

Farletuzumab in Platinum-Sensitive Ovarian Cancer in First Relapse

A Randomized, Double-blind, Placebo-controlled, Phase III Study to Assess the Efficacy and Safety of Weekly Farletuzumab (MORAb-003) in Combination With Carboplatin and Taxane in Subjects With Platinum-sensitive Ovarian Cancer in First Relapse

PURPOSE¹:

To assess the efficacy of 2 doses of farletuzumab in combination with carboplatin and taxane in patients with platinum-sensitive ovarian cancer in first relapse

STUDY DESIGN¹:

Multicenter, double-blind, randomized, placebo-controlled, parallel-group, safety/efficacy study (N=900)

PRIMARY OBJECTIVE¹:

Progression-free survival based on central, independent radiologic assessments utilizing Response Evaluation Criteria in Solid Tumors (RECIST)

KEY SECONDARY OBJECTIVES¹:

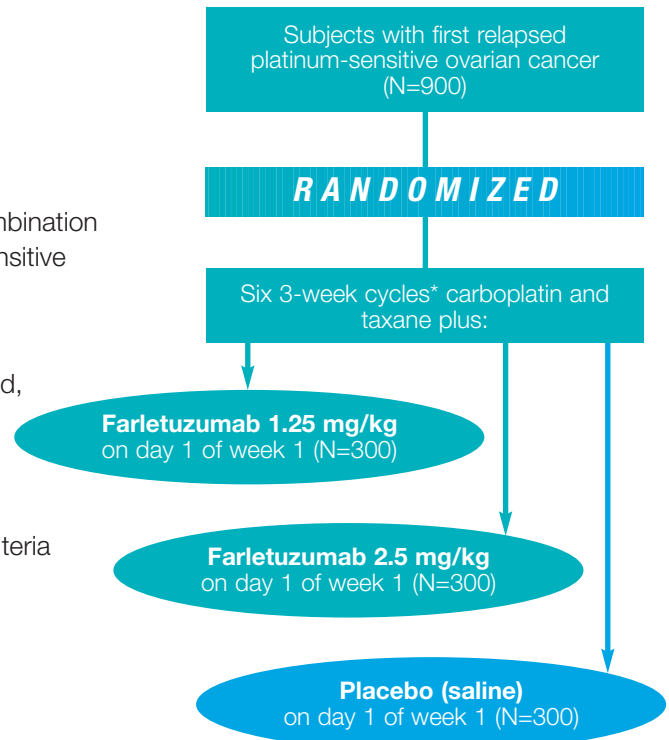
- Overall survival
- CA-125 PFS (Rustin Criteria)
- Gynecologic Cancer Inter Group (GCIG) PFS (GCIG criteria)
- Prolongation of second remission longer than first remission
- Tumor response (overall response, time to response, and duration of response per RECIST)
- Serologic response (CA-125)
- Subject-reported quality of life

KEY INCLUSION CRITERIA¹:

- Histologically or cytologically confirmed diagnosis of non-mucinous epithelial ovarian cancer (including primary peritoneal and fallopian tube malignancies)
- Treated initially with surgery and first-line platinum and taxane-based chemotherapy
- In first relapse after a remission of ≥ 6 and ≤ 24 months from their first-line platinum and taxane-based chemotherapy

KEY EXCLUSION CRITERIA¹:

- Subjects who never responded to first-line platinum-based therapy whose first relapse occurs < 6 months or > 24 months from the last platinum therapy
- Subjects who have received other therapy to treat their ovarian cancer since relapse
- Known central nervous system (CNS) tumor involvement



* Following completion of combination therapy, maintenance treatment with weekly single-agent MORAb-003 or placebo will continue until disease progression as defined by RECIST criteria using CT scan (or MRI)

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This agent is investigational as efficacy and safety have not been established. There is no guarantee that this agent will be available commercially. For more information about Morphotek clinical trials, please call **877-FAR-1311** or visit **www.far-trials.com**.



Now Enrolling

Farletuzumab in Platinum-Resistant or Refractory Relapsed Ovarian Cancer

A Randomized, Double-blind, Placebo-controlled Study of the Efficacy and Safety of Farletuzumab (MORAb-003) in Combination With Paclitaxel Therapy in Subjects With Platinum-resistant or Refractory Relapsed Ovarian Cancer

PURPOSE:

To compare the efficacy of weekly paclitaxel plus farletuzumab with weekly paclitaxel in subjects with relapsed platinum-resistant or refractory ovarian cancer

STUDY DESIGN:

Phase II, multicenter, randomized, double-blind, placebo-controlled, parallel group, safety/efficacy study (N=350)

PRIMARY OBJECTIVE:

Progression-free survival using Gynecologic Cancer Inter Group (GCIg) response criteria stratified by prior chemotherapy and geographic region

KEY SECONDARY OBJECTIVES:

- Overall response
- Overall survival
- Safety and tolerability
- Changes in CA-125 levels per GCIg criteria
- Cardiac substudy

KEY INCLUSION CRITERIA:

- Diagnosis of non-mucinous epithelial ovarian cancer measurable by computed tomography (CT) or magnetic resonance imaging (MRI) scan, or progression defined by radiologic criteria or by biomarker (CA-125 \geq 1.5 x ULN) assessed within 4 weeks prior to study entry
- Must have been initially treated with surgery and at least 1 line of platinum-based chemotherapy
- Must have relapsed within 6 months of first or second line platinum-containing chemotherapy. At least 1 of the lines of chemotherapy must have included a taxane

KEY EXCLUSION CRITERIA:

- Known central nervous system (CNS) tumor involvement
- Clinical contraindications to use of paclitaxel
- Evidence of active invasive malignancy other than ovarian cancer requiring treatment in the last 5 years

This agent is investigational as efficacy and safety have not been established. There is no guarantee that this agent will be available commercially.

For more information about Morphotek clinical trials, please call 877-FAR-1311 or visit www.far-trials.com.



Subjects with platinum-resistant or refractory relapsed ovarian cancer (N=350)

RANDOMIZED

Farletuzumab 2.5 mg/kg
in combination with paclitaxel 80 mg/m² on day 1 of weeks 1-12 (cycle 1), then in 4-week cycles on day 1 of weeks 1-3, with week 4 as a rest period until disease progression

Placebo 2.5 mg/kg
in combination with paclitaxel 80 mg/m² on day 1 of weeks 1-12 (cycle 1) then in 4-week cycles on day 1 of weeks 1-3, with week 4 as a rest period until disease progression

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