



Closed Trial – status update MITO 16b-MaNGOov2b

A multicenter phase III randomized study with second line chemotherapy ± bevacizumab in patients with platinum sensitive epithelial ovarian cancer recurrence after a bevacizumab/chemotherapy first line



Trial setting: **Second line OC**

Sponsor: **NCI Naples**

Lead groups: **MITO MaNGO**

Final No. of patients: **406**

Timeline: **FPI: 12/2013**

LPI: 11/2016

Publications: **Q1 2018 primary**

Planned substudies:

translational

CBDCA AUC5 + PAC 175 mg/m² q3w

or

CBDCA AUC4, d1 + GEM 1000mg /m², d1&8 q3w

or

CBDCA AUC5+PLD 30mg/m² q4w

- Plat sensitive OC
- Previous Bevacizumab
- ECOG 0-2
- Availability of samples for translational res.
- No Beva contraindications

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CBDCA AUC5 + PAC 175 mg/m² q3w

Plus bevacizumab 15mg/kg q3w**

or

CBDCA AUC4, d1 + GEM 1000mg /m², d1&8 q3w

Plus bevacizumab 15mg/kg q3w

or

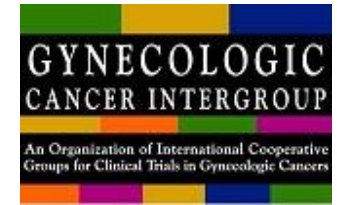
CBDCA AUC5+PLD 30mg/m² q4w

Plus bevacizumab 10mg/kg q2w



Ongoing Trials – status update

MITO 23; MANGO-OV2b



Randomized phase III trial on Trabectedin (ET 743) vs clinician's choice chemotherapy in recurrent ovarian, primary peritoneal or fallopian tube cancers of BRCA mutated or BRCAness phenotype patients

Trial setting: Patient BRCA mutated or BRCAness phenotype with recurrent ovarian, primary peritoneal or fallopian tube cancers

Sponsor(s): INT - Milan

Planned No. of patients: 244

Current accrual: 65

STRATIFICATION CRITERIA:
Measurable Disease
Platinum Sensitivity
Number of Previous CHT Lines
Mutational status

Recurrent ovarian, primary peritoneal or fallopian tube cancers of BRCA mutated or BRCAness phenotype patients

Random 1.1

Randomized phase III

II line chemotherapy (physician choice):

- PLD 40 mg/mq d1 q28;
- Topotecan 4 mg/mq d1,8,15 q 28
- Weekly Paclitaxel 80 mg/mq d1,8,15 q28
- Gemcitabine 1000 mg/mq gg1,8,15 q28
- Carboplatin AUC 5 g 1 q 21

Trabectedin 1.3 mg/mq d1 q 21 in 3 hours (central line)