Effectiveness of MORAb-003 in Women With Ovarian Cancer Who Have Relapsed After Platinum-Based Chemotherapy

This study has been completed.

Sponsor:
Morphotek

Information provided by (Responsible Party):
Morphotek

ClinicalTrials.gov Identifier:
NCT00318370

First received: April 24, 2006
Last updated: September 4, 2015
Last verified: September 2015
History of Changes

Results First Received: January 27, 2012

Study Type:	Interventional
Study Design:	Allocation: Non-Randomized; Endpoint Classification: Efficacy Study; Intervention Model: Parallel Assignment; Masking: Open Label; Primary Purpose: Treatment
Conditions:	Ovarian Cancer Fallopian Tube Cancer Peritoneal Neoplasms
Interventions:	Drug: Farletuzumab Drug: Chemo Plus Far

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
The first 6 participants enrolled in this study were dosed at farletuzumab, 37.5 mg/m2. The next 6 participants were dosed at farletuzumab, 62.5 mg/m2. The remaining participants received farletuzumab, 100 mg/m2.

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
Far Only	Farletuzumab only (Far Only): farletuzumab, 100 milligrams (mg)/square meter (m2).

Chemo Plus Far	Platinum-based Chemotherapy plus farletuzumab (Chemo+Far): farletuzumab, 100 mg/m2 plus paclitaxel 175 mg/m2 (or docetaxel, 75 mg/m2) plus carboplatin area under the concentration-time curve (AUC) 5-6 intravenously (IV) on Day 1 of a 21-day cycle.
Maintenance Far Only	Maintenance Far Only: farletuzumab, 100 milligrams (mg)/square meter (m2) for those subjects who completed Period 2, Chemo Plus Far.

Participant Flow for 3 periods

Period 1: Period 1

	Far Only	Chemo Plus Far	Maintenance Far Only
STARTED	28	0	0
COMPLETED	21 [1]	0	0
NOT COMPLETED	7	0	0
Lack of Efficacy	5	0	0
Physician Decision	1	0	0
Withdrawal by Subject	1	0	0

[1] 21 participants proceeded from Far Only to Chemo Plus Far.

Period 2: Period 2

	Far Only	Chemo Plus Far	Maintenance Far Only
STARTED	0	47 [1]	0
COMPLETED	0	36	0
NOT COMPLETED	0	11	0
Adverse Event	0	3	0
Lack of Efficacy	0	5	0
Physician Decision	0	1	0
Withdrawal by Subject	0	1	0
Other	0	1	0

[1] 26 participants enrolled directly into Chemo Plus Far plus 21 participants from Far Only.

Period 3: Period 3

	Far Only	Chemo Plus Far	Maintenance Far Only
STARTED	0	0	36
COMPLETED	0	0	3
NOT COMPLETED	0	0	33
Adverse Event	0	0	1
Lack of Efficacy	0	0	24
Death	0	0	1
Physician Decision	0	0	1
Withdrawal by Subject	0	0	3
Other	0	0	3

Baseline Characteristics

Hide Baseline Characteristics

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
No text entered.

Reporting Groups

	Description
Far Only and Chemo Plus Far and Maintenance Far Only	Farletuzumab only (Far Only): farletuzumab, 100 milligrams (mg)/square meter (m2). Chemo+Far: paclitaxel 175 mg/m2 (or docetaxel, 75 mg/m2) plus carboplatin area under the concentration-time curve (AUC) 5-6 intravenously (IV) on Day 1 of a 21-day cycle plus farletuzumab, 100 mg/m2. Maintenance Far Only: farletuzumab, 100 milligrams (mg)/square meter (m2) for those subjects who completed the Period, Chemo Plus Far.

Baseline Measures

	Far Only and Chemo Plus Far and Maintenance Far Only
Overall Participants Analyzed [Units: Participants]	**54**
Age [Units: Years] Mean (Standard Deviation)	**63.2 (11.66)**
Gender [Units: Participants]	
Female	**54**
Male	**0**
Race/Ethnicity, Customized [Units: Participants]	
American Indian or Alaska Native	**0**
Asian	**5**
Native Hawaiian or Other Pacific Islander	**0**
Black or African American	**1**
White	**44**
More than one race	**0**
Unknown or Not Reported	**0**
Hispanic	**4**

Outcome Measures

Hide All Outcome Measures

1. Primary: Serologic Response (Change in CA125 Level) [Time Frame: Baseline to response (up to 30 weeks)]

Measure Type	Primary
Measure Title	Serologic Response (Change in CA125 Level)

Measure Description	Defined using modified Gynecologic Cancer Intergroup (GCIG) criteria: Number of participants who achieved a 50% response = >50% decrease from baseline CA-125 (higher of 2 pretreatment CA-125 assessments and the level must be at least 52.5 kU/L).
Time Frame	Baseline to response (up to 30 weeks)
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
All participants enrolled to initial farletuzumab only.

Reporting Groups

	Description
Far Only	Farletuzumab only (Far Only): farletuzumab, 100 milligrams (mg)/square meter (m2).

Measured Values

	Far Only
Participants Analyzed [Units: Participants]	**21**
Serologic Response (Change in CA125 Level) [Units: Participants] Number (95% Confidence Interval)	**2** **(0.9 to 23.5)**

No statistical analysis provided for Serologic Response (Change in CA125 Level)

2. Primary: Serologic Response (Change in Cancer Antigen [CA-125] Level) [Time Frame: Baseline to response (up to 27 weeks)]

Measure Type	Primary
Measure Title	Serologic Response (Change in Cancer Antigen [CA-125] Level)
Measure Description	Defined using modified Gynecologic Cancer Intergroup (GCIG) criteria: Number of participants who had a 50% response = >50% decrease from baseline CA-125 (higher of 2 pretreatment CA-125 assessments and the level must be at least 52.5 kU/L).
Time Frame	Baseline to response (up to 27 weeks)
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
All participants enrolled to chemotherapy plus farletuzumab.

Reporting Groups

	Description
Chemo Plus Far	Platinum-based Chemotherapy plus farletuzumab (Chemo+Far): farletuzumab, 100 mg/m2 plus paclitaxel 175 mg/m2 (or docetaxel, 75 mg/m2) plus carboplatin area under the concentration-time curve (AUC) 5-6 intravenously (IV) on Day 1 of a 21-day cycle.

Measured Values

	Chemo Plus Far
Participants Analyzed [Units: Participants]	**47**
Serologic Response (Change in Cancer Antigen [CA-125] Level) [Units: Participants]	**41**

No statistical analysis provided for Serologic Response (Change in Cancer Antigen [CA-125] Level)

3. Secondary: Time to Serologic Response (Change in CA-125 Level) [Time Frame: Baseline to response (up to 27 weeks)]

Measure Type	Secondary
Measure Title	Time to Serologic Response (Change in CA-125 Level)
Measure Description	Time to Serologic Response is defined as the time (weeks) from the date of first farletuzumab infusion to first documentation of 50% decrease from baseline CA-125 (higher of 2 pretreatment CA-125 assessments and at least twice the upper limit of normal) and then confirmed after 21 days.
Time Frame	Baseline to response (up to 27 weeks)
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
All participants enrolled to intial chemotherapy plus farletuzumab.

Reporting Groups

	Description
Chemo Plus Far	Platinum-based Chemotherapy plus farletuzumab (Chemo+Far): farletuzumab, 100 mg/m2 plus paclitaxel 175 mg/m2 (or docetaxel, 75 mg/m2) plus carboplatin area under the concentration-time curve (AUC) 5-6 intravenously (IV) on Day 1 of a 21-day cycle.

Measured Values

	Chemo Plus Far
Participants Analyzed [Units: Participants]	**47**
Time to Serologic Response (Change in CA-125 Level) [Units: Weeks] Median (95% Confidence Interval)	**3.3** **(3.1 to 6.1)**

No statistical analysis provided for Time to Serologic Response (Change in CA-125 Level)

4. Secondary: Duration of Serologic Response (CA-125) [Time Frame: Baseline to response (up to 44 months)]

Measure Type	Secondary
Measure Title	Duration of Serologic Response (CA-125)

Measure Description	Calculated as the time from the first documentation of 50% or greater reduction in CA-125 to the first documentation of serologic progression or death due to any cause. Serologic progression was defined as the first date of the CA-125 level being >2 X ULN on two occasions.
Time Frame	Baseline to response (up to 44 months)
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
All participants enrolled to initial chemotherapy plus farletuzumab.

Reporting Groups

	Description
Chemo Plus Far	Platinum-based Chemotherapy plus farletuzumab (Chemo+Far): farletuzumab, 100 mg/m2 plus paclitaxel 175 mg/m2 (or docetaxel, 75 mg/m2) plus carboplatin area under the concentration-time curve (AUC) 5-6 intravenously (IV) on Day 1 of a 21-day cycle.

Measured Values

	Chemo Plus Far
Participants Analyzed [Units: Participants]	**47**
Duration of Serologic Response (CA-125) [Units: Months] Median (95% Confidence Interval)	**NA** [1] **(9.9 to N/A)**

[1] NA = Not Estimable because the median number of participants did not progress or die.

No statistical analysis provided for Duration of Serologic Response (CA-125)

5. Secondary: Overall Response Rate [Time Frame: Baseline to response (up to 44 months)]

Measure Type	Secondary
Measure Title	Overall Response Rate
Measure Description	The Overall Response Rate (ORR) will be determined by applying standard RECIST criteria to objective measures of disease, such as CT or MRI scans. Participants will be assigned to one of the categories of change in disease status, namely, “complete response” (CR), “partial response” (PR), “stable disease” (SD), or “progressive disease” (PD). ORR is defined as the percentage of participants with objective evidence of CR or PR.
Time Frame	Baseline to response (up to 44 months)
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
No text entered.

Reporting Groups

	Description

Chemo Plus Far	Platinum-based Chemotherapy plus farletuzumab (Chemo+Far): farletuzumab, 100 mg/m2 plus paclitaxel 175 mg/m2 (or docetaxel, 75 mg/m2) plus carboplatin area under the concentration-time curve (AUC) 5-6 intravenously (IV) on Day 1 of a 21-day cycle.

Measured Values

	Chemo Plus Far
Participants Analyzed [Units: Participants]	**47**
Overall Response Rate [Units: Percentage of participants]	
Complete Response	**6.8**
Partial Response	**63.6**
Stable Disease	**20.5**
Progressive Disease	**4.5**
Not Evaluable	**6.8**

No statistical analysis provided for Overall Response Rate

6. Secondary: Progression-free Survival (PFS) [Time Frame: Baseline to response (up to 44 months)]

Measure Type	Secondary
Measure Title	Progression-free Survival (PFS)
Measure Description	PFS is defined for participants treated in Chemo Plus Far as the time (in months) from date of first dose in Chemo Plus Far until date of the first observation of progression based on first date of the CA-125 >2 X ULN on two occasions, or date of death, whatever the cause. If progression or death is not observed for a participant, the PFS time is censored at the later date of last tumor assessment or CA125 assessment without evidence of progression prior to the date of initiation of further anti-tumor treatment.
Time Frame	Baseline to response (up to 44 months)
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
All participants who received chemotherapy plus farletuzumab as well as those who continued on maintenance farletuzumab.

Reporting Groups

	Description
Chemo Plus Far Plus Maintenance Far Only	Platinum-based Chemotherapy plus farletuzumab (Chemo+Far): farletuzumab, 100 mg/m2 plus paclitaxel 175 mg/m2 (or docetaxel, 75 mg/m2) plus carboplatin area under the concentration-time curve (AUC) 5-6 intravenously (IV) on Day 1 of a 21-day cycle. Maintenace Far Only: farletuzumab, 100 mg/m2

Measured Values

	Chemo Plus Far Plus Maintenance Far Only
Participants Analyzed [Units: Participants]	**47**

Progression-free Survival (PFS) [Units: Months] Median (95% Confidence Interval)	**10.2** **(7.4 to 13.1)**

No statistical analysis provided for Progression-free Survival (PFS)

7. Secondary: Percentage of Participants Who Had a Prolongation of Remission [Time Frame: Baseline to response (up to 44 months)]

Measure Type	Secondary
Measure Title	Percentage of Participants Who Had a Prolongation of Remission
Measure Description	Percentage of participants whose second remission was longer than their first remission. The length of remission will be determined for participants who attain CR or PR (or SD and investigator's assessment of clinical benefit). Prolongation of remission will be defined as a length of remission occurring on this study that is ≥ 1 day longer than the length of remission to the original therapy. The length of remission on this study (second remission) will be defined as the amount of time from the date of first CR or PR to the end of this remission.
Time Frame	Baseline to response (up to 44 months)
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
All participants who received chemotherapy plus farletuzumab as well as those who continued on maintenance farletuzumab.

Reporting Groups

	Description
Chemo Plus Far Plus Maintenance Far Only	Platinum-based Chemotherapy plus farletuzumab (Chemo+Far): farletuzumab, 100 mg/m2 plus paclitaxel 175 mg/m2 (or docetaxel, 75 mg/m2) plus carboplatin area under the concentration-time curve (AUC) 5-6 intravenously (IV) on Day 1 of a 21-day cycle. Maintenace Far Only: farletuzumab, 100 mg/m2

Measured Values

	Chemo Plus Far Plus Maintenance Far Only
Participants Analyzed [Units: Participants]	**39**
Percentage of Participants Who Had a Prolongation of Remission [Units: Percentage of participants] Number (95% Confidence Interval)	**25.6** **(13.0 to 42.1)**

No statistical analysis provided for Percentage of Participants Who Had a Prolongation of Remission

Serious Adverse Events

Hide Serious Adverse Events

Time Frame	No text entered.

Additional Description	No text entered.

Reporting Groups

	Description
Far Only and Chemo Plus Far and Maintenance Far Only	Farletuzumab only (Far Only): farletuzumab, 100 milligrams (mg)/square meter (m2). Chemo+Far: paclitaxel 175 mg/m2 (or docetaxel, 75 mg/m2) plus carboplatin area under the concentration-time curve (AUC) 5-6 intravenously (IV) on Day 1 of a 21-day cycle plus farletuzumab, 100 mg/m2. Maintenance Far Only: farletuzumab, 100 milligrams (mg)/square meter (m2) for those subjects who completed the Period, Chemo Plus Far.

Serious Adverse Events

	Far Only and Chemo Plus Far and Maintenance Far Only
Total, serious adverse events	
# participants affected / at risk	**20/54 (37.04%)**
Blood and lymphatic system disorders	
Febrile neutropenia † 1	
# participants affected / at risk	**2/54 (3.70%)**
Thrombocytopenia † 1	
# participants affected / at risk	**2/54 (3.70%)**
Anaemia of chronic disease † 1	
# participants affected / at risk	**1/54 (1.85%)**
Leukopenia † 1	
# participants affected / at risk	**1/54 (1.85%)**
Cardiac disorders	
Acute coronary syndrome † 1	
# participants affected / at risk	**1/54 (1.85%)**
Aortic valve stenosis † 1	
# participants affected / at risk	**1/54 (1.85%)**
Coronary artery disease † 1	
# participants affected / at risk	**1/54 (1.85%)**
Gastrointestinal disorders	
Abdominal Pain † 1	
# participants affected / at risk	**2/54 (3.70%)**
Diarrhoea † 1	
# participants affected / at risk	**2/54 (3.70%)**
Large intestinal obstruction † 1	
# participants affected / at risk	**2/54 (3.70%)**
Subileus † 1	
# participants affected / at risk	**2/54 (3.70%)**
Constipation † 1	
# participants affected / at risk	**1/54 (1.85%)**
Rectal haemorrohage † 1	
# participants affected / at risk	**1/54 (1.85%)**
Small intestinal obstruction † 1	
# participants affected / at risk	**1/54 (1.85%)**

Vomiting † 1	
# participants affected / at risk	1/54 (1.85%)
General disorders	
Adverse drug reaction † 1	
# participants affected / at risk	1/54 (1.85%)
Chest discomfort † 1	
# participants affected / at risk	1/54 (1.85%)
Injection site reaction † 1	
# participants affected / at risk	1/54 (1.85%)
Hepatobiliary disorders	
Portal vein thrombosis † 1	
# participants affected / at risk	1/54 (1.85%)
Immune system disorders	
Cytokine release syndrome † 1	
# participants affected / at risk	1/54 (1.85%)
Infections and infestations	
Urosepsis † 1	
# participants affected / at risk	2/54 (3.70%)
Clostridium colitis † 1	
# participants affected / at risk	1/54 (1.85%)
Diverticulitis † 1	
# participants affected / at risk	1/54 (1.85%)
Pneumonia † 1	
# participants affected / at risk	1/54 (1.85%)
Injury, poisoning and procedural complications	
Wound dehiscence † 1	
# participants affected / at risk	1/54 (1.85%)
Investigations	
Psychiatric evaluation † 1	
# participants affected / at risk	1/54 (1.85%)
Metabolism and nutrition disorders	
Hyperglycemia † 1	
# participants affected / at risk	2/54 (3.70%)
Dehydration † 1	
# participants affected / at risk	1/54 (1.85%)
Electrolyte imbalance † 1	
# participants affected / at risk	1/54 (1.85%)
Hypovolaemia † 1	
# participants affected / at risk	1/54 (1.85%)
Musculoskeletal and connective tissue disorders	
Arthralgia † 1	
# participants affected / at risk	1/54 (1.85%)
Back pain † 1	
# participants affected / at risk	1/54 (1.85%)

Limb discomfort † 1	
# participants affected / at risk	1/54 (1.85%)
Pain in extremity † 1	
# participants affected / at risk	1/54 (1.85%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	
Ovarian cancer † 1	
# participants affected / at risk	1/54 (1.85%)
Nervous system disorders	
Grand mal convulsion † 1	
# participants affected / at risk	1/54 (1.85%)
Nervous system disorder † 1	
# participants affected / at risk	1/54 (1.85%)
Syncope † 1	
# participants affected / at risk	1/54 (1.85%)
Renal and urinary disorders	
Hydronephrosis † 1	
# participants affected / at risk	1/54 (1.85%)
Respiratory, thoracic and mediastinal disorders	
Chronic obstructive airways disease exacerbated † 1	
# participants affected / at risk	1/54 (1.85%)
Dyspnoea † 1	
# participants affected / at risk	1/54 (1.85%)
Lung infiltration † 1	
# participants affected / at risk	1/54 (1.85%)
Pulmonary embolism † 1	
# participants affected / at risk	1/54 (1.85%)
Pulmonary hypertension † 1	
# participants affected / at risk	1/54 (1.85%)
Vascular disorders	
Aortic stenosis † 1	
# participants affected / at risk	1/54 (1.85%)
Deep vein thrombosis † 1	
# participants affected / at risk	1/54 (1.85%)
Femoral artery occlusion † 1	
# participants affected / at risk	1/54 (1.85%)
Peripheral occlusive disease † 1	
# participants affected / at risk	1/54 (1.85%)

† Events were collected by systematic assessment
1 Term from vocabulary, MedDRA (Unspecified)

Other Adverse Events

Hide Other Adverse Events

Time Frame	No text entered.

Additional Description	No text entered.

Frequency Threshold

Threshold above which other adverse events are reported	5

Reporting Groups

	Description
Far Only and Chemo Plus Far and Maintenance Far Only	Farletuzumab only (Far Only): farletuzumab, 100 milligrams (mg)/square meter (m2). Chemo+Far: paclitaxel 175 mg/m2 (or docetaxel, 75 mg/m2) plus carboplatin area under the concentration-time curve (AUC) 5-6 intravenously (IV) on Day 1 of a 21-day cycle plus farletuzumab, 100 mg/m2. Maintenance Far Only: farletuzumab, 100 milligrams (mg)/square meter (m2) for those subjects who completed the Period, Chemo Plus Far.

Other Adverse Events

	Far Only and Chemo Plus Far and Maintenance Far Only
Total, other (not including serious) adverse events	
# participants affected / at risk	**54/54 (100.00%)**
Blood and lymphatic system disorders	
Anaemia † 1	
# participants affected / at risk	**23/54 (42.59%)**
Neutropenia † 1	
# participants affected / at risk	**23/54 (42.59%)**
Thrombocytopenia † 1	
# participants affected / at risk	**20/54 (37.04%)**
Leukopenia † 1	
# participants affected / at risk	**8/54 (14.81%)**
Lymphadenopathy † 1	
# participants affected / at risk	**4/54 (7.41%)**
Cardiac disorders	
Tachycardia † 1	
# participants affected / at risk	**3/54 (5.56%)**
Ear and labyrinth disorders	
Ear pain † 1	
# participants affected / at risk	**5/54 (9.26%)**
Vertigo † 1	
# participants affected / at risk	**5/54 (9.26%)**
Eye disorders	
Lacrimation increased † 1	
# participants affected / at risk	**4/54 (7.41%)**
Vision blurred † 1	
# participants affected / at risk	**4/54 (7.41%)**
Gastrointestinal disorders	
Nausea † 1	
# participants affected / at risk	**35/54 (64.81%)**

Constipation † 1	
# participants affected / at risk	33/54 (61.11%)
Diarrhoea † 1	
# participants affected / at risk	26/54 (48.15%)
Vomiting † 1	
# participants affected / at risk	25/54 (46.30%)
Abdominal Pain † 1	
# participants affected / at risk	24/54 (44.44%)
Abdominal distension † 1	
# participants affected / at risk	13/54 (24.07%)
Abdominal pain upper † 1	
# participants affected / at risk	8/54 (14.81%)
Dyspepsia † 1	
# participants affected / at risk	8/54 (14.81%)
Oral pain † 1	
# participants affected / at risk	7/54 (12.96%)
Ascites † 1	
# participants affected / at risk	5/54 (9.26%)
Flatulence † 1	
# participants affected / at risk	4/54 (7.41%)
Hiatus hernia † 1	
# participants affected / at risk	4/54 (7.41%)
Stomatitis † 1	
# participants affected / at risk	4/54 (7.41%)
Abdominal pain lower † 1	
# participants affected / at risk	3/54 (5.56%)
Abdominal tenderness † 1	
# participants affected / at risk	3/54 (5.56%)
General disorders	
Fatigue † 1	
# participants affected / at risk	51/54 (94.44%)
Pyrexia † 1	
# participants affected / at risk	22/54 (40.74%)
Chills † 1	
# participants affected / at risk	14/54 (25.93%)
Oedema peripheral † 1	
# participants affected / at risk	14/54 (25.93%)
Asthenia † 1	
# participants affected / at risk	9/54 (16.67%)
Adverse drug reaction † 1	
# participants affected / at risk	8/54 (14.81%)
Pain † 1	
# participants affected / at risk	7/54 (12.96%)
Chest discomfort † 1	
# participants affected / at risk	5/54 (9.26%)
Influenza-like illness † 1	

# participants affected / at risk	4/54 (7.41%)
Mucosal inflammation † 1	
# participants affected / at risk	4/54 (7.41%)
Chest pain † 1	
# participants affected / at risk	3/54 (5.56%)
Infusion site pain † 1	
# participants affected / at risk	3/54 (5.56%)
Malaise † 1	
# participants affected / at risk	3/54 (5.56%)
Immune system disorders	
Seasonal allergy † 1	
# participants affected / at risk	4/54 (7.41%)
Cytokine release syndrome † 1	
# participants affected / at risk	3/54 (5.56%)
Hypersensitivity † 1	
# participants affected / at risk	3/54 (5.56%)
Infections and infestations	
Urinary tract infection † 1	
# participants affected / at risk	19/54 (35.19%)
Nasopharyngitis † 1	
# participants affected / at risk	13/54 (24.07%)
Upper respiratory tract infection † 1	
# participants affected / at risk	7/54 (12.96%)
Bronchitis † 1	
# participants affected / at risk	6/54 (11.11%)
Pneumonia † 1	
# participants affected / at risk	3/54 (5.56%)
Sinusitis † 1	
# participants affected / at risk	3/54 (5.56%)
Injury, poisoning and procedural complications	
Contusion † 1	
# participants affected / at risk	5/54 (9.26%)
Investigations	
Weight decreased † 1	
# participants affected / at risk	6/54 (11.11%)
White blood cell count decreased † 1	
# participants affected / at risk	4/54 (7.41%)
Haemoglobin decreased † 1	
# participants affected / at risk	3/54 (5.56%)
Red blood cell count decreased † 1	
# participants affected / at risk	3/54 (5.56%)
Metabolism and nutrition disorders	
Anorexia † 1	
# participants affected / at risk	7/54 (12.96%)
Decreased appetite † 1	

# participants affected / at risk	6/54 (11.11%)
Hypokalaemia † 1	
# participants affected / at risk	4/54 (7.41%)
Hypomagnesaemia † 1	
# participants affected / at risk	4/54 (7.41%)
Dehydration † 1	
# participants affected / at risk	3/54 (5.56%)
Hyperglycaemia † 1	
# participants affected / at risk	3/54 (5.56%)
Musculoskeletal and connective tissue disorders	
Back pain † 1	
# participants affected / at risk	15/54 (27.78%)
Arthralgia † 1	
# participants affected / at risk	13/54 (24.07%)
Pain in extremity † 1	
# participants affected / at risk	10/54 (18.52%)
Bone pain † 1	
# participants affected / at risk	7/54 (12.96%)
Chest wall pain † 1	
# participants affected / at risk	5/54 (9.26%)
Myalgia † 1	
# participants affected / at risk	5/54 (9.26%)
Muscle spasms † 1	
# participants affected / at risk	4/54 (7.41%)
Shoulder pain † 1	
# participants affected / at risk	4/54 (7.41%)
Musculoskeletal pain † 1	
# participants affected / at risk	3/54 (5.56%)
Nervous system disorders	
Headache † 1	
# participants affected / at risk	27/54 (50.00%)
Dizziness † 1	
# participants affected / at risk	11/54 (20.37%)
Neuropathy peripheral † 1	
# participants affected / at risk	8/54 (14.81%)
Neuropathy † 1	
# participants affected / at risk	6/54 (11.11%)
Peripheral sensory neuropathy † 1	
# participants affected / at risk	5/54 (9.26%)
Hypoaesthesia † 1	
# participants affected / at risk	4/54 (7.41%)
Psychiatric disorders	
Anxiety † 1	
# participants affected / at risk	9/54 (16.67%)
Depression † 1	
# participants affected / at risk	8/54 (14.81%)

Insomnia † 1	
# participants affected / at risk	8/54 (14.81%)
Renal and urinary disorders	
Haematuria † 1	
# participants affected / at risk	8/54 (14.81%)
Dysuria † 1	
# participants affected / at risk	5/54 (9.26%)
Urinary incontinence † 1	
# participants affected / at risk	3/54 (5.56%)
Respiratory, thoracic and mediastinal disorders	
Dyspnoea † 1	
# participants affected / at risk	20/54 (37.04%)
Cough † 1	
# participants affected / at risk	15/54 (27.78%)
Pharyngolaryngeal pain † 1	
# participants affected / at risk	9/54 (16.67%)
Dyspnoea exertional † 1	
# participants affected / at risk	6/54 (11.11%)
Atelectasis † 1	
# participants affected / at risk	4/54 (7.41%)
Pleural effusion † 1	
# participants affected / at risk	4/54 (7.41%)
Rhinitis allergic † 1	
# participants affected / at risk	3/54 (5.56%)
Sinus congestion † 1	
# participants affected / at risk	3/54 (5.56%)
Wheezing † 1	
# participants affected / at risk	3/54 (5.56%)
Skin and subcutaneous tissue disorders	
Alopecia † 1	
# participants affected / at risk	24/54 (44.44%)
Rash † 1	
# participants affected / at risk	11/54 (20.37%)
Pruritus † 1	
# participants affected / at risk	10/54 (18.52%)
Dry skin † 1	
# participants affected / at risk	7/54 (12.96%)
Erythema † 1	
# participants affected / at risk	5/54 (9.26%)
Hyperhidrosis † 1	
# participants affected / at risk	5/54 (9.26%)
Drug eruption † 1	
# participants affected / at risk	3/54 (5.56%)
Night sweats † 1	
# participants affected / at risk	3/54 (5.56%)

Vascular disorders	
Hypertension † 1	
# participants affected / at risk	**6/54 (11.11%)**
Flushing † 1	
# participants affected / at risk	**4/54 (7.41%)**
Hypotension † 1	
# participants affected / at risk	**4/54 (7.41%)**
Hot flush † 1	
# participants affected / at risk	**3/54 (5.56%)**

† Events were collected by systematic assessment
1 Term from vocabulary, MedDRA (Unspecified)

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
No text entered.

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:

- [x] 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.

Results Point of Contact:

Name/Title: Susan Weil, MD
Organization: Morphotek, Inc.
phone: 610-423-6182
e-mail: sweil@morphotek.com

Publications automatically indexed to this study by ClinicalTrials.gov Identifier (NCT Number):

Armstrong DK, White AJ, Weil SC, Phillips M, Coleman RL. Farletuzumab (a monoclonal antibody against folate receptor alpha) in relapsed platinum-sensitive ovarian cancer. Gynecol Oncol. 2013 Jun;129(3):452-8. doi: 10.1016/j.ygyno.2013.03.002.

Responsible Party:	Morphotek
ClinicalTrials.gov Identifier:	NCT00318370 History of Changes
Other Study ID Numbers:	MORAb-003-002
Study First Received:	April 24, 2006
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Last Updated:	September 4, 2015
Health Authority:	United States: Food and Drug Administration

TO TOP

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

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