to study completion i.e. approximately 3.2 years

<b>End point values</b>	Farletuzumab (per GCIG criteria)	Farletuzumab (CA125 criteria)	Farletuzumab (per RECIST)	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	3	3	3	
Units: Months				
number (not applicable)				
Participant 003-1002 (dose group: 62.5 mg/m <sup>2</sup> ) - C	77.8	77.9	77.8	
Participant 008-1004 (dose group: 62.5 mg/m <sup>2</sup> ) - C	75.8	76.5	75.8	
Participant 028-1004 (dose group: 100 mg/m <sup>2</sup> )	25.1	59.2	25.1	

### Statistical analyses

No statistical analyses for this end point

### Secondary: Overall Survival (OS)

End point title	Overall Survival (OS)
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End point description:

OS was defined from the date of first dose of study medication during the parent study to date of death due to any cause. Participants who were alive had their OS time censored at the date they were last known to be alive. C= censored data.

End point type	Secondary
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End point timeframe:

From Baseline (Day 1) until date of death from any cause or up to study completion i.e. approximately 3.2 years

<b>End point values</b>	Farletuzumab			
Subject group type	Reporting group			
Number of subjects analysed	3			
Units: Months				
number (not applicable)				
Participant 003-1002 (dose group: 62.5 mg/m <sup>2</sup> ) - C	78.3			
Participant 008-1004 (dose group: 62.5 mg/m <sup>2</sup> ) - C	76.7			
Participant 028-1004 (dose group: 100 mg/m <sup>2</sup> )	59.5			

### Statistical analyses

No statistical analyses for this end point

### Secondary: Duration of Second Remission

End point title	Duration of Second Remission
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End point description:

The prolongation of second and subsequent responses to chemotherapy plus farletuzumab relative to initial remission was assessed. Length of 1st remission in parent study was determined prior to entry in parent study. The 'length of 2nd remission (1st remission in this study)' was defined as the duration from the start of carboplatin/taxane therapy in parent study to the start date of carboplatin/taxane in this study. The length of 2nd remission is censored at date of study discontinuation if participant did not receive any carboplatin/taxane therapy during this study. C = censored data.

End point type	Secondary
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End point timeframe:

From Baseline (Day 1) until date of death from any cause or up to study completion i.e. approximately 3.2 years

End point values	Farletuzumab			
Subject group type	Reporting group			
Number of subjects analysed	3			
Units: Months				
number (not applicable)				
Participant 003-1002 (dose group: 62.5 mg/m <sup>2</sup> )	41			
Participant 008-1004 (dose group: 62.5 mg/m <sup>2</sup> ) - C	74.2			
Participant 028-1004 (dose group: 100 mg/m <sup>2</sup> )	29.5			

## Statistical analyses

No statistical analyses for this end point

## Secondary: Duration of Third Remission

End point title	Duration of Third Remission
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End point description:

The 'length of 3rd remission (2nd remission in this study)' is defined as the duration from the start of carboplatin/taxane therapy in this study to the start date of subsequent carboplatin/taxane in this study. The length of 3rd remission is censored at date of study discontinuation if participant did not receive subsequent carboplatin/taxane therapy during this study. C = censored data.

End point type	Secondary
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End point timeframe:

From Baseline (Day 1) until date of death from any cause or up to study completion i.e. approximately 3.2 years

End point values	Farletuzumab			
Subject group type	Reporting group			
Number of subjects analysed	3			
Units: Months				
number (not applicable)				
Participant 003-1002 (dose group: 62.5 mg/m <sup>2</sup> ) - C	37.3			

Participant 028-1004 (dose group: 100 mg/m2) - C	25			
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### **Statistical analyses**

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No statistical analyses for this end point

## Adverse events

### Adverse events information

Timeframe for reporting adverse events:

For each participant, from the first dose till 30 days after the last dose or up to study completion i.e. approximately 3.2 years

Adverse event reporting additional description:

Treatment emergent adverse events (TEAEs), defined as an AE 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 presented in this section. The data presented in the other AE section includes serious adverse events.

Assessment type	Systematic
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### Dictionary used

Dictionary name	MedDRA
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Dictionary version	14.1
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### Reporting groups

Reporting group title	Farletuzumab
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Reporting group description: -

<b>Serious adverse events</b>	Farletuzumab		
Total subjects affected by serious adverse events			
subjects affected / exposed	2 / 3 (66.67%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		
Investigations			
Neutrophil count decreased			
subjects affected / exposed	1 / 3 (33.33%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Lymphoma			
subjects affected / exposed	1 / 3 (33.33%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
General disorders and administration site conditions			
Disease progression			
subjects affected / exposed	1 / 3 (33.33%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Metabolism and nutrition disorders			

Dehydration			
subjects affected / exposed	1 / 3 (33.33%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		

Frequency threshold for reporting non-serious adverse events: 0 %

<b>Non-serious adverse events</b>	Farletuzumab		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	3 / 3 (100.00%)		
Vascular disorders			
Hypertension			
subjects affected / exposed	1 / 3 (33.33%)		
occurrences (all)	5		
Hypotension			
subjects affected / exposed	1 / 3 (33.33%)		
occurrences (all)	1		
Surgical and medical procedures			
Tooth extraction			
subjects affected / exposed	1 / 3 (33.33%)		
occurrences (all)	1		
General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	2 / 3 (66.67%)		
occurrences (all)	14		
Asthenia			
subjects affected / exposed	1 / 3 (33.33%)		
occurrences (all)	2		
Local swelling			
subjects affected / exposed	1 / 3 (33.33%)		
occurrences (all)	1		
Oedema peripheral			
subjects affected / exposed	1 / 3 (33.33%)		
occurrences (all)	4		
Respiratory, thoracic and mediastinal disorders			

Cough subjects affected / exposed occurrences (all)	1 / 3 (33.33%) 2		
Dyspnoea subjects affected / exposed occurrences (all)	1 / 3 (33.33%) 1		
Nasal congestion subjects affected / exposed occurrences (all)	1 / 3 (33.33%) 1		
Investigations			
Blood alkaline phosphatase increased subjects affected / exposed occurrences (all)	1 / 3 (33.33%) 2		
Haemoglobin decreased subjects affected / exposed occurrences (all)	1 / 3 (33.33%) 4		
Platelet count decreased subjects affected / exposed occurrences (all)	1 / 3 (33.33%) 2		
Red blood cell count decreased subjects affected / exposed occurrences (all)	1 / 3 (33.33%) 1		
White blood cell count decreased subjects affected / exposed occurrences (all)	1 / 3 (33.33%) 4		
Injury, poisoning and procedural complications			
Procedural pain subjects affected / exposed occurrences (all)	1 / 3 (33.33%) 4		
Traumatic haematoma subjects affected / exposed occurrences (all)	1 / 3 (33.33%) 1		
Nervous system disorders			
Headache subjects affected / exposed occurrences (all)	2 / 3 (66.67%) 95		

Tremor subjects affected / exposed occurrences (all)	1 / 3 (33.33%) 3		
Blood and lymphatic system disorders			
Iron deficiency anaemia subjects affected / exposed occurrences (all)	1 / 3 (33.33%) 1		
Leukopenia subjects affected / exposed occurrences (all)	1 / 3 (33.33%) 1		
Neutropenia subjects affected / exposed occurrences (all)	1 / 3 (33.33%) 2		
Thrombocytopenia subjects affected / exposed occurrences (all)	1 / 3 (33.33%) 2		
Eye disorders			
Eyelid oedema subjects affected / exposed occurrences (all)	1 / 3 (33.33%) 1		
Gastrointestinal disorders			
Diarrhoea subjects affected / exposed occurrences (all)	2 / 3 (66.67%) 9		
Nausea subjects affected / exposed occurrences (all)	2 / 3 (66.67%) 5		
Stomatitis subjects affected / exposed occurrences (all)	2 / 3 (66.67%) 2		
Abdominal distension subjects affected / exposed occurrences (all)	1 / 3 (33.33%) 1		
Abdominal pain subjects affected / exposed occurrences (all)	1 / 3 (33.33%) 1		
Colitis			

subjects affected / exposed occurrences (all)	1 / 3 (33.33%) 1		
Dry mouth subjects affected / exposed occurrences (all)	1 / 3 (33.33%) 1		
Dysphagia subjects affected / exposed occurrences (all)	1 / 3 (33.33%) 1		
Flatulence subjects affected / exposed occurrences (all)	1 / 3 (33.33%) 3		
Vomiting subjects affected / exposed occurrences (all)	1 / 3 (33.33%) 1		
Skin and subcutaneous tissue disorders			
Pruritus subjects affected / exposed occurrences (all)	1 / 3 (33.33%) 1		
Pruritus allergic subjects affected / exposed occurrences (all)	1 / 3 (33.33%) 1		
Rash subjects affected / exposed occurrences (all)	1 / 3 (33.33%) 2		
Swelling face subjects affected / exposed occurrences (all)	1 / 3 (33.33%) 1		
Musculoskeletal and connective tissue disorders			
Back pain subjects affected / exposed occurrences (all)	1 / 3 (33.33%) 3		
Myalgia subjects affected / exposed occurrences (all)	1 / 3 (33.33%) 1		
Neck pain			

subjects affected / exposed occurrences (all)	1 / 3 (33.33%) 1		
<b>Infections and infestations</b>			
Urinary tract infection subjects affected / exposed occurrences (all)	2 / 3 (66.67%) 2		
Fungal skin infection subjects affected / exposed occurrences (all)	1 / 3 (33.33%) 1		
Nasopharyngitis subjects affected / exposed occurrences (all)	1 / 3 (33.33%) 3		
Otitis media subjects affected / exposed occurrences (all)	1 / 3 (33.33%) 1		
Pharyngeal abscess subjects affected / exposed occurrences (all)	1 / 3 (33.33%) 1		
Tinea versicolour subjects affected / exposed occurrences (all)	1 / 3 (33.33%) 1		
Tooth infection subjects affected / exposed occurrences (all)	1 / 3 (33.33%) 1		
<b>Metabolism and nutrition disorders</b>			
Hypophosphataemia subjects affected / exposed occurrences (all)	2 / 3 (66.67%) 4		
Decreased appetite subjects affected / exposed occurrences (all)	1 / 3 (33.33%) 1		
Hypokalaemia subjects affected / exposed occurrences (all)	1 / 3 (33.33%) 1		
Hypomagnesaemia			

subjects affected / exposed	1 / 3 (33.33%)		
occurrences (all)	2		
Vitamin B12 deficiency			
subjects affected / exposed	1 / 3 (33.33%)		
occurrences (all)	1		

## More information

### Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
12 May 2011	<p>Part A.</p> <ul style="list-style-type: none"><li>- Based on results of population pharmacokinetic (PK) studies, farletuzumab dosage was changed to Q3W intervals, using 3 times the weekly dose previously given. Due to this change, visits were changed to every 3 weeks, and all references to cycles were deleted. With the increased dose level, there was no need to dilute farletuzumab with normal saline. Instructions for preparation and administration of farletuzumab were updated accordingly</li><li>- Farletuzumab was added to the product name to reflect the United States Adopted Names designation for MORAb-003</li><li>- Collection of serum samples for farletuzumab concentration was changed to every other visit (every 6 weeks) pre- and postinfusion in order to obtain additional information on serum levels maintained in this population. In addition, pre- and postinfusion serum samples were to be collected during the final 2 weekly visits prior to switching to the Q3W schedule</li><li>- Collection of Human Anti-Human Antibody (HAHA) Results samples was changed to pre-infusion every other visit (every 6 weeks)</li><li>- Due to the long-term follow-up in this population, the interval between Response Evaluation Criteria in Solid Tumors (RECIST) v.1.0 (Therasse et al., 2000) evaluations was increased to every 6 visits (every 18 weeks) as long as subjects remained clinically stable and the CA125 remained within normal limits. For any subjects receiving chemotherapy, the RECIST evaluations were changed to every 9 weeks (every 3 visits). Also, all RECIST evaluations were to be based on local radiology readings. All references to a central reader were deleted</li></ul>
12 May 2011	<p>Part B.</p> <ul style="list-style-type: none"><li>- A secondary objective was added to assess farletuzumab levels during Q3W dosing compared to drug levels during weekly dosing</li><li>- The expected number of subjects was revised from 4 to 3. One of the expected subjects experienced a relapse and discontinued from the main study prior to initiation of the extension</li><li>- Antibody-dependent cell cytotoxicity testing was removed from the protocol due to sample stability issues</li><li>- Criteria for removal and replacement of study subjects were updated to include:<ul style="list-style-type: none"><li>&gt; An AE deemed to be intolerable, including a farletuzumab-related allergic reaction</li><li>&gt; A subject being lost to follow-up</li><li>&gt; A subject experiencing progressive disease by RECIST or CA125 criteria that is determined to be platinum-resistant/-refractory</li><li>&gt; A subject's death</li></ul></li></ul>

Notes:

### Interruptions (globally)

Were there any global interruptions to the trial? No

### Limitations and caveats

Limitations of the trial such as small numbers of subjects analysed or technical problems leading to unreliable data.

Study was terminated by the sponsor following the futile results of the analysis of a phase 3 study in a similar patient population.

Notes: