ClinicalTrials.gov Protocol Registration and Results System (PRS) Receipt
Release Date: December 16, 2016

ClinicalTrials.gov ID: NCT00738699

Study Identification

Unique Protocol ID:	MORAb003-003PR
Brief Title:	An Efficacy and Safety Study of MORAb-003 in Platinum-Resistant or Refractory Relapsed Ovarian Cancer (FAR-122)
Official Title:	A Randomized, Double Blind, Placebo-Controlled Study of the Efficacy and Safety oF MORAb-003(Farletuzumab) in Combination With Paclitaxel Therapy in Subjects With Platinum-Resistant or Refractory Relapsed Ovarian Cancer
Secondary IDs:	

Study Status

Record Verification:	December 2016
Overall Status:	Terminated [study did not meet pre-specified criteria for continuation following interim futility analysis]
Study Start:	September 2008
Primary Completion:	December 2011 [Actual]
Study Completion:	January 2012 [Actual]

Sponsor/Collaborators

Sponsor:	Morphotek
Responsible Party:	Sponsor
Collaborators:	

Oversight

FDA Regulated?:	Yes
Applicable Trial?:	Section 801 Clinical Trial? Yes

	Delayed Posting? No
IND/IDE Protocol?:	Yes
IND/IDE Information:	Grantor: CDER IND/IDE Number: BB12219 Serial Number: Has Expanded Access? No
Review Board:	Approval Status: Approved Approval Number: 09/05/2008 Board Name: Western Institutional Review Board Board Affiliation: Western Institutional Review Board, Inc. Phone: 360-252-2500 Email:
Data Monitoring?:	Yes
Plan to Share IPD?:	
Oversight Authorities:	United States: Food and Drug Administration

Study Description

Brief Summary:	The study is being conducted to find out if paclitaxel works better when given together with an experimental drug called MORAb-003 (farletuzumab) or alone in patients with platinum-resistant or refractory relapsed ovarian cancer
Detailed Description:	Safety was assessed by the monitoring and recording of all adverse events (AEs), including drug hypersensitivity adverse events (DHAE), and serious adverse events (SAEs); clinical laboratory test (serum chemistry, hematology, urinalysis); tolerability (discontinuations, treatment delays, dose reductions); physical examinations (including vital signs assessment); 12-lead electrocardiograms (ECG) obtained in triplicate and reviewed by independent blinded cardiologist, and Karnofsky's performance status.

Conditions

Conditions:	Ovarian Cancer
Keywords:	ovarian cancer relapsed ovarian cancer refractory ovarian cancer

Study Design

Study Type:	Interventional
Primary Purpose:	Treatment

Study Phase:	Phase 2
Intervention Model:	Parallel Assignment
Number of Arms:	2
Masking:	Double Blind (Subject, Caregiver, Investigator, Outcomes Assessor)
Allocation:	Randomized
Endpoint Classification:	Safety/Efficacy Study
Enrollment:	415 [Actual]

Arms and Interventions

Arms	Assigned Interventions
Active Comparator: 1 MORAb-003 (Farletuzumab) Plus Paclitaxel	Drug: MORAb-003 (farletuzumab) 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. Drug: Paclitaxel Other Names: • Paclitaxel (80 mg/m^2) was administered by IV infusion over 1 hour following administration of FAR.
Placebo Comparator: 2 Placebo Plus Paclitaxel	Drug: 0.9% Saline 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. Drug: Paclitaxel Other Names: • Paclitaxel (80 mg/m^2) was administered by IV infusion over 1 hour following administration of FAR.

Outcome Measures

[See Results Section.]

Eligibility

Minimum Age:	18 Years
Maximum Age:	99 Years

Gender: Female

Accepts Healthy Volunteers?: No

Criteria: Inclusion Criteria:

- Diagnosis of non-mucinous epithelial ovarian cancer, including primary peritoneal and fallopian tube malignancies, measurable by CT or MRI scan assessed within 4 weeks prior to study entry
- Must have evidence of relapse by CA-125 (2xUpper Limit of Normal) or radiographically within 6 months of most recent platinum-containing chemotherapy. At least one of the lines of chemotherapy must have included a taxane.
- Must have been treated with debulking surgery and at least one line platinum-based chemotherapy;
- Subjects may have received up to four additional lines of chemotherapy after they developed platinum-resistance.
- Subjects must be candidate for repeat paclitaxel treatment

Exclusion Criteria:

- Clinical contraindications to use of paclitaxel, which include:
    a. persistent Grade 2 or greater peripheral neuropathy
    b. prior hypersensitivity reaction that persisted despite rechallenge with or without desensitization or resulted in bronchospasm or hemodynamic instability or was at least Grade 2 and resulted in medication discontinuation
- Current diagnosis of epithelial ovarian tumor of low malignant potential (borderline carcinomas). Note: EOC with prior diagnosis of a low malignant potential tumor that has been surgically resected is acceptable provided the subject did
- Prior radiation therapy is excluded with the exception that it is allowable only if measurable disease for ovarian cancer is completely outside the radiation portal
- Known allergic reaction to a prior monoclonal antibody therapy or have any documented human anti-human antibody (HAHA).
- Previous treatment with MORAb-003 (farletuzumab).

Contacts/Locations

Study Officials:

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Winfield, Illinois, United States, 60190

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References

Citations:

Links:

Study Data/Documents:

Delayed Results

Delay Type	Certify Initial Approval
Intervention Name(s)	MORAb-003 (farletuzumab)

Study Results

Participant Flow

Pre-Assignment Details	The number of participants enrolled/randomized was 415. Of the 415 participants, 412 participants were treated.

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.

Overall Study

	MORAb-003 (Farletuzumab) Plus Paclitaxel	Placebo (Normal Saline) Plus Paclitaxel
Started	275	140
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

Baseline Analysis Population Description

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.

Baseline Measures

		MORAb-003 (Farletuzumab) Plus Paclitaxel	Placebo (Normal Saline) Plus Paclitaxel	Total
Overall Number of Participants		275	140	415
Age, Continuous Geometric Mean (Standard Deviation) Unit of measure: Years	Number Analyzed	275 participants	140 participants	415 participants
		60.9 (10.74)	61.2 (9.44)	61.0 (10.31)
Gender, Male/ Female Measure Type: Count of Participants Unit of measure: participants	Number Analyzed	275 participants	140 participants	415 participants
	Female	275 100%	140 100%	415 100%
	Male	0 0%	0 0%	0 0%

Outcome Measures

1. Primary Outcome Measure:

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). 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; complete response (CR), partial response (PR), progressive disease (PD), stable disease (SD), or not evaluable (NE).
Time Frame	Date of Randomization to date of disease progression or death (whichever came first), assessed up to study termination (28NOV2011), or up to approximately 2.5 years.
Safety Issue?	No

Analysis Population Description

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
Number of Participants Analyzed	275	140

	MORAb-003 (Farletuzumab) Plus Paclitaxel	Placebo (Normal Saline) Plus Paclitaxel
Progression-Free Survival (PFS) Median (95% Confidence Interval) Unit of measure: Months	3.5 (3.3 to 3.9)	3.7 (3.3 to 5.2)

Statistical Analysis 1 for Progression-Free Survival (PFS)

Statistical Analysis Overview	Comparison Groups	MORAb-003 (Farletuzumab) Plus Paclitaxel, Placebo (Normal Saline) Plus Paclitaxel
	Comments	[Not specified]
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.8360
	Comments	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).
	Method	Log Rank
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Cox Proportional Hazard
	Estimated Value	1.13
	Confidence Interval	(2-Sided) 95% 0.88 to 1.46
	Estimation Comments	Stratified as described above.

2. Primary Outcome Measure:

Measure Title	Overall Survival (OS)
Measure Description	Overall survival 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 (28NOV2011), or up to approximately 2.5 years.
Safety Issue?	No

Analysis Population Description

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
Number of Participants Analyzed	275	140
Overall Survival (OS) Median (95% Confidence Interval) Unit of measure: Months	11.3 (10.3 to 12.7)	13.1 (10.3 to 16.7)

Statistical Analysis 1 for Overall Survival (OS)

Statistical Analysis Overview	Comparison Groups	MORAb-003 (Farletuzumab) Plus Paclitaxel, Placebo (Normal Saline) Plus Paclitaxel
	Comments	[Not specified]
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.7568
	Comments	One-sided log rank test stratified by route of administration for primary chemotherapy and geographic region.
	Method	Log Rank
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Cox Proportional Hazard
	Estimated Value	1.11
	Confidence Interval	(2-Sided) 95% 0.83 to 1.48
	Estimation Comments	Stratified as described above

3. Secondary Outcome Measure:

Measure Title	Best Overall Response
Measure Description	The best overall response, (also referred to as objective response), was defined as the percentage of participants having either a confirmed CR or confirmed 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 assessment performed up to the initiation of further antitumor treatment were considered. Participants were assigned to one of the categories of change in disease state; CR, PR, PD, SD, or NE.
Time Frame	Date of first study drug to disease progression/recurrence, assessed up to study termination (28NOV2011), or up to approximately 2.5 years
Safety Issue?	No

Analysis Population Description

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.

	Description
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
Number of Participants Analyzed	275	140
Best Overall Response Measure Type: Number Unit of measure: Percentage of participants		
Complete response (CR)	0.4	0
Partial response (PR)	7.3	15.0

Statistical Analysis 1 for Best Overall Response

Statistical Analysis Overview	Comparison Groups	MORAb-003 (Farletuzumab) Plus Paclitaxel, Placebo (Normal Saline) Plus Paclitaxel
	Comments	[Not specified]
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.0399
	Comments	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.
	Method	Cochran-Mantel-Haenszel
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Other [Difference]
	Estimated Value	-7.4
	Confidence Interval	(2-Sided) 95%

		-14.1 to -0.7
	Estimation Comments	(FAR + Paclitaxel) minus (Placebo + Paclitaxel). Confidence interval based on a normal approximation to the binomial distribution.

4. Secondary Outcome Measure:

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 (28NOV2011), or up to approximately 2.5 years
Safety Issue?	No

Analysis Population Description

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
Number of Participants Analyzed	21	21

	MORAb-003 (Farletuzumab) Plus Paclitaxel	Placebo (Normal Saline) Plus Paclitaxel
Time to Tumor Response (TTR) Median (95% Confidence Interval) Unit of measure: Months	2.0 (1.6 to 3.5)	1.7 (1.6 to 3.3)

5. Other Pre-specified Outcome Measure:

Measure Title	Progression Free Survival Based on Gynecologic Cancer InterGroup (GCIG)
Measure Description	Because the study was stopped for futility, this secondary efficacy endpoints was not analyzed.
Time Frame	Length of study
Safety Issue?	No

Analysis Population Description

Because the study was stopped for futility, this secondary efficacy endpoints 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
Number of Participants Analyzed	0	0

No data displayed because Outcome Measure has zero total participants analyzed.

6. Other Pre-specified Outcome Measure:

Measure Title	Serologic Response Rate
Measure Description	Because the study was stopped for futility, this secondary efficacy endpoints was not analyzed.
Time Frame	Length of study
Safety Issue?	No

Analysis Population Description

Because the study was stopped for futility, this secondary efficacy endpoints 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
Number of Participants Analyzed	0	0

No data displayed because Outcome Measure has zero total participants analyzed.

Reported Adverse Events

Time Frame	Adverse Events (AEs) were collected from the time the participant signed the study informed consent form (ICF) until 30 days after the last dose of study drug (FAR or placebo). Participants were followed for up to 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 AEs were reported.

Reporting Groups

	Description
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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
	Affected/At Risk (%)	Affected/At Risk (%)
Total	127/279 (45.52%)	55/133 (41.35%)
Blood and lymphatic system disorders		
Anaemia [A] *	7/279 (2.51%)	7/133 (5.26%)
Febrile Neutropenia [B] *	4/279 (1.43%)	1/133 (0.75%)
Leukopenia [B] *	2/279 (0.72%)	0/133 (0%)
Neutropenia [B] *	6/279 (2.15%)	1/133 (0.75%)

	MORAb-003 (Farletuzumab) Plus Paclitaxel	Placebo (Normal Saline) Plus Paclitaxel
	Affected/At Risk (%)	Affected/At Risk (%)
Cardiac disorders		
Atrial Fibrillation [B] *	2/279 (0.72%)	1/133 (0.75%)
Cardiac Failure Congestive [B] *	1/279 (0.36%)	0/133 (0%)
Cardio-Respiratory Arrest [B] *	1/279 (0.36%)	0/133 (0%)
Gastrointestinal disorders		
Abdominal Pain [B] *	5/279 (1.79%)	1/133 (0.75%)
Abdominal adhesions [B] *	1/279 (0.36%)	0/133 (0%)
Ascites [B] *	8/279 (2.87%)	2/133 (1.5%)
Colonic Obstruction [B] *	3/279 (1.08%)	0/133 (0%)
Colonic Pseudo-obstruction [B] *	1/279 (0.36%)	0/133 (0%)
Constipation [B] *	9/279 (3.23%)	2/133 (1.5%)
Diarrhoea [B] *	2/279 (0.72%)	3/133 (2.26%)
Diverticulum [B] *	1/279 (0.36%)	0/133 (0%)
Enterocutaneous Fistula [B] *	1/279 (0.36%)	0/133 (0%)
Faecal Volume Decreased [B] *	1/279 (0.36%)	0/133 (0%)
Faecal Volume Increased [B] *	1/279 (0.36%)	0/133 (0%)
Gastric Ulcer [B] *	1/279 (0.36%)	0/133 (0%)
Gastrointestinal Haemorrhage [B] *	2/279 (0.72%)	0/133 (0%)
Gastrointestinal Inflammation [B] *	1/279 (0.36%)	0/133 (0%)
Gastrointestinal Obstruction [B] *	1/279 (0.36%)	1/133 (0.75%)
Gastrointestinal Perforation [B] *	1/279 (0.36%)	0/133 (0%)
Ileus [B] *	2/279 (0.72%)	1/133 (0.75%)
Intestinal Obstruction [B] *	10/279 (3.58%)	4/133 (3.01%)

	MORAb-003 (Farletuzumab) Plus Paclitaxel	Placebo (Normal Saline) Plus Paclitaxel
	Affected/At Risk (%)	Affected/At Risk (%)
Intestinal Perforation [B] *	2/279 (0.72%)	0/133 (0%)
Large Intestinal Obstruction [B] *	1/279 (0.36%)	1/133 (0.75%)
Large Intestine Perforation [B] *	1/279 (0.36%)	1/133 (0.75%)
Nausea [B] *	5/279 (1.79%)	3/133 (2.26%)
Oesophageal Obstruction [B] *	1/279 (0.36%)	0/133 (0%)
Rectourethral Fistula [B] *	1/279 (0.36%)	0/133 (0%)
Short-Bowel Syndrome [B] *	1/279 (0.36%)	0/133 (0%)
Small Intestinal Obstruction [B] *	18/279 (6.45%)	7/133 (5.26%)
Vomiting [B] *	9/279 (3.23%)	5/133 (3.76%)
General disorders		
Asthenia [B] *	1/279 (0.36%)	1/133 (0.75%)
Disease Progression [B] *	17/279 (6.09%)	7/133 (5.26%)
Fatigue [B] *	3/279 (1.08%)	1/133 (0.75%)
Generalised Oedema [A] *	1/279 (0.36%)	0/133 (0%)
Hernia Obstructive [B] *	1/279 (0.36%)	0/133 (0%)
Obstruction [B] *	1/279 (0.36%)	1/133 (0.75%)
Oedema Peripheral [B] *	1/279 (0.36%)	0/133 (0%)
Pain [B] *	1/279 (0.36%)	1/133 (0.75%)
Pyrexia [B] *	15/279 (5.38%)	2/133 (1.5%)
Hepatobiliary disorders		
Cholangitis [B] *	1/279 (0.36%)	0/133 (0%)
Cholecystitis Acute [A] *	1/279 (0.36%)	1/133 (0.75%)
Infections and infestations		

	MORAb-003 (Farletuzumab) Plus Paclitaxel	Placebo (Normal Saline) Plus Paclitaxel
	Affected/At Risk (%)	Affected/At Risk (%)
Abdominal Infection [B] *	0/279 (0%)	1/133 (0.75%)
Bacterial Pyelonephritis [B] *	1/279 (0.36%)	0/133 (0%)
Candida Sepsis [A] *	1/279 (0.36%)	0/133 (0%)
Catheter Site Infection [B] *	1/279 (0.36%)	1/133 (0.75%)
Cellulitis [A] *	6/279 (2.15%)	2/133 (1.5%)
Clostridium Difficile Colitis [B] *	1/279 (0.36%)	0/133 (0%)
Device Related Infection [B] *	1/279 (0.36%)	1/133 (0.75%)
Escherichia Sepsis [B] *	0/279 (0%)	1/133 (0.75%)
Herpes Zoster [B] *	1/279 (0.36%)	0/133 (0%)
Incision Site Infection [B] *	0/279 (0%)	1/133 (0.75%)
Infection [B] *	1/279 (0.36%)	1/133 (0.75%)
Infectious Peritonitis [B] *	0/279 (0%)	1/133 (0.75%)
Klebsiella Bacteraemia [B] *	0/279 (0%)	1/133 (0.75%)
Lobar Pneumonia [B] *	1/279 (0.36%)	1/133 (0.75%)
Meningitis [B] *	0/279 (0%)	1/133 (0.75%)
Parotitis [B] *	1/279 (0.36%)	0/133 (0%)
Pelvic Infection [B] *	1/279 (0.36%)	0/133 (0%)
Pneumonia [B] *	4/279 (1.43%)	2/133 (1.5%)
Pneumonia bacterial [A] *	1/279 (0.36%)	0/133 (0%)
Postoperative Wound Infection [B] *	1/279 (0.36%)	0/133 (0%)
Pseudomonal Sepsis [B] *	1/279 (0.36%)	0/133 (0%)
Respiratory Tract Infection [A] *	1/279 (0.36%)	0/133 (0%)

	MORAb-003 (Farletuzumab) Plus Paclitaxel	Placebo (Normal Saline) Plus Paclitaxel
	Affected/At Risk (%)	Affected/At Risk (%)
Retroperitoneal Abcess [B] *	1/279 (0.36%)	0/133 (0%)
Sepsis [B] *	3/279 (1.08%)	1/133 (0.75%)
Urinary Tract Infection [B] *	5/279 (1.79%)	3/133 (2.26%)
Urosepsis [B] *	1/279 (0.36%)	0/133 (0%)
Injury, poisoning and procedural complications		
Postoperative Ileus [B] *	0/279 (0%)	1/133 (0.75%)
Tibia fracture [B] *	1/279 (0.36%)	0/133 (0%)
Investigations		
Haemoglobin Decreased [B] *	0/279 (0%)	1/133 (0.75%)
Weight decreased [B] *	1/279 (0.36%)	0/133 (0%)
Metabolism and nutrition disorders		
Decreased Appetite [B] *	1/279 (0.36%)	0/133 (0%)
Dehydration [B] *	4/279 (1.43%)	0/133 (0%)
Failure to thrive [B] *	1/279 (0.36%)	0/133 (0%)
Hypocalcaemia [B] *	1/279 (0.36%)	0/133 (0%)
Hypokalaemia [B] *	1/279 (0.36%)	0/133 (0%)
Hypomagnesaemia [A] *	1/279 (0.36%)	0/133 (0%)
Hyponatraemia [B] *	1/279 (0.36%)	0/133 (0%)
Hypophagia [A] *	1/279 (0.36%)	0/133 (0%)
Malnutrition [B] *	1/279 (0.36%)	0/133 (0%)
Musculoskeletal and connective tissue disorders		
Back Pain [B] *	2/279 (0.72%)	1/133 (0.75%)
Fistula [B] *	1/279 (0.36%)	0/133 (0%)

	MORAb-003 (Farletuzumab) Plus Paclitaxel	Placebo (Normal Saline) Plus Paclitaxel
	Affected/At Risk (%)	Affected/At Risk (%)
Muscle Necrosis [B] *	0/279 (0%)	1/133 (0.75%)
Muscular Weakness [B] *	1/279 (0.36%)	0/133 (0%)
Musculoskeletal Chest Pain [B] *	0/279 (0%)	1/133 (0.75%)
Myalgia [B] *	1/279 (0.36%)	0/133 (0%)
Pain in Extremity [B] *	1/279 (0.36%)	0/133 (0%)
Systemic Lupus Erythematosus [B] *	0/279 (0%)	1/133 (0.75%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		
Colon Cancer [B] *	1/279 (0.36%)	0/133 (0%)
Metastases to Central Nervous System [B] *	0/279 (0%)	2/133 (1.5%)
Metastatic Neoplasm [B] *	1/279 (0.36%)	0/133 (0%)
Oncologic Complication [A] *	3/279 (1.08%)	0/133 (0%)
Tumour Associated Fever [B] *	1/279 (0.36%)	0/133 (0%)
Nervous system disorders		
Brain Mass [B] *	1/279 (0.36%)	0/133 (0%)
Convulsion [B] *	1/279 (0.36%)	0/133 (0%)
Encephelopathy [B] *	0/279 (0%)	1/133 (0.75%)
Lethargy [B] *	1/279 (0.36%)	0/133 (0%)
Mononeuritis [B] *	0/279 (0%)	1/133 (0.75%)
Neuropathy Peripheral [B] *	1/279 (0.36%)	0/133 (0%)
Posterior Reversible Encephelopathy Syndrome [B] *	1/279 (0.36%)	0/133 (0%)
Syncope [B] *	2/279 (0.72%)	1/133 (0.75%)
Psychiatric disorders		

	MORAb-003 (Farletuzumab) Plus Paclitaxel	Placebo (Normal Saline) Plus Paclitaxel
	Affected/At Risk (%)	Affected/At Risk (%)
Anxiety [B] *	1/279 (0.36%)	0/133 (0%)
Depression [A] *	2/279 (0.72%)	1/133 (0.75%)
Disorientation [B] *	1/279 (0.36%)	0/133 (0%)
Mental Status Change [B] *	1/279 (0.36%)	0/133 (0%)
Renal and urinary disorders		
Bladder Spasm [B] *	1/279 (0.36%)	0/133 (0%)
Dysuria [B] *	1/279 (0.36%)	0/133 (0%)
Hydronephrosis [B] *	2/279 (0.72%)	1/133 (0.75%)
Renal Failure [B] *	1/279 (0.36%)	2/133 (1.5%)
Renal Failure Acute [B] *	2/279 (0.72%)	2/133 (1.5%)
Renal Impairment [B] *	0/279 (0%)	1/133 (0.75%)
Ureteric Obstruction [B] *	1/279 (0.36%)	0/133 (0%)
Urinary Tract Obstruction [B] *	1/279 (0.36%)	0/133 (0%)
Respiratory, thoracic and mediastinal disorders		
Dyspnoea [B] *	7/279 (2.51%)	4/133 (3.01%)
Epistaxis [B] *	1/279 (0.36%)	0/133 (0%)
Interstitial Lung Disease [B] *	1/279 (0.36%)	0/133 (0%)
Pleural Effusion [B] *	3/279 (1.08%)	2/133 (1.5%)
Pneumonitis [A] *	5/279 (1.79%)	0/133 (0%)
Pulmonary Embolism [A] *	10/279 (3.58%)	4/133 (3.01%)
Respiratory Failure [B] *	1/279 (0.36%)	0/133 (0%)
Tachypnoea [B] *	0/279 (0%)	1/133 (0.75%)
Skin and subcutaneous tissue disorders		

	MORAb-003 (Farletuzumab) Plus Paclitaxel	Placebo (Normal Saline) Plus Paclitaxel
	Affected/At Risk (%)	Affected/At Risk (%)
Dermatits Exfoliative [B] *	0/279 (0%)	1/133 (0.75%)
Palmar-Plantar Erythrodysaesthesia Syndrome [B] *	1/279 (0.36%)	0/133 (0%)
Rash [B] *	1/279 (0.36%)	0/133 (0%)
Skin Toxicity [B] *	1/279 (0.36%)	0/133 (0%)
Vascular disorders		
Deep Vein Thrombosis [B] *	1/279 (0.36%)	1/133 (0.75%)
Hypotension [B] *	2/279 (0.72%)	2/133 (1.5%)
Subclavian Vein Thrombosis [B] *	1/279 (0.36%)	0/133 (0%)
Superior Vena Cava Syndrome [B] *	0/279 (0%)	1/133 (0.75%)
Thrombosis [B] *	3/279 (1.08%)	0/133 (0%)
Venous Thrombosis Limb [B] *	1/279 (0.36%)	0/133 (0%)

* Indicates events were collected by non-systematic methods.
A Term from vocabulary, MedDra 14.1
B Term from vocabulary, Select

Other Adverse Events

Frequency Threshold Above Which Other Adverse Events are Reported: 5%

	MORAb-003 (Farletuzumab) Plus Paclitaxel	Placebo (Normal Saline) Plus Paclitaxel
	Affected/At Risk (%)	Affected/At Risk (%)
Total	278/279 (99.64%)	133/133 (100%)
Blood and lymphatic system disorders		
Anaemia [A] *	78/279 (27.96%)	37/133 (27.82%)
Leukopenia [A] *	16/279 (5.73%)	9/133 (6.77%)
Neutropenia [A] *	38/279 (13.62%)	18/133 (13.53%)
Eye disorders		

	MORAb-003 (Farletuzumab) Plus Paclitaxel	Placebo (Normal Saline) Plus Paclitaxel
	Affected/At Risk (%)	Affected/At Risk (%)
Vision Blurred [A] *	14/279 (5.02%)	8/133 (6.02%)
Gastrointestinal disorders		
Abdominal Distension [A] *	51/279 (18.28%)	21/133 (15.79%)
Abdominal Pain Upper [A] *	25/279 (8.96%)	6/133 (4.51%)
Abdominal pain [A] *	88/279 (31.54%)	34/133 (25.56%)
Ascites [A] *	22/279 (7.89%)	11/133 (8.27%)
Constipation [A] *	96/279 (34.41%)	53/133 (39.85%)
Diarrhoea [A] *	119/279 (42.65%)	53/133 (39.85%)
Dry mouth [A] *	19/279 (6.81%)	8/133 (6.02%)
Dyspepsia [A] *	22/279 (7.89%)	10/133 (7.52%)
Flatulence [A] *	18/279 (6.45%)	5/133 (3.76%)
Gastroresophageal Reflux Disease [A] *	10/279 (3.58%)	8/133 (6.02%)
Nausea [B] *	132/279 (47.31%)	66/133 (49.62%)
Small intestinal Obstruction [A] *	19/279 (6.81%)	7/133 (5.26%)
Stomatitis [A] *	26/279 (9.32%)	7/133 (5.26%)
Vomiting [A] *	84/279 (30.11%)	37/133 (27.82%)
General disorders		
Asthenia [A] *	24/279 (8.6%)	12/133 (9.02%)
Chills [A] *	18/279 (6.45%)	7/133 (5.26%)
Disease Progression [A] *	17/279 (6.09%)	7/133 (5.26%)
Fatigue [A] *	184/279 (65.95%)	82/133 (61.65%)
Mucosal Inflammation [A] *	24/279 (8.6%)	11/133 (8.27%)
Oedema [A] *	6/279 (2.15%)	7/133 (5.26%)

	MORAb-003 (Farletuzumab) Plus Paclitaxel	Placebo (Normal Saline) Plus Paclitaxel
	Affected/At Risk (%)	Affected/At Risk (%)
Oedema Peripheral [A] *	60/279 (21.51%)	26/133 (19.55%)
Pain [A] *	17/279 (6.09%)	7/133 (5.26%)
Pyrexia [A] *	43/279 (15.41%)	18/133 (13.53%)
Infections and infestations		
Nasopharyngitits [A] *	16/279 (5.73%)	4/133 (3.01%)
Sinusitis [A] *	10/279 (3.58%)	9/133 (6.77%)
Upper Respiratory Tract Infection [A] *	24/279 (8.6%)	6/133 (4.51%)
Urinary Tract Infection [A] *	47/279 (16.85%)	30/133 (22.56%)
Injury, poisoning and procedural complications		
Contusion [A] *	19/279 (6.81%)	1/133 (0.75%)
Metabolism and nutrition disorders		
Decreased Appetite [A] *	67/279 (24.01%)	27/133 (20.3%)
Dehydration [A] *	14/279 (5.02%)	5/133 (3.76%)
Hypokalaemia [A] *	28/279 (10.04%)	9/133 (6.77%)
Hypomagnesaemia [A] *	31/279 (11.11%)	18/133 (13.53%)
Musculoskeletal and connective tissue disorders		
Arthralgia [B] *	43/279 (15.41%)	22/133 (16.54%)
Back Pain [A] *	36/279 (12.9%)	26/133 (19.55%)
Muscle Spasms [A] *	14/279 (5.02%)	12/133 (9.02%)
Musculoskeletal Chest Pain [A] *	14/279 (5.02%)	6/133 (4.51%)
Musculoskeletal Pain [A] *	15/279 (5.38%)	6/133 (4.51%)
Myalgia [A] *	28/279 (10.04%)	17/133 (12.78%)
Pain In Extremity [A] *	31/279 (11.11%)	12/133 (9.02%)

	MORAb-003 (Farletuzumab) Plus Paclitaxel	Placebo (Normal Saline) Plus Paclitaxel
	Affected/At Risk (%)	Affected/At Risk (%)
Nervous system disorders		
Dizziness [A] *	42/279 (15.05%)	18/133 (13.53%)
Dysguesia [A] *	29/279 (10.39%)	22/133 (16.54%)
Headache [A] *	72/279 (25.81%)	28/133 (21.05%)
Hypoaesthesia [A] *	6/279 (2.15%)	7/133 (5.26%)
Neuropathy Peripheral [B] *	75/279 (26.88%)	37/133 (27.82%)
Peripheral Sensory Neuropathy [A] *	38/279 (13.62%)	15/133 (11.28%)
Restless Legs Syndrome [A] *	14/279 (5.02%)	2/133 (1.5%)
Psychiatric disorders		
Anxiety [A] *	25/279 (8.96%)	16/133 (12.03%)
Depression [A] *	24/279 (8.6%)	8/133 (6.02%)
Insomnia [A] *	54/279 (19.35%)	23/133 (17.29%)
Renal and urinary disorders		
Dysuria [A] *	9/279 (3.23%)	12/133 (9.02%)
Pollakiuria [A] *	7/279 (2.51%)	9/133 (6.77%)
Respiratory, thoracic and mediastinal disorders		
Cough [B] *	58/279 (20.79%)	27/133 (20.3%)
Dyspnoea [A] *	56/279 (20.07%)	21/133 (15.79%)
Dyspnoea Exertional [A] *	29/279 (10.39%)	6/133 (4.51%)
Epistaxis [A] *	50/279 (17.92%)	25/133 (18.8%)
Nasal Congestion [A] *	9/279 (3.23%)	9/133 (6.77%)
Oropharyngeal Pain [A] *	16/279 (5.73%)	13/133 (9.77%)
Skin and subcutaneous tissue disorders		

	MORAb-003 (Farletuzumab) Plus Paclitaxel	Placebo (Normal Saline) Plus Paclitaxel
	Affected/At Risk (%)	Affected/At Risk (%)
Alopecia [B] *	143/279 (51.25%)	59/133 (44.36%)
Dry skin [A] *	18/279 (6.45%)	7/133 (5.26%)
Erythema [A] *	18/279 (6.45%)	6/133 (4.51%)
Hyperhidrosis [A] *	13/279 (4.66%)	7/133 (5.26%)
Nail discolouration [A] *	11/279 (3.94%)	7/133 (5.26%)
Nail disorder [A] *	47/279 (16.85%)	19/133 (14.29%)
Pruritus [A] *	15/279 (5.38%)	8/133 (6.02%)
Rash [A] *	55/279 (19.71%)	19/133 (14.29%)
Vascular disorders		
Flushing [A] *	28/279 (10.04%)	9/133 (6.77%)
Hypotension [A] *	10/279 (3.58%)	7/133 (5.26%)

* Indicates events were collected by non-systematic methods.
A Term from vocabulary, Select
B Term from vocabulary, MedDra 14.1

Limitations and Caveats

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

Certain Agreements:

Principal Investigators are NOT employed by the organization sponsoring the study.

There IS an agreement between the Principal Investigator and the Sponsor (or its agents) that restricts the PI's rights to discuss or publish trial results after the trial is completed.

Results Point of Contact:

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