An Efficacy and Safety Study of MORAb-003 in Platinum-Resistant or Refractory Relapsed Ovarian Cancer (FAR-122)

This study has been terminated.

(study did not meet pre-specified criteria for continuation following interim futility analysis)

Sponsor:
Morphotek

Information provided by (Responsible Party):
Morphotek

ClinicalTrials.gov Identifier:
NCT00738699

First received: August 18, 2008
Last updated: February 10, 2017
Last verified: February 2017
History of Changes

Results First Received: December 13, 2016

Study Type:	Interventional
Study Design:	Allocation: Randomized; Intervention Model: Parallel Assignment; Masking: Participant, Care Provider, Investigator, Outcomes Assessor; Primary Purpose: Treatment
Condition:	Ovarian Cancer
Interventions:	Drug: MORAb-003 (farletuzumab) Drug: 0.9% Saline Drug: Paclitaxel

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
No text entered.

Reporting Groups

	Description

MORAb-003 (Farletuzumab) Plus Paclitaxel	Farletuzumab (FAR) at 2.5 mg/kg was administered by intravenous (IV) infusion weekly on Day 1 of Weeks 1 to 12 (Cycle 1) and then in 4-week cycles with treatment administered on Day 1 of Weeks 1 to 3 for all subsequent cycles. Paclitaxel (80 mg/m^2) was administered weekly by IV infusion over 1 hour following administration of FAR. During the 4-week cycle, Week 4 was to be a rest period with no study treatment (test article or paclitaxel) administered. All participants were required to be premedicated with steroids before paclitaxel administration, and with acetaminophen (650 mg orally) or clinically equivalent per clinic routine within 4 hours prior to test article infusion.
Placebo (Normal Saline) Plus Paclitaxel	An equivalent volume of placebo (0.9% normal saline) was administered by IV infusion weekly on Day 1 of Weeks 1 to 12 (Cycle 1) and then in 4-week cycles with treatment administered on Day 1 of Weeks 1 to 3 for all subsequent cycles. Paclitaxel (80 mg/m^2) was administered weekly by IV infusion over 1 hour following administration of FAR. During the 4-week cycle, Week 4 was to be a rest period with no study treatment (test article or paclitaxel) administered. All participants were required to be premedicated with steroids before paclitaxel administration, and with acetaminophen (650 mg orally) or clinically equivalent per clinic routine within 4 hours prior to test article infusion.

Participant Flow: Overall Study

	MORAb-003 (Farletuzumab) Plus Paclitaxel	Placebo (Normal Saline) Plus Paclitaxel
STARTED	**275**	**140**
Participants Not Treated	**2**	**1**
Participants Treated	**273**	**139**
COMPLETED	**0**	**0**
NOT COMPLETED	**275**	**140**
Withdrawal by Subject	**5**	**0**
Lost to Follow-up	**1**	**0**
Death	**144**	**68**
Discontinuation of study by Sponsor	**123**	**72**
Not specified	**2**	**0**

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.
Intent-to-Treat population included, the primary population for the evaluation of efficacy, was defined as all participant who were randomly assigned to test article, analyzed by the treatment assigned.

Reporting Groups

	Description
MORAb-003 (Farletuzumab) Plus Paclitaxel	Farletuzumab (FAR) at 2.5 mg/kg was administered by intravenous (IV) infusion weekly on Day 1 of Weeks 1 to 12 (Cycle 1) and then in 4-week cycles with treatment administered on Day 1 of Weeks 1 to 3 for all subsequent cycles. Paclitaxel (80 mg/m^2) was administered weekly by IV infusion over 1 hour following administration of FAR. During the 4-week cycle, Week 4 was to be a rest period with no study treatment (test article or paclitaxel) administered. All participants were required to be premedicated with steroids before paclitaxel administration, and with acetaminophen (650 mg orally) or clinically equivalent per clinic routine within 4 hours prior to test article infusion.

Placebo (Normal Saline) Plus Paclitaxel	An equivalent volume of placebo (0.9% normal saline) was administered by IV infusion weekly on Day 1 of Weeks 1 to 12 (Cycle 1) and then in 4-week cycles with treatment administered on Day 1 of Weeks 1 to 3 for all subsequent cycles. Paclitaxel (80 mg/m^2) was administered weekly by IV infusion over 1 hour following administration of FAR. During the 4-week cycle, Week 4 was to be a rest period with no study treatment (test article or paclitaxel) administered. All participants were required to be premedicated with steroids before paclitaxel administration, and with acetaminophen (650 mg orally) or clinically equivalent per clinic routine within 4 hours prior to test article infusion.
Total	Total of all reporting groups

Baseline Measures

	MORAb-003 (Farletuzumab) Plus Paclitaxel	Placebo (Normal Saline) Plus Paclitaxel	Total
Overall Participants Analyzed [Units: Participants]	**275**	**140**	**415**
Age [Units: Years] Geometric Mean (Standard Deviation)	**60.9 (10.74)**	**61.2 (9.44)**	**61.0 (10.31)**
Sex: Female, Male [Units: Participants] Count of Participants			
Female	**275** 100.0%	**140** 100.0%	**415** 100.0%
Male	**0** 0.0%	**0** 0.0%	**0** 0.0%

Outcome Measures

Hide All Outcome Measures

1. Primary: Progression-Free Survival (PFS) [Time Frame: Date of Randomization to date of disease progression or death (whichever came first), assessed up to study termination (28 Nov 2011), or up to approximately 2 years 10 months]

Measure Type	Primary
Measure Title	Progression-Free Survival (PFS)
Measure Description	PFS was defined as the time (in months) from the date of randomization to the date of the first observation of progression as determined by modified Response Evaluation Criteria in Solid Tumors (RECIST), or death regardless of cause. If progression or death was not observed, the PFS time was censored at the date of the last tumor assessment without evidence of progression before the date of initiation of further antitumor treatment, or the cutoff date (whichever was earlier).
Time Frame	Date of Randomization to date of disease progression or death (whichever came first), assessed up to study termination (28 Nov 2011), or up to approximately 2 years 10 months

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.
Intent-To-Treat (ITT) population included all participants who were randomly assigned to study drug, analyzed by treatment assignment.

Reporting Groups

	Description
MORAb-003 (Farletuzumab) Plus Paclitaxel	Farletuzumab (FAR) at 2.5 mg/kg was administered by intravenous (IV) infusion weekly on Day 1 of Weeks 1 to 12 (Cycle 1) and then in 4-week cycles with treatment administered on Day 1 of Weeks 1 to 3 for all subsequent cycles. Paclitaxel (80 mg/m^2) was administered weekly by IV

	infusion over 1 hour following administration of FAR. During the 4-week cycle, Week 4 was to be a rest period with no study treatment (test article or paclitaxel) administered. All participants were required to be premedicated with steroids before paclitaxel administration, and with acetaminophen (650 mg orally) or clinically equivalent per clinic routine within 4 hours prior to test article infusion.
Placebo (Normal Saline) Plus Paclitaxel	An equivalent volume of placebo (0.9% normal saline) was administered by IV infusion weekly on Day 1 of Weeks 1 to 12 (Cycle 1) and then in 4-week cycles with treatment administered on Day 1 of Weeks 1 to 3 for all subsequent cycles. Paclitaxel (80 mg/m^2) was administered weekly by IV infusion over 1 hour following administration of FAR. During the 4-week cycle, Week 4 was to be a rest period with no study treatment (test article or paclitaxel) administered. All participants were required to be premedicated with steroids before paclitaxel administration, and with acetaminophen (650 mg orally) or clinically equivalent per clinic routine within 4 hours prior to test article infusion.

Measured Values

	MORAb-003 (Farletuzumab) Plus Paclitaxel	Placebo (Normal Saline) Plus Paclitaxel
Participants Analyzed [Units: Participants]	**275**	**140**
Progression-Free Survival (PFS) [Units: Months] Median (95% Confidence Interval)	**3.5** **(3.3 to 3.9)**	**3.7** **(3.3 to 5.2)**

Statistical Analysis 1 for Progression-Free Survival (PFS)

Groups [1]	All groups
Statistical Test Type [2]	Superiority or Other
Statistical Method [3]	Log Rank
P Value [4]	0.8360
Cox Proportional Hazard [5]	1.13
95% Confidence Interval	0.88 to 1.46

[1] Additional details about the analysis, such as null hypothesis and power calculation:

No text entered.

[2] Details of power calculation, definition of non-inferiority margin, and other key parameters:

No text entered.

[3] Other relevant method information, such as adjustments or degrees of freedom:

No text entered.

[4] Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:

One-sided log rank test stratified by route of administration for primary chemotherapy (intraperitoneal vs intravenous) and geographic region (North America, Europe, and other participating countries).

[5] Other relevant estimation information:

Stratified as described above.

2. Primary: Overall Survival (OS) [Time Frame: Date of Randomization to date of death, assessed up to study termination (28 Nov 2011), or up to approximately 2 years 10 months]

Measure Type	Primary

Measure Title	Overall Survival (OS)
Measure Description	OS was defined as the time (in months) from the date of randomization to the date of death, whatever the cause. If death was not observed for a participant, the survival time was censored on the last date the participant was known to be alive or the cutoff date, whichever was earlier.
Time Frame	Date of Randomization to date of death, assessed up to study termination (28 Nov 2011), or up to approximately 2 years 10 months

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.
ITT population included all participants who were randomly assigned to study drug and analyzed by the treatment assigned.

Reporting Groups

	Description
MORAb-003 (Farletuzumab) Plus Paclitaxel	Farletuzumab (FAR) at 2.5 mg/kg was administered by intravenous (IV) infusion weekly on Day 1 of Weeks 1 to 12 (Cycle 1) and then in 4-week cycles with treatment administered on Day 1 of Weeks 1 to 3 for all subsequent cycles. Paclitaxel (80 mg/m^2) was administered weekly by IV infusion over 1 hour following administration of FAR. During the 4-week cycle, Week 4 was to be a rest period with no study treatment (test article or paclitaxel) administered. All participants were required to be premedicated with steroids before paclitaxel administration, and with acetaminophen (650 mg orally) or clinically equivalent per clinic routine within 4 hours prior to test article infusion.
Placebo (Normal Saline) Plus Paclitaxel	An equivalent volume of placebo (0.9% normal saline) was administered by IV infusion weekly on Day 1 of Weeks 1 to 12 (Cycle 1) and then in 4-week cycles with treatment administered on Day 1 of Weeks 1 to 3 for all subsequent cycles. Paclitaxel (80 mg/m^2) was administered weekly by IV infusion over 1 hour following administration of FAR. During the 4-week cycle, Week 4 was to be a rest period with no study treatment (test article or paclitaxel) administered. All participants were required to be premedicated with steroids before paclitaxel administration, and with acetaminophen (650 mg orally) or clinically equivalent per clinic routine within 4 hours prior to test article infusion.

Measured Values

	MORAb-003 (Farletuzumab) Plus Paclitaxel	**Placebo (Normal Saline) Plus Paclitaxel**
Participants Analyzed [Units: Participants]	**275**	**140**
Overall Survival (OS) [Units: Months] Median (95% Confidence Interval)	**11.3** **(10.3 to 12.7)**	**13.1** **(10.3 to 16.7)**

Statistical Analysis 1 for Overall Survival (OS)

Groups [1]	All groups
Statistical Test Type [2]	Superiority or Other
Statistical Method [3]	Log Rank
P Value [4]	0.7568
Cox Proportional Hazard [5]	1.11
95% Confidence Interval	0.83 to 1.48

[1]

Additional details about the analysis, such as null hypothesis and power calculation:

No text entered.

[2] Details of power calculation, definition of non-inferiority margin, and other key parameters:

No text entered.

[3] Other relevant method information, such as adjustments or degrees of freedom:

No text entered.

[4] Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:

One-sided log rank test stratified by route of administration for primary chemotherapy and geographic region.

[5] Other relevant estimation information:

Stratified as described above

3. Secondary: Best Overall Response [Time Frame: Date of first study drug to disease progression/recurrence, assessed up to study termination (28 Nov 2011), or up to approximately 2 years 10 months]

Measure Type	Secondary
Measure Title	Best Overall Response
Measure Description	BOR was defined as the percentage of participants having either a confirmed complete response (CR) or confirmed partial response (PR) using modified RECIST criteria by independent radiologist review. RECIST criteria was adjusted based on current medical practices and on possible differences between ovarian cancer and other solid tumors. Tumor assessments performed up to the initiation of further antitumor treatment were considered. Target lesions selected for response assessment were measured using computed tomography (CT) or magnetic resonance imaging (MRI) scans then graded according to the modified RECIST criteria, adjusted based on current medical practices and on possible differences between ovarian cancer and other solid tumors. Participants were assigned to one of the categories of change in disease state; CR, PR, progressive disease (PD), stable disease (S)D, or not evaluable (NE).
Time Frame	Date of first study drug to disease progression/recurrence, assessed up to study termination (28 Nov 2011), or up to approximately 2 years 10 months

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.
ITT population included all participants who were randomly assigned to study drug and analyzed by the treatment assigned.

Reporting Groups

	Description
MORAb-003 (Farletuzumab) Plus Paclitaxel	Farletuzumab (FAR) at 2.5 mg/kg was administered by intravenous (IV) infusion weekly on Day 1 of Weeks 1 to 12 (Cycle 1) and then in 4-week cycles with treatment administered on Day 1 of Weeks 1 to 3 for all subsequent cycles. Paclitaxel (80 mg/m^2) was administered weekly by IV infusion over 1 hour following administration of FAR. During the 4-week cycle, Week 4 was to be a rest period with no study treatment (test article or paclitaxel) administered. All participants were required to be premedicated with steroids before paclitaxel administration, and with acetaminophen (650 mg orally) or clinically equivalent per clinic routine within 4 hours prior to test article infusion.
Placebo (Normal Saline) Plus Paclitaxel	An equivalent volume of placebo (0.9% normal saline) was administered by IV infusion weekly on Day 1 of Weeks 1 to 12 (Cycle 1) and then in 4-week cycles with treatment administered on Day 1 of Weeks 1 to 3 for all subsequent cycles. Paclitaxel (80 mg/m^2) was administered weekly by IV infusion over 1 hour following administration of FAR. During the 4-week cycle, Week 4 was to be a rest period with no study treatment (test article or paclitaxel) administered. All participants were required to be premedicated with steroids before paclitaxel administration, and with acetaminophen (650 mg orally) or clinically equivalent per clinic routine within 4 hours prior to test article infusion.

Measured Values

	MORAb-003 (Farletuzumab) Plus Paclitaxel	Placebo (Normal Saline) Plus Paclitaxel
Participants Analyzed [Units: Participants]	**275**	**140**
Best Overall Response [Units: Percentage of participants]		
Complete response (CR)	**0.4**	**0**
Partial response (PR)	**7.3**	**15.0**

Statistical Analysis 1 for Best Overall Response

Groups [1]	All groups
Statistical Test Type [2]	Superiority or Other
Statistical Method [3]	Cochran-Mantel-Haenszel
P Value [4]	0.0399
Difference [5]	-7.4
95% Confidence Interval	-14.1 to -0.7

[1] Additional details about the analysis, such as null hypothesis and power calculation:

No text entered.

[2] Details of power calculation, definition of non-inferiority margin, and other key parameters:

No text entered.

[3] Other relevant method information, such as adjustments or degrees of freedom:

No text entered.

[4] Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:

Compared the ratio of complete or partial responders in the two arms. Stratified by route of administration for first line therapy and geographic region as specified at baseline.

[5] Other relevant estimation information:

(FAR + Paclitaxel) minus (Placebo + Paclitaxel). Confidence interval based on a normal approximation to the binomial distribution.

4. Secondary: Time to Tumor Response (TTR) [Time Frame: Date of Randomization to the first documentation of objective TR, assessed up to study termination (28 Nov 2011), or up to approximately 2 years 10 months]

Measure Type	Secondary
Measure Title	Time to Tumor Response (TTR)
Measure Description	TTR was derived for those participants with objective evidence of CR or PR, and was defined as the time (in months) from the date of randomization to the first documentation of object tumor response (TR). Analysis was based on the Kaplan-Meier estimated percentage of responders. This statistical analysis method measures the effect of study drug on tumor response over a period of time.
Time Frame	Date of Randomization to the first documentation of objective TR, assessed up to study termination (28 Nov 2011), or up to approximately 2 years 10 months

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.
ITT population (Responders only) included all participants who were randomly assigned to study drug and analyzed by the treatment assigned.

Reporting Groups

	Description
MORAb-003 (Farletuzumab) Plus Paclitaxel	Farletuzumab (FAR) at 2.5 mg/kg was administered by intravenous (IV) infusion weekly on Day 1 of Weeks 1 to 12 (Cycle 1) and then in 4-week cycles with treatment administered on Day 1 of Weeks 1 to 3 for all subsequent cycles. Paclitaxel (80 mg/m^2) was administered weekly by IV infusion over 1 hour following administration of FAR. During the 4-week cycle, Week 4 was to be a rest period with no study treatment (test article or paclitaxel) administered. All participants were required to be premedicated with steroids before paclitaxel administration, and with acetaminophen (650 mg orally) or clinically equivalent per clinic routine within 4 hours prior to test article infusion.
Placebo (Normal Saline) Plus Paclitaxel	An equivalent volume of placebo (0.9% normal saline) was administered by IV infusion weekly on Day 1 of Weeks 1 to 12 (Cycle 1) and then in 4-week cycles with treatment administered on Day 1 of Weeks 1 to 3 for all subsequent cycles. Paclitaxel (80 mg/m^2) was administered weekly by IV infusion over 1 hour following administration of FAR. During the 4-week cycle, Week 4 was to be a rest period with no study treatment (test article or paclitaxel) administered. All participants were required to be premedicated with steroids before paclitaxel administration, and with acetaminophen (650 mg orally) or clinically equivalent per clinic routine within 4 hours prior to test article infusion.

Measured Values

	MORAb-003 (Farletuzumab) Plus Paclitaxel	**Placebo (Normal Saline) Plus Paclitaxel**
Participants Analyzed [Units: Participants]	**21**	**21**
Time to Tumor Response (TTR) [Units: Months] Median (95% Confidence Interval)	**2.0** **(1.6 to 3.5)**	**1.7** **(1.6 to 3.3)**

No statistical analysis provided for Time to Tumor Response (TTR)

5. Other Pre-specified: Progression Free Survival Based on Gynecologic Cancer InterGroup (GCIG) [Time Frame: Length of study]

Measure Type	Other Pre-specified
Measure Title	Progression Free Survival Based on Gynecologic Cancer InterGroup (GCIG)
Measure Description	Due to termination of the study, data were not collected and the outcome measure for PFS based on GCIG was not analyzed.
Time Frame	Length of study

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 termination of the study, data were not collected and the outcome measure for PFS based on GCIG was not analyzed.

Reporting Groups

	Description
MORAb-003 (Farletuzumab) Plus Paclitaxel	Farletuzumab (FAR) at 2.5 mg/kg was administered by intravenous (IV) infusion weekly on Day 1

	of Weeks 1 to 12 (Cycle 1) and then in 4-week cycles with treatment administered on Day 1 of Weeks 1 to 3 for all subsequent cycles. Paclitaxel (80 mg/m^2) was administered weekly by IV infusion over 1 hour following administration of FAR. During the 4-week cycle, Week 4 was to be a rest period with no study treatment (test article or paclitaxel) administered. All participants were required to be premedicated with steroids before paclitaxel administration, and with acetaminophen (650 mg orally) or clinically equivalent per clinic routine within 4 hours prior to test article infusion.
Placebo (Normal Saline) Plus Paclitaxel	An equivalent volume of placebo (0.9% normal saline) was administered by IV infusion weekly on Day 1 of Weeks 1 to 12 (Cycle 1) and then in 4-week cycles with treatment administered on Day 1 of Weeks 1 to 3 for all subsequent cycles. Paclitaxel (80 mg/m^2) was administered weekly by IV infusion over 1 hour following administration of FAR. During the 4-week cycle, Week 4 was to be a rest period with no study treatment (test article or paclitaxel) administered. All participants were required to be premedicated with steroids before paclitaxel administration, and with acetaminophen (650 mg orally) or clinically equivalent per clinic routine within 4 hours prior to test article infusion.

Measured Values

	MORAb-003 (Farletuzumab) Plus Paclitaxel	Placebo (Normal Saline) Plus Paclitaxel
Participants Analyzed [Units: Participants]	**0**	**0**
Progression Free Survival Based on Gynecologic Cancer InterGroup (GCIG)		

No statistical analysis provided for Progression Free Survival Based on Gynecologic Cancer InterGroup (GCIG)

6. Other Pre-specified: Serologic Response Rate [Time Frame: Length of study]

Measure Type	Other Pre-specified
Measure Title	Serologic Response Rate
Measure Description	Due to termination of the study, data were not collected and the outcome measure for Serologic Response Rate was not analyzed.
Time Frame	Length of study

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 termination of the study, data were not collected and the outcome measure for Serologic Response Rate was not analyzed.

Reporting Groups

	Description
MORAb-003 (Farletuzumab) Plus Paclitaxel	Farletuzumab (FAR) at 2.5 mg/kg was administered by intravenous (IV) infusion weekly on Day 1 of Weeks 1 to 12 (Cycle 1) and then in 4-week cycles with treatment administered on Day 1 of Weeks 1 to 3 for all subsequent cycles. Paclitaxel (80 mg/m^2) was administered weekly by IV infusion over 1 hour following administration of FAR. During the 4-week cycle, Week 4 was to be a rest period with no study treatment (test article or paclitaxel) administered. All participants were required to be premedicated with steroids before paclitaxel administration, and with acetaminophen (650 mg orally) or clinically equivalent per clinic routine within 4 hours prior to test article infusion.
Placebo (Normal Saline) Plus Paclitaxel	An equivalent volume of placebo (0.9% normal saline) was administered by IV infusion weekly on

	Day 1 of Weeks 1 to 12 (Cycle 1) and then in 4-week cycles with treatment administered on Day 1 of Weeks 1 to 3 for all subsequent cycles. Paclitaxel (80 mg/m^2) was administered weekly by IV infusion over 1 hour following administration of FAR. During the 4-week cycle, Week 4 was to be a rest period with no study treatment (test article or paclitaxel) administered. All participants were required to be premedicated with steroids before paclitaxel administration, and with acetaminophen (650 mg orally) or clinically equivalent per clinic routine within 4 hours prior to test article infusion.

Measured Values

	MORAb-003 (Farletuzumab) Plus Paclitaxel	Placebo (Normal Saline) Plus Paclitaxel
Participants Analyzed [Units: Participants]	**0**	**0**
Serologic Response Rate		

No statistical analysis provided for Serologic Response Rate

Serious Adverse Events

Hide Serious Adverse Events

Time Frame	From the time the participant signed the study informed consent form until 30 days after the last dose of study drug (FAR or placebo), for up to approximately 3 years.
Additional Description	Safety Analysis Set was defined as all randomized participants who received any dose of FAR or placebo, analyzed according to the test article received. The National Cancer Institute Common Terminology Criteria for Adverse Events (NCI CTCAE) version 3.0 was used to grade severity of AEs. Treatment-emergent adverse events were reported.

Reporting Groups

	Description
MORAb-003 (Farletuzumab) Plus Paclitaxel	Farletuzumab (FAR) at 2.5 mg/kg was administered by intravenous (IV) infusion weekly on Day 1 of Weeks 1 to 12 (Cycle 1) and then in 4-week cycles with treatment administered on Day 1 of Weeks 1 to 3 for all subsequent cycles. Paclitaxel (80 mg/m^2) was administered weekly by IV infusion over 1 hour following administration of FAR. During the 4-week cycle, Week 4 was to be a rest period with no study treatment (test article or paclitaxel) administered. All participants were required to be premedicated with steroids before paclitaxel administration, and with acetaminophen (650 mg orally) or clinically equivalent per clinic routine within 4 hours prior to test article infusion.
Placebo (Normal Saline) Plus Paclitaxel	An equivalent volume of placebo (0.9% normal saline) was administered by IV infusion weekly on Day 1 of Weeks 1 to 12 (Cycle 1) and then in 4-week cycles with treatment administered on Day 1 of Weeks 1 to 3 for all subsequent cycles. Paclitaxel (80 mg/m^2) was administered weekly by IV infusion over 1 hour following administration of FAR. During the 4-week cycle, Week 4 was to be a rest period with no study treatment (test article or paclitaxel) administered. All participants were required to be premedicated with steroids before paclitaxel administration, and with acetaminophen (650 mg orally) or clinically equivalent per clinic routine within 4 hours prior to test article infusion.

Serious Adverse Events

	MORAb-003 (Farletuzumab) Plus Paclitaxel	Placebo (Normal Saline) Plus Paclitaxel
Total, Serious Adverse Events		
# participants affected / at risk	**127/279 (45.52%)**	**55/133 (41.35%)**

Blood and lymphatic system disorders		
Anaemia [*1]		
# participants affected / at risk	7/279 (2.51%)	7/133 (5.26%)
Neutropenia [†2]		
# participants affected / at risk	6/279 (2.15%)	1/133 (0.75%)
Febrile Neutropenia [†2]		
# participants affected / at risk	4/279 (1.43%)	1/133 (0.75%)
Leukopenia [†2]		
# participants affected / at risk	2/279 (0.72%)	0/133 (0.00%)
Cardiac disorders		
Atrial Fibrillation [†2]		
# participants affected / at risk	2/279 (0.72%)	1/133 (0.75%)
Cardiac Failure Congestive [†2]		
# participants affected / at risk	1/279 (0.36%)	0/133 (0.00%)
Cardio-Respiratory Arrest [†2]		
# participants affected / at risk	1/279 (0.36%)	0/133 (0.00%)
Gastrointestinal disorders		
Small Intestinal Obstruction [†2]		
# participants affected / at risk	18/279 (6.45%)	7/133 (5.26%)
Intestinal Obstruction [†2]		
# participants affected / at risk	10/279 (3.58%)	4/133 (3.01%)
Vomiting [†2]		
# participants affected / at risk	9/279 (3.23%)	5/133 (3.76%)
Constipation [†2]		
# participants affected / at risk	9/279 (3.23%)	2/133 (1.50%)
Ascites [†2]		
# participants affected / at risk	8/279 (2.87%)	2/133 (1.50%)
Nausea [†2]		
# participants affected / at risk	5/279 (1.79%)	3/133 (2.26%)
Abdominal Pain [†2]		
# participants affected / at risk	5/279 (1.79%)	1/133 (0.75%)
Diarrhoea [†2]		
# participants affected / at risk	2/279 (0.72%)	3/133 (2.26%)
Colonic Obstruction [†2]		
# participants affected / at risk	3/279 (1.08%)	0/133 (0.00%)
Ileus [†2]		
# participants affected / at risk	2/279 (0.72%)	1/133 (0.75%)
Gastrointestinal Haemorrhage [†2]		
# participants affected / at risk	2/279 (0.72%)	0/133 (0.00%)
Gastrointestinal Obstruction [†2]		
# participants affected / at risk	1/279 (0.36%)	1/133 (0.75%)
Intestinal Perforation [†2]		
# participants affected / at risk	2/279 (0.72%)	0/133 (0.00%)
Large Intestinal Obstruction [†2]		
# participants affected / at risk	1/279 (0.36%)	1/133 (0.75%)
Large Intestine Perforation [†2]		

# participants affected / at risk	1/279 (0.36%)	1/133 (0.75%)
Abdominal adhesions † 2		
# participants affected / at risk	1/279 (0.36%)	0/133 (0.00%)
Colonic Pseudo-obstruction † 2		
# participants affected / at risk	1/279 (0.36%)	0/133 (0.00%)
Diverticulum † 2		
# participants affected / at risk	1/279 (0.36%)	0/133 (0.00%)
Enterocutaneous Fistula † 2		
# participants affected / at risk	1/279 (0.36%)	0/133 (0.00%)
Faecal Volume Decreased † 2		
# participants affected / at risk	1/279 (0.36%)	0/133 (0.00%)
Faecal Volume Increased † 2		
# participants affected / at risk	1/279 (0.36%)	0/133 (0.00%)
Gastric Ulcer † 2		
# participants affected / at risk	1/279 (0.36%)	0/133 (0.00%)
Gastrointestinal Inflammation † 2		
# participants affected / at risk	1/279 (0.36%)	0/133 (0.00%)
Gastrointestinal Perforation † 2		
# participants affected / at risk	1/279 (0.36%)	0/133 (0.00%)
Oesophageal Obstruction † 2		
# participants affected / at risk	1/279 (0.36%)	0/133 (0.00%)
Rectourethral Fistula † 2		
# participants affected / at risk	1/279 (0.36%)	0/133 (0.00%)
Short-Bowel Syndrome † 2		
# participants affected / at risk	1/279 (0.36%)	0/133 (0.00%)
General disorders		
Disease Progression † 2		
# participants affected / at risk	17/279 (6.09%)	7/133 (5.26%)
Pyrexia † 2		
# participants affected / at risk	15/279 (5.38%)	2/133 (1.50%)
Fatigue † 2		
# participants affected / at risk	3/279 (1.08%)	1/133 (0.75%)
Asthenia † 2		
# participants affected / at risk	1/279 (0.36%)	1/133 (0.75%)
Obstruction † 2		
# participants affected / at risk	1/279 (0.36%)	1/133 (0.75%)
Pain † 2		
# participants affected / at risk	1/279 (0.36%)	1/133 (0.75%)
Generalised Oedema * 1		
# participants affected / at risk	1/279 (0.36%)	0/133 (0.00%)
Hernia Obstructive † 2		
# participants affected / at risk	1/279 (0.36%)	0/133 (0.00%)
Oedema Peripheral † 2		
# participants affected / at risk	1/279 (0.36%)	0/133 (0.00%)
Hepatobiliary disorders		
Cholecystitis Acute * 1		

# participants affected / at risk	1/279 (0.36%)	1/133 (0.75%)
Cholangitis † 2		
# participants affected / at risk	1/279 (0.36%)	0/133 (0.00%)
Infections and infestations		
Cellulitis * 1		
# participants affected / at risk	6/279 (2.15%)	2/133 (1.50%)
Urinary Tract Infection † 2		
# participants affected / at risk	5/279 (1.79%)	3/133 (2.26%)
Pneumonia † 2		
# participants affected / at risk	4/279 (1.43%)	2/133 (1.50%)
Sepsis † 2		
# participants affected / at risk	3/279 (1.08%)	1/133 (0.75%)
Catheter Site Infection † 2		
# participants affected / at risk	1/279 (0.36%)	1/133 (0.75%)
Device Related Infection † 2		
# participants affected / at risk	1/279 (0.36%)	1/133 (0.75%)
Infection † 2		
# participants affected / at risk	1/279 (0.36%)	1/133 (0.75%)
Lobar Pneumonia † 2		
# participants affected / at risk	1/279 (0.36%)	1/133 (0.75%)
Abdominal Infection † 2		
# participants affected / at risk	0/279 (0.00%)	1/133 (0.75%)
Bacterial Pyelonephritis † 2		
# participants affected / at risk	1/279 (0.36%)	0/133 (0.00%)
Candida Sepsis * 1		
# participants affected / at risk	1/279 (0.36%)	0/133 (0.00%)
Clostridium Difficile Colitis † 2		
# participants affected / at risk	1/279 (0.36%)	0/133 (0.00%)
Escherichia Sepsis † 2		
# participants affected / at risk	0/279 (0.00%)	1/133 (0.75%)
Herpes Zoster † 2		
# participants affected / at risk	1/279 (0.36%)	0/133 (0.00%)
Incision Site Infection † 2		
# participants affected / at risk	0/279 (0.00%)	1/133 (0.75%)
Infectious Peritonitis † 2		
# participants affected / at risk	0/279 (0.00%)	1/133 (0.75%)
Klebsiella Bacteraemia † 2		
# participants affected / at risk	0/279 (0.00%)	1/133 (0.75%)
Meningitis † 2		
# participants affected / at risk	0/279 (0.00%)	1/133 (0.75%)
Parotitis † 2		
# participants affected / at risk	1/279 (0.36%)	0/133 (0.00%)
Pelvic Infection † 2		
# participants affected / at risk	1/279 (0.36%)	0/133 (0.00%)
Postoperative Wound Infection † 2		
# participants affected / at risk	1/279 (0.36%)	0/133 (0.00%)

Pseudomonal Sepsis † 2		
# participants affected / at risk	1/279 (0.36%)	0/133 (0.00%)
Respiratory Tract Infection * 1		
# participants affected / at risk	1/279 (0.36%)	0/133 (0.00%)
Retroperitoneal Abcess † 2		
# participants affected / at risk	1/279 (0.36%)	0/133 (0.00%)
Urosepsis † 2		
# participants affected / at risk	1/279 (0.36%)	0/133 (0.00%)
Pneumonia bacterial * 1		
# participants affected / at risk	1/279 (0.36%)	0/133 (0.00%)
Injury, poisoning and procedural complications		
Postoperative Ileus † 2		
# participants affected / at risk	0/279 (0.00%)	1/133 (0.75%)
Tibia fracture † 2		
# participants affected / at risk	1/279 (0.36%)	0/133 (0.00%)
Investigations		
Haemoglobin Decreased † 2		
# participants affected / at risk	0/279 (0.00%)	1/133 (0.75%)
Weight decreased † 2		
# participants affected / at risk	1/279 (0.36%)	0/133 (0.00%)
Metabolism and nutrition disorders		
Dehydration † 2		
# participants affected / at risk	4/279 (1.43%)	0/133 (0.00%)
Decreased Appetite † 2		
# participants affected / at risk	1/279 (0.36%)	0/133 (0.00%)
Failure to thrive † 2		
# participants affected / at risk	1/279 (0.36%)	0/133 (0.00%)
Hypocalcaemia † 2		
# participants affected / at risk	1/279 (0.36%)	0/133 (0.00%)
Hypokalaemia † 2		
# participants affected / at risk	1/279 (0.36%)	0/133 (0.00%)
Hypomagnesaemia * 1		
# participants affected / at risk	1/279 (0.36%)	0/133 (0.00%)
Hyponatraemia † 2		
# participants affected / at risk	1/279 (0.36%)	0/133 (0.00%)
Hypophagia * 1		
# participants affected / at risk	1/279 (0.36%)	0/133 (0.00%)
Malnutrition † 2		
# participants affected / at risk	1/279 (0.36%)	0/133 (0.00%)
Musculoskeletal and connective tissue disorders		
Back Pain † 2		
# participants affected / at risk	2/279 (0.72%)	1/133 (0.75%)
Fistula † 2		
# participants affected / at risk	1/279 (0.36%)	0/133 (0.00%)
Muscle Necrosis † 2		

# participants affected / at risk	0/279 (0.00%)	1/133 (0.75%)
Muscular Weakness † 2		
# participants affected / at risk	1/279 (0.36%)	0/133 (0.00%)
Musculoskeletal Chest Pain † 2		
# participants affected / at risk	0/279 (0.00%)	1/133 (0.75%)
Myalgia † 2		
# participants affected / at risk	1/279 (0.36%)	0/133 (0.00%)
Pain in Extremity † 2		
# participants affected / at risk	1/279 (0.36%)	0/133 (0.00%)
Systemic Lupus Erythematosus † 2		
# participants affected / at risk	0/279 (0.00%)	1/133 (0.75%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		
Oncologic Complication * 1		
# participants affected / at risk	3/279 (1.08%)	0/133 (0.00%)
Metastases to Central Nervous System † 2		
# participants affected / at risk	0/279 (0.00%)	2/133 (1.50%)
Colon Cancer † 2		
# participants affected / at risk	1/279 (0.36%)	0/133 (0.00%)
Metastatic Neoplasm † 2		
# participants affected / at risk	1/279 (0.36%)	0/133 (0.00%)
Tumour Associated Fever † 2		
# participants affected / at risk	1/279 (0.36%)	0/133 (0.00%)
Nervous system disorders		
Syncope † 2		
# participants affected / at risk	2/279 (0.72%)	1/133 (0.75%)
Brain Mass † 2		
# participants affected / at risk	1/279 (0.36%)	0/133 (0.00%)
Convulsion † 2		
# participants affected / at risk	1/279 (0.36%)	0/133 (0.00%)
Encephelopathy † 2		
# participants affected / at risk	0/279 (0.00%)	1/133 (0.75%)
Lethargy † 2		
# participants affected / at risk	1/279 (0.36%)	0/133 (0.00%)
Mononeuritis † 2		
# participants affected / at risk	0/279 (0.00%)	1/133 (0.75%)
Neuropathy Peripheral † 2		
# participants affected / at risk	1/279 (0.36%)	0/133 (0.00%)
Posterior Reversible Encephelopathy Syndrome † 2		
# participants affected / at risk	1/279 (0.36%)	0/133 (0.00%)
Psychiatric disorders		
Depression * 1		
# participants affected / at risk	2/279 (0.72%)	1/133 (0.75%)
Anxiety † 2		
# participants affected / at risk	1/279 (0.36%)	0/133 (0.00%)
Disorientation † 2		

# participants affected / at risk	1/279 (0.36%)	0/133 (0.00%)
Mental Status Change † 2		
# participants affected / at risk	1/279 (0.36%)	0/133 (0.00%)
Renal and urinary disorders		
Renal Failure Acute † 2		
# participants affected / at risk	2/279 (0.72%)	2/133 (1.50%)
Hydronephrosis † 2		
# participants affected / at risk	2/279 (0.72%)	1/133 (0.75%)
Renal Failure † 2		
# participants affected / at risk	1/279 (0.36%)	2/133 (1.50%)
Bladder Spasm † 2		
# participants affected / at risk	1/279 (0.36%)	0/133 (0.00%)
Dysuria † 2		
# participants affected / at risk	1/279 (0.36%)	0/133 (0.00%)
Renal Impairment † 2		
# participants affected / at risk	0/279 (0.00%)	1/133 (0.75%)
Ureteric Obstruction † 2		
# participants affected / at risk	1/279 (0.36%)	0/133 (0.00%)
Urinary Tract Obstruction † 2		
# participants affected / at risk	1/279 (0.36%)	0/133 (0.00%)
Respiratory, thoracic and mediastinal disorders		
Pulmonary Embolism * 1		
# participants affected / at risk	10/279 (3.58%)	4/133 (3.01%)
Dyspnoea † 2		
# participants affected / at risk	7/279 (2.51%)	4/133 (3.01%)
Pleural Effusion † 2		
# participants affected / at risk	3/279 (1.08%)	2/133 (1.50%)
Pneumonitis * 1		
# participants affected / at risk	5/279 (1.79%)	0/133 (0.00%)
Epistaxis † 2		
# participants affected / at risk	1/279 (0.36%)	0/133 (0.00%)
Interstitial Lung Disease † 2		
# participants affected / at risk	1/279 (0.36%)	0/133 (0.00%)
Respiratory Failure † 2		
# participants affected / at risk	1/279 (0.36%)	0/133 (0.00%)
Tachypnoea † 2		
# participants affected / at risk	0/279 (0.00%)	1/133 (0.75%)
Skin and subcutaneous tissue disorders		
Dermatits Exfoliative † 2		
# participants affected / at risk	0/279 (0.00%)	1/133 (0.75%)
Palmar-Plantar Erythrodysaesthesia Syndrome † 2		
# participants affected / at risk	1/279 (0.36%)	0/133 (0.00%)
Rash † 2		
# participants affected / at risk	1/279 (0.36%)	0/133 (0.00%)
Skin Toxicity † 2		
# participants affected / at risk	1/279 (0.36%)	0/133 (0.00%)

Vascular disorders		
Hypotension † 2		
# participants affected / at risk	**2/279 (0.72%)**	**2/133 (1.50%)**
Thrombosis † 2		
# participants affected / at risk	**3/279 (1.08%)**	**0/133 (0.00%)**
Deep Vein Thrombosis † 2		
# participants affected / at risk	**1/279 (0.36%)**	**1/133 (0.75%)**
Subclavian Vein Thrombosis † 2		
# participants affected / at risk	**1/279 (0.36%)**	**0/133 (0.00%)**
Superior Vena Cava Syndrome † 2		
# participants affected / at risk	**0/279 (0.00%)**	**1/133 (0.75%)**
Venous Thrombosis Limb † 2		
# participants affected / at risk	**1/279 (0.36%)**	**0/133 (0.00%)**

† Events were collected by systematic assessment
* Events were collected by non-systematic assessment
1 Term from vocabulary, MedDra 14.1
2 Term from vocabulary, Select

Other Adverse Events

Hide Other Adverse Events

Time Frame	From the time the participant signed the study informed consent form until 30 days after the last dose of study drug (FAR or placebo), for up to approximately 3 years.
Additional Description	Safety Analysis Set was defined as all randomized participants who received any dose of FAR or placebo, analyzed according to the test article received. The National Cancer Institute Common Terminology Criteria for Adverse Events (NCI CTCAE) version 3.0 was used to grade severity of AEs. Treatment-emergent adverse events were reported.

Frequency Threshold

Threshold above which other adverse events are reported	5%

Reporting Groups

	Description
MORAb-003 (Farletuzumab) Plus Paclitaxel	Farletuzumab (FAR) at 2.5 mg/kg was administered by intravenous (IV) infusion weekly on Day 1 of Weeks 1 to 12 (Cycle 1) and then in 4-week cycles with treatment administered on Day 1 of Weeks 1 to 3 for all subsequent cycles. Paclitaxel (80 mg/m^2) was administered weekly by IV infusion over 1 hour following administration of FAR. During the 4-week cycle, Week 4 was to be a rest period with no study treatment (test article or paclitaxel) administered. All participants were required to be premedicated with steroids before paclitaxel administration, and with acetaminophen (650 mg orally) or clinically equivalent per clinic routine within 4 hours prior to test article infusion.
Placebo (Normal Saline) Plus Paclitaxel	An equivalent volume of placebo (0.9% normal saline) was administered by IV infusion weekly on Day 1 of Weeks 1 to 12 (Cycle 1) and then in 4-week cycles with treatment administered on Day 1 of Weeks 1 to 3 for all subsequent cycles. Paclitaxel (80 mg/m^2) was administered weekly by IV infusion over 1 hour following administration of FAR. During the 4-week cycle, Week 4 was to be a rest period with no study treatment (test article or paclitaxel) administered. All participants were required to be premedicated with steroids before paclitaxel administration, and with acetaminophen (650 mg orally) or clinically equivalent per clinic routine within 4 hours prior to test article infusion.

Other Adverse Events

	MORAb-003 (Farletuzumab) Plus Paclitaxel	Placebo (Normal Saline) Plus Paclitaxel
Total, Other (not including serious) Adverse Events		
# participants affected / at risk	278/279 (99.64%)	133/133 (100.00%)
Blood and lymphatic system disorders		
Anaemia † 2		
# participants affected / at risk	78/279 (27.96%)	37/133 (27.82%)
Neutropenia † 2		
# participants affected / at risk	38/279 (13.62%)	18/133 (13.53%)
Leukopenia † 2		
# participants affected / at risk	16/279 (5.73%)	9/133 (6.77%)
Eye disorders		
Vision Blurred † 2		
# participants affected / at risk	14/279 (5.02%)	8/133 (6.02%)
Gastrointestinal disorders		
Nausea * 1		
# participants affected / at risk	132/279 (47.31%)	66/133 (49.62%)
Diarrhoea † 2		
# participants affected / at risk	119/279 (42.65%)	53/133 (39.85%)
Constipation † 2		
# participants affected / at risk	96/279 (34.41%)	53/133 (39.85%)
Abdominal pain † 2		
# participants affected / at risk	88/279 (31.54%)	34/133 (25.56%)
Vomiting † 2		
# participants affected / at risk	84/279 (30.11%)	37/133 (27.82%)
Abdominal Distension † 2		
# participants affected / at risk	51/279 (18.28%)	21/133 (15.79%)
Ascites † 2		
# participants affected / at risk	22/279 (7.89%)	11/133 (8.27%)
Stomatitis † 2		
# participants affected / at risk	26/279 (9.32%)	7/133 (5.26%)
Dyspepsia † 2		
# participants affected / at risk	22/279 (7.89%)	10/133 (7.52%)
Abdominal Pain Upper † 2		
# participants affected / at risk	25/279 (8.96%)	6/133 (4.51%)
Dry mouth † 2		
# participants affected / at risk	19/279 (6.81%)	8/133 (6.02%)
Small intestinal Obstruction † 2		
# participants affected / at risk	19/279 (6.81%)	7/133 (5.26%)
Flatulence † 2		
# participants affected / at risk	18/279 (6.45%)	5/133 (3.76%)
Gastroresophageal Reflux Disease † 2		
# participants affected / at risk	10/279 (3.58%)	8/133 (6.02%)
General disorders		
Fatigue † 2		

# participants affected / at risk	184/279 (65.95%)	82/133 (61.65%)
Oedema Peripheral † 2		
# participants affected / at risk	60/279 (21.51%)	26/133 (19.55%)
Pyrexia † 2		
# participants affected / at risk	43/279 (15.41%)	18/133 (13.53%)
Asthenia † 2		
# participants affected / at risk	24/279 (8.60%)	12/133 (9.02%)
Mucosal Inflammation † 2		
# participants affected / at risk	24/279 (8.60%)	11/133 (8.27%)
Chills † 2		
# participants affected / at risk	18/279 (6.45%)	7/133 (5.26%)
Disease Progression † 2		
# participants affected / at risk	17/279 (6.09%)	7/133 (5.26%)
Pain † 2		
# participants affected / at risk	17/279 (6.09%)	7/133 (5.26%)
Oedema † 2		
# participants affected / at risk	6/279 (2.15%)	7/133 (5.26%)
Infections and infestations		
Urinary Tract Infection † 2		
# participants affected / at risk	47/279 (16.85%)	30/133 (22.56%)
Upper Respiratory Tract Infection † 2		
# participants affected / at risk	24/279 (8.60%)	6/133 (4.51%)
Nasopharyngitits † 2		
# participants affected / at risk	16/279 (5.73%)	4/133 (3.01%)
Sinusitis † 2		
# participants affected / at risk	10/279 (3.58%)	9/133 (6.77%)
Injury, poisoning and procedural complications		
Contusion † 2		
# participants affected / at risk	19/279 (6.81%)	1/133 (0.75%)
Metabolism and nutrition disorders		
Decreased Appetite † 2		
# participants affected / at risk	67/279 (24.01%)	27/133 (20.30%)
Hypomagnesaemia † 2		
# participants affected / at risk	31/279 (11.11%)	18/133 (13.53%)
Hypokalaemia † 2		
# participants affected / at risk	28/279 (10.04%)	9/133 (6.77%)
Dehydration † 2		
# participants affected / at risk	14/279 (5.02%)	5/133 (3.76%)
Musculoskeletal and connective tissue disorders		
Arthralgia * 1		
# participants affected / at risk	43/279 (15.41%)	22/133 (16.54%)
Back Pain † 2		
# participants affected / at risk	36/279 (12.90%)	26/133 (19.55%)
Myalgia † 2		
# participants affected / at risk	28/279 (10.04%)	17/133 (12.78%)

Pain In Extremity [†2]		
# participants affected / at risk	31/279 (11.11%)	12/133 (9.02%)
Muscle Spasms [†2]		
# participants affected / at risk	14/279 (5.02%)	12/133 (9.02%)
Musculoskeletal Pain [†2]		
# participants affected / at risk	15/279 (5.38%)	6/133 (4.51%)
Musculoskeletal Chest Pain [†2]		
# participants affected / at risk	14/279 (5.02%)	6/133 (4.51%)
Nervous system disorders		
Neuropathy Peripheral [*1]		
# participants affected / at risk	75/279 (26.88%)	37/133 (27.82%)
Headache [†2]		
# participants affected / at risk	72/279 (25.81%)	28/133 (21.05%)
Dizziness [†2]		
# participants affected / at risk	42/279 (15.05%)	18/133 (13.53%)
Peripheral Sensory Neuropathy [†2]		
# participants affected / at risk	38/279 (13.62%)	15/133 (11.28%)
Dysguesia [†2]		
# participants affected / at risk	29/279 (10.39%)	22/133 (16.54%)
Restless Legs Syndrome [†2]		
# participants affected / at risk	14/279 (5.02%)	2/133 (1.50%)
Hypoaesthesia [†2]		
# participants affected / at risk	6/279 (2.15%)	7/133 (5.26%)
Psychiatric disorders		
Insomnia [†2]		
# participants affected / at risk	54/279 (19.35%)	23/133 (17.29%)
Anxiety [†2]		
# participants affected / at risk	25/279 (8.96%)	16/133 (12.03%)
Depression [†2]		
# participants affected / at risk	24/279 (8.60%)	8/133 (6.02%)
Renal and urinary disorders		
Dysuria [†2]		
# participants affected / at risk	9/279 (3.23%)	12/133 (9.02%)
Pollakiuria [†2]		
# participants affected / at risk	7/279 (2.51%)	9/133 (6.77%)
Respiratory, thoracic and mediastinal disorders		
Cough [*1]		
# participants affected / at risk	58/279 (20.79%)	27/133 (20.30%)
Dyspnoea [†2]		
# participants affected / at risk	56/279 (20.07%)	21/133 (15.79%)
Epistaxis [†2]		
# participants affected / at risk	50/279 (17.92%)	25/133 (18.80%)
Dyspnoea Exertional [†2]		
# participants affected / at risk	29/279 (10.39%)	6/133 (4.51%)
Oropharyngeal Pain [†2]		

# participants affected / at risk	16/279 (5.73%)	13/133 (9.77%)
Nasal Congestion † 2		
# participants affected / at risk	9/279 (3.23%)	9/133 (6.77%)
Skin and subcutaneous tissue disorders		
Alopecia * 1		
# participants affected / at risk	143/279 (51.25%)	59/133 (44.36%)
Rash † 2		
# participants affected / at risk	55/279 (19.71%)	19/133 (14.29%)
Nail disorder † 2		
# participants affected / at risk	47/279 (16.85%)	19/133 (14.29%)
Dry skin † 2		
# participants affected / at risk	18/279 (6.45%)	7/133 (5.26%)
Erythema † 2		
# participants affected / at risk	18/279 (6.45%)	6/133 (4.51%)
Pruritus † 2		
# participants affected / at risk	15/279 (5.38%)	8/133 (6.02%)
Hyperhidrosis † 2		
# participants affected / at risk	13/279 (4.66%)	7/133 (5.26%)
Nail discolouration † 2		
# participants affected / at risk	11/279 (3.94%)	7/133 (5.26%)
Vascular disorders		
Flushing † 2		
# participants affected / at risk	28/279 (10.04%)	9/133 (6.77%)
Hypotension † 2		
# participants affected / at risk	10/279 (3.58%)	7/133 (5.26%)

† Events were collected by systematic assessment
* Events were collected by non-systematic assessment
1 Term from vocabulary, MedDra 14.1
2 Term from vocabulary, Select

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

This study was prematurely terminated by the sponsor following results of the preplanned futility analysis showing the study was unlikely to meet its statistically-defined coprimary endpoints.

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

Responsible Party:	Morphotek
ClinicalTrials.gov Identifier:	NCT00738699 History of Changes
Other Study ID Numbers:	MORAb003-003PR
Study First Received:	August 18, 2008
Results First Received:	December 13, 2016
Last Updated:	February 10, 2017

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

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