



Closed Trial – status update

MITO 8; ENGOT Ov-1



A phase III international multicenter randomized study testing the effect on survival of prolonging platinum-free interval in patients with ovarian cancer recurring between 6 and 12 months after previous platinum based chemotherapy

Nonprofit Sponsor: **NCI Naples , MITO lead**

Final No. of patients: **215**

Timeline : **FPI 1/2009 LPI 10/2015**

Publications: Primary results

J Clin Oncol. 2017 Oct 10;35(29):3347-3353.

Epub 2017 Aug 21.

Planned publications: **QoL Q4 2017**

Planned substudies:

Enrollment by Group

GROUP	N. Patients
MITO	170
MANGO	20
BGOG	13
AGO	12
Total	215



Closed Trial – status update

**MITO 16b; MANGO-OV2b
ENGOT Ov-17**



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

Non profit Sponsor: **NCI Naples**

Lead groups: **MITO MaNGO**

Final No. of patients: **406**

Timeline: **FPI: 12/2013 LPI: 11/2016**

Primary results: Q1-2 / 2018

Translational: Q4 2018

Substudies:

Enrollment by Group

GROUP	N. Patients
MITO	206
GINECO	100
MANGO	72
SAKK	17
HeCOG	11
BGOG	0
Total	406



Ongoing Trials – status update

MITO 23 ENGOT Ov-32



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

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**

Random1.1

**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)**



Ongoing Trials – status update

MITO 23 ENGOT Ov-32



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

Primary Objective:

The primary objective is to compare the treatment groups in terms of overall survival (OS)

Secondary Objectives:

- Progression free survival (PFS)
- Radiological response rate (in patients with measurable disease)
- Duration of response
- CA-125 response rate per GCIG
- Toxicity profile
- Quality of life using the QLQ-C30 and QLQ-OV28



Ongoing Trials – status update

MITO 23 ENGOT Ov-32



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

Lead group: **MITO**

Planned No. of patients: **244**

No. of already recruited patients: **106**

Timeline: **FPI Feb 2016 , LPI Q4 2018**

Academic trial

NCI of Milano sponsor

Data center: NCI of Milan

Trabectedin provided

GEICO Group ready to start
40 patients