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	v4 (current)
This version publication date	09 February 2022
First version publication date	15 August 2015
Version creation reason	

Trial information

Trial identification

Sponsor protocol code	MORAb-003-002A

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Morphotek
Sponsor organisation address	210 Welsh Pool Road, Exton, United States, 19341
Public contact	Eisai Medical Information, Morphotek, 1 888 422 4743, esi_medinfo@eisai.com
Scientific contact	Eisai Medical Information, Morphotek, 1 888 422 4743, esi_medinfo@eisai.com

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 farletuzumab (MORAb-003) to subjects who were 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 of the sponsor (or designee), which are designed to ensure adherence to GCP guidelines as required by the following:- Principles of the World Medical Association Declaration of Helsinki 2013; - International Council on Harmonisation (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 Council on Harmonisation of Technical Requirements for Pharmaceuticals for Human Use; - Title 21 of the United States Code of Federal Regulations (US 21 CFR) regarding clinical studies, including Part 50 and Part 56 concerning informed subject consent and IRB regulations and applicable sections of US 21 CFR Part 312;- European Good Clinical Practice Directive 2005/28/EC and Clinical Trial Directive 2001/20/EC for studies conducted within any European Union (EU) country. All SUSARs will be reported, as required, to the Competent Authorities of all involved EU member states.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	13 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	Germany: 1
Country: Number of subjects enrolled	United States: 2
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 participated and received single-agent farletuzumab maintenance therapy in MORAb-003-002 study, achieved normalization of cancer antigen 125 levels and/or tumor assessment of complete/partial response(or stable disease and an investigator's assessment of a clinical benefit) after receiving farletuzumab plus chemotherapy to enter study.

Pre-assignment

Screening details:

Study enrolled 3 subjects who participated in the MORAb-003-002 study (NCT00318370), achieved a normalization of CA 125 levels and/or complete response or partial response after MORAb-003 in combination with standard chemotherapy, and received single-agent MORAb-003 maintenance therapy.

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	Farletuzumab 62.5 mg/m^2

Arm description:

Subjects received farletuzumab 62.5 milligram per meter square (mg/m^2), intravenous infusion once weekly at the same dose level which subjects received in the MORAb-003-002 (NCT00318370) parent study for up to approximately 37.7 months in this study.

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 administered by intravenous infusion once weekly at the same dose subjects were receiving in the MORAb-003-002 parent study (ie, 62.5 or 100 mg/m^2).

Arm title	Farletuzumab 100 mg/m^2

Arm description:

Subjects received farletuzumab 100 mg/m^2, intravenous infusion once weekly at the same dose subjects received in the MORAb-003-002 (NCT00318370) parent study up to approximately 37.7 months in this study.

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 administered by intravenous infusion once weekly at the same dose subjects were receiving in the MORAb-003-002 parent study (ie, 62.5 or 100 mg/m^2).

Number of subjects in period 1	Farletuzumab 62.5 mg/m^2	Farletuzumab 100 mg/m^2
Started	2	1
Completed	0	0
Not completed	2	1
Termination of the study by Sponsor	2	1

Baseline characteristics

Reporting groups	
Reporting group title	Overall Study
Reporting group description:	
Subjects received farletuzumab 62.5 or 100 mg/m^2, intravenous infusion once weekly at the same dose level which subjects received in the MORAb-003-002 (NCT00318370) parent study for up to 37.7 months in this study.	

Reporting group values	Overall Study	Total	
Number of subjects	3	3	
Age categorical Units: subjects			
In utero	0	0	
Preterm newborn infants (gestational age < 37 wks)	0	0	
Newborns (0-27 days)	0	0	
Infants and toddlers (28 days-23 months)	0	0	
Children (2-11 years)	0	0	
Adolescents (12-17 years)	0	0	
Adults (18-64 years)	2	2	
From 65-84 years	1	1	
85 years and over	0	0	
Age Continuous Units: years			
median	58.0		
full range (min-max)	38 to 74	-	
Gender, Male/Female Units: subjects			
Female	3	3	
Male	0	0	
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	2	2	
Not Hispanic or Latino	0	0	
Unknown or Not Reported	1	1	
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	0	0	
Asian	0	0	
Native Hawaiian or Other Pacific Islander	0	0	
Black or African American	0	0	
White	1	1	
More than one race	0	0	
Unknown or Not Reported	2	2	

Subject analysis sets

Subject analysis set title	Farletuzumab- All Subjects
Subject analysis set type	Intention-to-treat

Subject analysis set description:

As per the planned analysis, the intention to treat population analysis set included all 3 subjects who were enrolled and received at least 1 dose of farletuzumab in this extension-of-treatment study.

Reporting group values	Farletuzumab- All Subjects		
Number of subjects	3		
Age categorical Units: subjects			
In utero	0		
Preterm newborn infants (gestational age < 37 wks)	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 65-84 years	1		
85 years and over	0		
Age Continuous Units: years			
median	58.0		
full range (min-max)	38 to 74		
Gender, Male/Female Units: subjects			
Female	3		
Male	0		
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	2		
Not Hispanic or Latino	0		
Unknown or Not Reported	1		
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	0		
Asian	0		
Native Hawaiian or Other Pacific Islander	0		
Black or African American	0		
White	1		
More than one race	0		
Unknown or Not Reported	2		

End points

End points reporting groups

Reporting group title	Farletuzumab 62.5 mg/m^2

Reporting group description:

Subjects received farletuzumab 62.5 milligram per meter square (mg/m^2), intravenous infusion once weekly at the same dose level which subjects received in the MORAb-003-002 (NCT00318370) parent study for up to approximately 37.7 months in this study.

Reporting group title	Farletuzumab 100 mg/m^2

Reporting group description:

Subjects received farletuzumab 100 mg/m^2, intravenous infusion once weekly at the same dose subjects received in the MORAb-003-002 (NCT00318370) parent study up to approximately 37.7 months in this study.

Subject analysis set title	Farletuzumab- All Subjects
Subject analysis set type	Intention-to-treat

Subject analysis set description:

As per the planned analysis, the intention to treat population analysis set included all 3 subjects who were enrolled and received at least 1 dose of farletuzumab in this extension-of-treatment study.

Primary: Duration of Ovarian Tumor Marker (Cancer Antigen 125 [CA125]) Response

End point title	Duration of Ovarian Tumor Marker (Cancer Antigen 125 [CA125]) Response[1]

End point description:

The duration of CA125 response, was defined the time from the date of the initial CA125 response (i.e., prior to enrollment in the parent study, was the starting point for assessment) to the first documentation of progressive disease (PD) by either Gynecologic Cancer Inter Group (GCIG) criteria for CA125 level or by the date of death due to any cause, whichever occurred first. Disease progression per CA125 was defined as the first of 2 consecutive CA125 values greater than (>) twice the upper limit of normal (ULN) (i.e. 35 kilo unit per liter [kU/L]) on two occasions. C= data censored at earlier non-PD assessment if PD did not occur. Intent-to-treat population included all 3 subjects who were enrolled. Data reported includes combined data from the parent study MORAb-003-002 (NCT00318370) and the current study MORAb-003-002A.

End point type	Primary

End point timeframe:

From screening of parent study (NCT00318370) until the current study was terminated (up to a maximum of 78.2 months including the parent study, or 37.7 months in this study only)

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Only descriptive statistics data were planned to be analysed for this endpoint.

End point values	Farletuzumab 62.5 mg/m^2	Farletuzumab 100 mg/m^2		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	2	1		
Units: months				
number (not applicable)				
Subject 1 (dose group: 62.5 mg/m^2)-C	77.2	0		
Subject 2 (dose group: 62.5 mg/m^2)-C	73.3	0		
Subject 3 (dose group: 100 mg/m^2)	0	18.0		

Statistical analyses

No statistical analyses for this end point

Secondary: Progression-Free Survival (PFS) by GCIG

End point title	Progression-Free Survival (PFS) by GCIG

End point description:

PFS was defined as time from first dose of study medication during parent study MORAb-003-002 (NCT00318370) to disease progression (either by GCIG for CA125 criteria or standard RECIST v.1.0 criteria) or death due to any cause in this study. PD per CA125 was the first of 2 consecutive CA125 values >2*ULN (35 kU/L) on two occasions. Subjects with no disease progression were censored at either the date of last CA125 assessment or date of last objective tumor evaluation, whichever was later. PFS was also censored if a subject received a non-study anticancer therapy or procedure, occurring at the date of the last RECIST or CA125 assessment prior to the start of a non-study anticancer therapy or procedure (whichever was earlier). C= data censored at earlier non-PD assessment if PD did not occur. Intent-to-treat population included all 3 subjects enrolled. Data reported includes combined data from the parent study MORAb-003-002 (NCT00318370) and the current study MORAb-003-002A.

End point type	Secondary

End point timeframe:

From the first dose of study medication in the parent study (NCT00318370) until the current study was terminated (up to a maximum of 78.2 months including the parent study, or 37.7 months in this study only)

End point values	Farletuzumab 62.5 mg/m^2	Farletuzumab 100 mg/m^2		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	2	1		
Units: months				
number (not applicable)				
Subject 1 (dose group: 62.5 mg/m^2)-C: GCIG	77.8	0		
Subject 2 (dose group: 62.5 mg/m^2)-C: GCIG	75.8	0		
Subject 3 (dose group: 100 mg/m^2): GCIG	0	25.1		

Statistical analyses

No statistical analyses for this end point

Secondary: Overall Survival (OS)

End point title	Overall Survival (OS)

End point description:

OS was defined from the date of first dose of farletuzumab during the parent study MORAb-003-002 (NCT00318370) to date of death due to any cause. Subjects who were alive had their OS time censored at the date they were last known to be alive. C= data censored at date subject was last known to be alive. Intent-to-treat population included all 3 subjects who were enrolled. Data reported includes combined data from the parent study MORAb-003-002 (NCT00318370) and the current study MORAb-003-002A.

End point type	Secondary

End point timeframe:

From Baseline (Day 1) in the parent study (NCT00318370) until date of death from any cause in this study, or until the current study was terminated (up to a maximum of 78.2 months including the parent study, or 37.7 months in this study only)

End point values	Farletuzumab 62.5 mg/m^2	Farletuzumab 100 mg/m^2		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	2	1		
Units: months				
number (not applicable)				
Subject 1 (dose group: 62.5 mg/m^2)-C	78.3	0		
Subject 2 (dose group: 62.5 mg/m^2)-C	76.7	0		
Subject 3 (dose group: 100 mg/m^2)	0	59.5		

Statistical analyses

No statistical analyses for this end point

Secondary: Duration of Second Remission

End point title	Duration of Second Remission

End point description:

The prolongation of second and subsequent responses to chemotherapy plus farletuzumab relative to initial remission was assessed. Length of first remission was determined in the parent study MORAb-003-002 (NCT00318370). The length of second remission (i.e., the first remission in this study) was calculated using the following formula: '(carboplatin/taxane start date in this study - carboplatin/taxane start date in NCT00318370 +1/30.4'. The length of second remission was censored at the date of study discontinuation if the subject did not receive any carboplatin/taxane therapy during this study. C = censored data. Intent-to-treat population included all 3 subjects who were enrolled. Data reported includes combined data from the parent study MORAb-003-002 (NCT00318370) and the current study MORAb-003-002A.

End point type	Secondary

End point timeframe:

From Baseline (Day 1) in the parent study (NCT00318370) until date of death from any cause in this study, or until the current study was terminated (up to a maximum of 78.2 months including the parent study, or 37.7 months in this study only)

End point values	Farletuzumab 62.5 mg/m^2	Farletuzumab 100 mg/m^2		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	2	1		
Units: months				
number (not applicable)				
Subject 1 (dose group: 62.5 mg/m^2)	41.0	0		
Subject 2 (dose group: 62.5 mg/m^2)-C	74.2	0		
Subject 3 (dose group: 100 mg/m^2)	0	29.5		

Statistical analyses

No statistical analyses for this end point

Secondary: Duration of Third Remission

End point title	Duration of Third Remission

End point description:

The length of third remission (i.e., second remission in this study) was calculated using the following formula: '(subsequent carboplatin/taxane start date in this study - carboplatin/taxane start date in NCT00318370 +1)/30.4'. The length of third remission was censored at the date of study discontinuation if the subject did not receive subsequent chemotherapy (carboplatin/taxane) during this study. Censored data is reported for all subjects. Intent-to-treat population included all 3 subjects who were enrolled.

End point type	Secondary

End point timeframe:

From Baseline (Day 1) of this study until date of death from any cause, or until the study was terminated (up to a maximum of 37.7 months)

End point values	Farletuzumab 62.5 mg/m^2	Farletuzumab 100 mg/m^2		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1	1		
Units: months				
number (not applicable)	37.3	25.0		

Statistical analyses

No statistical analyses for this end point

Other pre-specified: Number of Subjects With Best Overall Response as Evaluated by Response Evaluation Criteria in Solid Tumors (RECIST) V.1.0 Criteria

End point title	Number of Subjects With Best Overall Response as Evaluated by Response Evaluation Criteria in Solid Tumors (RECIST) V.1.0 Criteria

End point description:

Best overall response was the best response recorded from the start of treatment until disease progression/recurrence. Subjects were assigned to one of the following categories of change in disease status: complete response (CR), partial response (PR), stable disease (SD), or progressive disease (PD). CR was defined as CR in both target and non-target lesions with no new lesions. PR was defined as CR in target lesions and incomplete response or SD in non-target lesions with no new lesions, or PR in target lesions and non-PD in non-target lesions with no new lesions. SD was defined as SD in target lesions and non-PD in non-target lesions with no new lesions. PD was defined as PD in target lesions, any non-target lesions with either absence or presence of new lesions, or any target lesions, PD in non-target lesions with either absence or presence of new lesions, or any target or non-target lesions with new lesions. Intent-to-treat population included all 3 subjects who were enrolled.

End point type	Other pre-specified

End point timeframe:

From the start of the treatment until disease progression/recurrence (up to approximately 37.7 months)

End point values	Farletuzumab 62.5 mg/m^2	Farletuzumab 100 mg/m^2		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	2	1		
Units: subjects				
CR	1	1		
SD	1	0		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

For each subject, from the first dose till 30 days after the last dose or up to study completion (approximately 37.7 months)

Adverse event reporting additional description:

Intention to treat population analysis set included all 3 subjects who were enrolled.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	14.1

Reporting groups

Reporting group title	Farletuzumab 62.5 mg/m^2

Reporting group description:

Subjects received farletuzumab 62.5 mg/m^2, intravenous infusion once weekly at the same dose subjects received in the MORAb-003-002 (NCT00318370) parent study up to approximately 37.7 months in this study.

Reporting group title	Farletuzumab 100 mg/m^2

Reporting group description:

Subjects received farletuzumab 100 mg/m^2, intravenous infusion once weekly at the same dose subjects received in the MORAb-003-002 (NCT00318370) parent study up to approximately 37.7 months in this study.

Serious adverse events	Farletuzumab 62.5 mg/m^2	Farletuzumab 100 mg/m^2	
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 2 (50.00%)	1 / 1 (100.00%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events			
Investigations			
Neutrophil count decreased			
subjects affected / exposed	1 / 2 (50.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Lymphoma			
subjects affected / exposed	1 / 2 (50.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
General disorders and administration site conditions			
Disease progression			

subjects affected / exposed	0 / 2 (0.00%)	1 / 1 (100.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	1 / 2 (50.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

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

Non-serious adverse events	Farletuzumab 62.5 mg/m^2	Farletuzumab 100 mg/m^2	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	2 / 2 (100.00%)	1 / 1 (100.00%)	
Vascular disorders			
Hypertension			
subjects affected / exposed	0 / 2 (0.00%)	1 / 1 (100.00%)	
occurrences (all)	0	5	
Hypotension			
subjects affected / exposed	0 / 2 (0.00%)	1 / 1 (100.00%)	
occurrences (all)	0	1	
Surgical and medical procedures			
Tooth extraction			
subjects affected / exposed	1 / 2 (50.00%)	0 / 1 (0.00%)	
occurrences (all)	1	0	
General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	1 / 2 (50.00%)	1 / 1 (100.00%)	
occurrences (all)	2	11	
Asthenia			
subjects affected / exposed	1 / 2 (50.00%)	0 / 1 (0.00%)	
occurrences (all)	1	0	
Local swelling			
subjects affected / exposed	1 / 2 (50.00%)	0 / 1 (0.00%)	
occurrences (all)	1	0	
Oedema peripheral			

subjects affected / exposed	0 / 2 (0.00%)	1 / 1 (100.00%)	
occurrences (all)	0	4	
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	0 / 2 (0.00%)	1 / 1 (100.00%)	
occurrences (all)	0	2	
Dyspnoea			
subjects affected / exposed	0 / 2 (0.00%)	1 / 1 (100.00%)	
occurrences (all)	0	1	
Nasal congestion			
subjects affected / exposed	1 / 2 (50.00%)	0 / 1 (0.00%)	
occurrences (all)	1	0	
Obstructive Airways Disorder			
subjects affected / exposed	0 / 2 (0.00%)	1 / 1 (100.00%)	
occurrences (all)	0	1	
Psychiatric disorders			
Anxiety			
subjects affected / exposed	1 / 2 (50.00%)	1 / 1 (100.00%)	
occurrences (all)	1	1	
Depression			
subjects affected / exposed	0 / 2 (0.00%)	1 / 1 (100.00%)	
occurrences (all)	0	1	
Panic Attack			
subjects affected / exposed	0 / 2 (0.00%)	1 / 1 (100.00%)	
occurrences (all)	0	1	
Investigations			
Blood alkaline phosphatase increased			
subjects affected / exposed	1 / 2 (50.00%)	0 / 1 (0.00%)	
occurrences (all)	2	0	
Haemoglobin decreased			
subjects affected / exposed	1 / 2 (50.00%)	0 / 1 (0.00%)	
occurrences (all)	4	0	
Platelet count decreased			
subjects affected / exposed	1 / 2 (50.00%)	0 / 1 (0.00%)	
occurrences (all)	2	0	
Red blood cell count decreased			

subjects affected / exposed	1 / 2 (50.00%)	0 / 1 (0.00%)	
occurrences (all)	1	0	
White blood cell count decreased			
subjects affected / exposed	1 / 2 (50.00%)	0 / 1 (0.00%)	
occurrences (all)	4	0	
Neutrophil count decreased			
subjects affected / exposed	1 / 2 (50.00%)	0 / 1 (0.00%)	
occurrences (all)	1	0	
Injury, poisoning and procedural complications			
Procedural pain			
subjects affected / exposed	0 / 2 (0.00%)	1 / 1 (100.00%)	
occurrences (all)	0	4	
Traumatic haematoma			
subjects affected / exposed	0 / 2 (0.00%)	1 / 1 (100.00%)	
occurrences (all)	0	1	
Nervous system disorders			
Headache			
subjects affected / exposed	1 / 2 (50.00%)	1 / 1 (100.00%)	
occurrences (all)	93	2	
Tremor			
subjects affected / exposed	0 / 2 (0.00%)	1 / 1 (100.00%)	
occurrences (all)	0	3	
Blood and lymphatic system disorders			
Iron deficiency anaemia			
subjects affected / exposed	1 / 2 (50.00%)	0 / 1 (0.00%)	
occurrences (all)	1	0	
Leukopenia			
subjects affected / exposed	1 / 2 (50.00%)	1 / 1 (100.00%)	
occurrences (all)	1	1	
Neutropenia			
subjects affected / exposed	0 / 2 (0.00%)	1 / 1 (100.00%)	
occurrences (all)	0	2	
Thrombocytopenia			
subjects affected / exposed	0 / 2 (0.00%)	1 / 1 (100.00%)	
occurrences (all)	0	2	
Eye disorders			

Eyelid oedema			
subjects affected / exposed	0 / 2 (0.00%)	1 / 1 (100.00%)	
occurrences (all)	0	1	
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	1 / 2 (50.00%)	1 / 1 (100.00%)	
occurrences (all)	2	7	
Nausea			
subjects affected / exposed	1 / 2 (50.00%)	1 / 1 (100.00%)	
occurrences (all)	2	3	
Stomatitis			
subjects affected / exposed	2 / 2 (100.00%)	0 / 1 (0.00%)	
occurrences (all)	2	0	
Abdominal distension			
subjects affected / exposed	1 / 2 (50.00%)	1 / 1 (100.00%)	
occurrences (all)	1	1	
Abdominal pain			
subjects affected / exposed	1 / 2 (50.00%)	0 / 1 (0.00%)	
occurrences (all)	1	0	
Colitis			
subjects affected / exposed	1 / 2 (50.00%)	0 / 1 (0.00%)	
occurrences (all)	1	0	
Dry mouth			
subjects affected / exposed	1 / 2 (50.00%)	0 / 1 (0.00%)	
occurrences (all)	1	0	
Dysphagia			
subjects affected / exposed	1 / 2 (50.00%)	0 / 1 (0.00%)	
occurrences (all)	1	0	
Flatulence			
subjects affected / exposed	0 / 2 (0.00%)	1 / 1 (100.00%)	
occurrences (all)	0	3	
Vomiting			
subjects affected / exposed	1 / 2 (50.00%)	0 / 1 (0.00%)	
occurrences (all)	1	0	
Skin and subcutaneous tissue disorders			

Pruritus			
subjects affected / exposed	1 / 2 (50.00%)	1 / 1 (100.00%)	
occurrences (all)	1	1	
Pruritus allergic			
subjects affected / exposed	1 / 2 (50.00%)	1 / 1 (100.00%)	
occurrences (all)	1	1	
Rash			
subjects affected / exposed	1 / 2 (50.00%)	0 / 1 (0.00%)	
occurrences (all)	1	0	
Swelling face			
subjects affected / exposed	1 / 2 (50.00%)	0 / 1 (0.00%)	
occurrences (all)	1	0	
Musculoskeletal and connective tissue disorders			
Back pain			
subjects affected / exposed	1 / 2 (50.00%)	1 / 1 (100.00%)	
occurrences (all)	1	2	
Myalgia			
subjects affected / exposed	1 / 2 (50.00%)	0 / 1 (0.00%)	
occurrences (all)	1	0	
Neck pain			
subjects affected / exposed	1 / 2 (50.00%)	0 / 1 (0.00%)	
occurrences (all)	1	0	
Myosclerosis			
subjects affected / exposed	0 / 2 (0.00%)	1 / 1 (100.00%)	
occurrences (all)	0	1	
Synovial Cyst			
subjects affected / exposed	0 / 2 (0.00%)	1 / 1 (100.00%)	
occurrences (all)	0	1	
Muscle Spasms			
subjects affected / exposed	0 / 2 (0.00%)	1 / 1 (100.00%)	
occurrences (all)	0	1	
Scoliosis			
subjects affected / exposed	0 / 2 (0.00%)	1 / 1 (100.00%)	
occurrences (all)	0	1	
Infections and infestations			

Urinary tract infection			
subjects affected / exposed	1 / 2 (50.00%)	1 / 1 (100.00%)	
occurrences (all)	1	1	
Nasopharyngitis			
subjects affected / exposed	0 / 2 (0.00%)	1 / 1 (100.00%)	
occurrences (all)	0	3	
Fungal skin infection			
subjects affected / exposed	0 / 2 (0.00%)	1 / 1 (100.00%)	
occurrences (all)	0	1	
Otitis media			
subjects affected / exposed	0 / 2 (0.00%)	1 / 1 (100.00%)	
occurrences (all)	0	1	
Pharyngeal abscess			
subjects affected / exposed	1 / 2 (50.00%)	0 / 1 (0.00%)	
occurrences (all)	1	0	
Tooth infection			
subjects affected / exposed	1 / 2 (50.00%)	0 / 1 (0.00%)	
occurrences (all)	1	0	
Tinea versicolour			
subjects affected / exposed	0 / 2 (0.00%)	1 / 1 (100.00%)	
occurrences (all)	0	1	
Metabolism and nutrition disorders			
Hypophosphataemia			
subjects affected / exposed	1 / 2 (50.00%)	1 / 1 (100.00%)	
occurrences (all)	2	2	
Decreased appetite			
subjects affected / exposed	1 / 2 (50.00%)	0 / 1 (0.00%)	
occurrences (all)	1	0	
Hypokalaemia			
subjects affected / exposed	1 / 2 (50.00%)	0 / 1 (0.00%)	
occurrences (all)	1	0	
Hypomagnesaemia			
subjects affected / exposed	0 / 2 (0.00%)	1 / 1 (100.00%)	
occurrences (all)	0	2	
Vitamin B12 deficiency			

subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	1 / 1 (100.00%) 1	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
12 May 2011	Part A. - 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 - Farletuzumab was added to the product name to reflect the United States Adopted Names designation for MORAb-003 - 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 - Collection of Human Anti-Human Antibody (HAHA) Results samples was changed to pre-infusion every other visit (every 6 weeks) - 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
12 May 2011	Part B. - A secondary objective was added to assess farletuzumab levels during Q3W dosing compared to drug levels during weekly dosing - 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 - Antibody-dependent cell cytotoxicity testing was removed from the protocol due to sample stability issues - Criteria for removal and replacement of study subjects were updated to include: An AE deemed to be intolerable, including a farletuzumab-related allergic reaction; A subject being lost to follow-up; A subject experiencing progressive disease by RECIST or CA125 criteria that is determined to be platinum-resistant/-refractory; A subject’s death

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 sponsor due to futile results in the NCT00849667 (MORAb003-004) study.

Notes: