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## A Study to Assess the Efficacy and Safety of Farletuzumab (MORAb 003) in Combination With Carboplatin Plus Paclitaxel or Carboplatin Plus Pegylated Liposomal Doxorubicin (PLD) in Subjects With Low CA125 Platinum-Sensitive Ovarian Cancer

**This study is currently recruiting participants.** (see [Contacts and Locations](#))

Verified April 2016 by Morphotek

**Sponsor:**  
Morphotek

**Collaborator:**  
Eisai Co., Ltd.

**Information provided by (Responsible Party):**  
Morphotek

**ClinicalTrials.gov Identifier:**

NCT02289950

First received: November 10, 2014

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[History of Changes](#)

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[No Study Results Posted](#)

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### Purpose

MORAb-003-011 is a global, multicenter, double-blind, randomized placebo-controlled study to assess the safety and efficacy of farletuzumab in combination with standard chemotherapy in subjects with low CA125 platinum sensitive ovarian cancer in first relapse.

<a href="#">Condition</a>	<a href="#">Intervention</a>	<a href="#">Phase</a>
Platinum-Sensitive Ovarian Cancer in First Relapse	Drug: Farletuzumab Drug: Placebo	Phase 2

Study Type: [Interventional](#)  
 Study Design: [Allocation: Randomized](#)  
[Endpoint Classification: Safety/Efficacy Study](#)  
[Intervention Model: Parallel Assignment](#)  
[Masking: Double Blind \(Subject, Investigator\)](#)  
[Primary Purpose: Treatment](#)

**Official Title:** A Randomized, Double-Blind, Placebo-Controlled, Phase 2 Study to Assess the Efficacy and Safety of Farletuzumab (MORAb 003) in Combination With Carboplatin Plus Paclitaxel or Carboplatin Plus Pegylated Liposomal Doxorubicin (PLD) in Subjects With Low CA125 Platinum-Sensitive Ovarian Cancer

#### Resource links provided by NLM:

[Genetics Home Reference](#) related topics: [ovarian cancer](#)

[MedlinePlus](#) related topics: [Cancer](#) [Ovarian Cancer](#)

[Drug Information](#) available for: [Doxorubicin](#) [Carboplatin](#)

[Genetic and Rare Diseases Information Center](#) resources: [Ovarian Cancer](#)

[U.S. FDA Resources](#)

**Further study details as provided by Morphotek:**

**Primary Outcome Measures:**

- Progression Free Survival (PFS) based on the investigators' radiographic assessments utilizing RECIST 1.1 criteria [ Time Frame: Up to approximately 46 months ] [ Designated as safety issue: No ]

PFS is defined as the time (in months) from the date of randomization to the date of the first observation of progression or date of death, whatever the cause. If progression or death is not observed for a subject, the PFS time will be censored at the date of last tumor assessment without evidence of progression prior to the date of initiation of further antitumor treatment or the cut-off date, whichever is earliest.

**Secondary Outcome Measures:**

- Overall Survival Rate [ Time Frame: Up to approximately 46 months ] [ Designated as safety issue: No ]

Defined as the time from the date of randomization to the date of death, due to all causes. If death is not observed for a subject, the overall survival (OS) time will be censored at the last date known to be alive or the cut-off date, whichever is earliest.

- Length of First vs Second Platinum-Free Interval [ Time Frame: Up to approximately 46 months ] [ Designated as safety issue: No ]

Length of first platinum-free interval is defined as the period of time (in months) from the date of completion of previous platinum based chemotherapy until date of first relapse, as recorded on the eCRF. The date of first relapse is the progression date based on a radiographic assessment. Similarly, length of second platinum-free interval is defined as the period of time (in months) from the date of completion of platinum based chemotherapy (last dosing date) during the study until the date of progression based on the investigator's radiographic assessment (RECIST 1.1).

- Tumor Response: Objective Response (OR) per RECIST 1.1 [ Time Frame: Up to approximately 46 months ] [ Designated as safety issue: No ]

OR is defined as either a complete response (CR) or a partial response (PR) using RECIST 1.1 criteria. Tumor assessments performed up to the initiation of further anti-tumor treatment will be considered.

- Tumor Response: Time to Response (TTR) per RECIST 1.1 [ Time Frame: Up to approximately 46 months ] [ Designated as safety issue: No ]

TTR is defined as the time (in months) from the date of randomization to the date of first observation of response (PR or CR).

- Tumor Response: Duration of Response (DR) per RECIST 1.1 [ Time Frame: Up to approximately 46 months ] [ Designated as safety issue: No ]

DR is defined as the time (in months) from the date of first observation of response (PR or CR) to the date of the first observation of progression based on the investigator's radiographic assessment (RECIST 1.1), or date of death, whatever the cause.

Estimated Enrollment: 210  
 Study Start Date: March 2015  
 Estimated Study Completion Date: August 2019  
 Estimated Primary Completion Date: November 2017 (Final data collection date for primary outcome measure)

<b>Arms</b>	<b>Assigned Interventions</b>
<b>Experimental: Farletuzumab</b> All subjects will receive a loading dose for the first 2 weeks of 10 mg/kg farletuzumab, followed by 5 mg/kg weekly farletuzumab administered intravenously (IV)	<b>Drug: Farletuzumab</b> Farletuzumab will be administered intravenously (IV) weekly
<b>Placebo Comparator: Placebo</b> All subjects will receive placebo weekly, administered intravenously (IV).	<b>Drug: Placebo</b> Placebo will be administered intravenously (IV) weekly

**Detailed Description:**

Subjects will be enrolled in a targeted 1:1 stratification ratio into 1 of 2 chemotherapy treatment arms at the investigator's discretion: carboplatin plus paclitaxel or carboplatin plus Pegylated Liposomal Doxorubicin (PLD), and then randomized in a 2:1 ratio to receive weekly farletuzumab 5 mg/kg or placebo (ie, Test Article). All subjects will receive a loading dose for the first 2 weeks of 10 mg/kg Test Article (farletuzumab or placebo). Subjects will be stratified at randomization by individual chemotherapy treatment regimen (targeted 1:1 ratio) and platinum-free interval following first-line therapy (6 to 12 months vs greater than 12 to 36 months).

**▶ Eligibility**

Ages Eligible for Study: 18 Years and older  
 Genders Eligible for Study: Female  
 Accepts Healthy Volunteers: No

**Criteria**

## Inclusion Criteria:

1. Female subjects who are at least 18 years of age at the time of informed consent
2. CA125 less than or equal to 3 x upper limit of normal (ULN) ( $10^5$  U/mL) confirmed within 2 weeks of randomization using a centralized laboratory assay
3. A histologically confirmed diagnosis of high-grade serous epithelial ovarian cancer including primary peritoneal and fallopian tube malignancies; all other histologies, including mixed histology, are excluded
4. Have been treated with debulking surgery and a first-line platinum-based chemotherapy regimen
5. Maintenance therapy during the first platinum-free interval is allowed; however, the last dose must have been at least 21 days prior to Randomization. No cancer vaccine therapy is allowed.
6. Must have evaluable disease by Computed Tomography (CT) or Magnetic Resonance Imaging (MRI) scan, according to RECIST 1.1 (subjects with measurable disease per RECIST 1.1 or radiographically visible and evaluable disease). Subjects with only ascites or pleural effusion are excluded.
7. Must have relapsed radiographically between 6 months and 36 months of completion of first-line platinum chemotherapy and should be randomized within 16 weeks of radiographic relapse
8. Must be a candidate for treatment with either carboplatin plus paclitaxel or carboplatin plus PLD
9. Have a life expectancy of at least 6 months, as estimated by the investigator
10. Other significant medical conditions must be well-controlled and stable in the opinion of the investigator for at least 30 days prior to Randomization
11. Have an Eastern Cooperative Oncology Group (ECOG) Performance Status 0-2
12. Subjects being enrolled to receive paclitaxel plus carboplatin treatment must have neuropathic function (sensory and motor less than or equal to Grade 2 according to the National Cancer Institute's Common Terminology Criteria for Adverse Events (CTCAE) v4.03 (2010))
13. Laboratory results within the 2 weeks prior to Randomization must be as follows:
  - Absolute neutrophil count (ANC) greater than or equal to  $1.5 \times 10^9/L$
  - Platelet count greater than or equal to  $100 \times 10^9/L$
  - Hemoglobin greater than or equal to 9 g/dL
  - Creatinine less than  $1.5 \times ULN$  (CTCAE Grade 1)
  - Bilirubin less than  $1.5 \times ULN$  (CTCAE Grade 1)
  - Aspartate Aminotransferase (AST) and Alanine Aminotransferase (ALT) less than  $3 \times ULN$
  - Alkaline Phosphatase less than  $2.5 \times ULN$  (CTCAE Grade 1)
  - Baseline albumin greater than or equal to Lower Limit of Normal
14. Subjects of childbearing potential must be surgically sterile or consent to use a medically acceptable method of contraception throughout the study period. All females will be considered to be of childbearing potential unless they are postmenopausal (amenorrheic for at least 12 consecutive months, in the appropriate age group, and without other known or suspected cause) or have been sterilized surgically (ie, bilateral tubal ligation, total hysterectomy, or bilateral oophorectomy). If a patient of childbearing potential is neither surgically sterile nor postmenopausal, contraceptive measures must start either prior to or at Screening and continue throughout the entire study period and for 5 months after the last dose of Test Article is administered. Pregnant and/or lactating females are excluded
15. Subject must provide written informed consent and be willing and able to comply with all aspects of the protocol

## Exclusion Criteria:

1. Known central nervous system (CNS) tumor involvement
2. Evidence of other active invasive malignancy requiring treatment other than surgery in the past 3 years
3. Clinically significant heart disease (eg, congestive heart failure of New York Heart Association Class 3 or 4 angina, not well controlled by medication, or myocardial infarction within 6 months)
4. Electrocardiogram (ECG) demonstrating clinically significant arrhythmias that are not adequately medically managed (Note: subjects with chronic atrial arrhythmia, ie, atrial fibrillation or paroxysmal supraventricular tachycardia [SVT], are eligible)
5. Active serious systemic disease, including active bacterial or fungal infection
6. Active viral hepatitis or active human immunodeficiency virus (HIV) infection. Asymptomatic positive serology is not exclusionary.
7. Other concurrent immunotherapy (eg, immunosuppressants or chronic use of systemic corticosteroids, with the exception that low-dose corticosteroids [50 mg/day prednisone or equivalent corticosteroid] are allowed; these should be discussed with the Medical Monitor)
8. Known allergic reaction to a prior monoclonal antibody therapy or have any documented Anti-Drug Antibody (ADA) response
9. Previous treatment with farletuzumab or other folate receptor targeting agents
10. For subjects being enrolled to receive PLD plus carboplatin, prior treatment with anthracyclines or anthracenodiones
11. Breast-feeding, pregnant, or likely to become pregnant during the study
12. Any medical or other condition that, in the opinion of the investigator, would preclude the subject's participation in a clinical study
13. Patients who have had secondary debulking surgery
14. Currently enrolled in another clinical study or used any investigational drug or device within 30 days (or  $5 \times$  half-life for investigational drugs where the half-life is known) preceding informed consent

## ▶ Contacts and Locations

Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the Contacts provided below. For general information, see [Learn About Clinical Studies](#).

Please refer to this study by its ClinicalTrials.gov identifier: NCT02289950

### Contacts

Contact: Susan C Weil 610-423-6182 [weil@morphotek.com](mailto:weil@morphotek.com)

### + Show 70 Study Locations

### Sponsors and Collaborators

Morphotek

Eisai Co., Ltd.

## ▶ More Information

Responsible Party: Morphotek  
 ClinicalTrials.gov Identifier: [NCT02289950](#) [History of Changes](#)  
 Other Study ID Numbers: MORAb-003-011  
 Study First Received: November 10, 2014  
 Last Updated: April 28, 2016  
 Health Authority: Belgium: Federal Agency for Medicinal Products and Health Products  
 Germany: Paul-Ehrlich-Institut  
 Italy: The Italian Medicines Agency  
 Japan: Pharmaceuticals and Medical Devices Agency  
 United Kingdom: Medicines and Healthcare Products Regulatory Agency  
 United States: Food and Drug Administration

Keywords provided by Morphotek:

Ovarian Cancer in in first relapse  
 Platinum-Sensitive

Additional relevant MeSH terms:

Ovarian Neoplasms	Urogenital Neoplasms
Adnexal Diseases	Carboplatin
Endocrine Gland Neoplasms	Doxorubicin
Endocrine System Diseases	Liposomal doxorubicin
Genital Diseases, Female	Antibiotics, Antineoplastic
Genital Neoplasms, Female	Antineoplastic Agents
Gonadal Disorders	Enzyme Inhibitors
Neoplasms	Molecular Mechanisms of Pharmacological Action
Neoplasms by Site	Topoisomerase II Inhibitors
Ovarian Diseases	Topoisomerase Inhibitors

ClinicalTrials.gov processed this record on June 09, 2016