OVAIO
MITO 35b

Olaparib beyond progression compared to platinum chemotherapy after secondary cytoreductive surgery in recurrent ovarian cancer patients

The phase III randomized: a project of the MITO-MANGO groups

MITO 35b trial is an open label, randomized, phase III study aimed to evaluate if olaparib maintenance beyond progression after secondary cytoreductive surgery is superior, in terms of progression-free survival, to standard chemotherapy in patients who experience disease recurrence during or after first-line maintenance with a PARPi.

Patients will be stratified according to:
- **BRCA 1/2 genes status (mutated vs wild type)**
- **residual disease after secondary surgery (absent vs present)**
- **type of recurrence (during PARPi vs after the end of maintenance therapy)**

Primary endpoint:
- **to determine the efficacy (as assessed by Investigators using progression-free survival) of olaparib maintenance beyond progression when compared to standard chemotherapy in patients with recurrent ovarian cancer undergone secondary cytoreductive surgery for recurrent or progressive disease.**
- **To determine the efficacy of the experimental therapies on subsequent treatment (as assessed by Investigators using progression-free survival 2) after progression**

Secondary endpoint:
- **to determine the efficacy (as assessed by overall survival) of olaparib when compared to a platinum-based chemotherapy in patients with recurrent ovarian cancer who have undergone secondary surgery at progression to first line PARPi maintenance**
- **to compare the two arms in terms of the safety and tolerability (CTCAE 5.0 version and PRO-CTCAE)**
- **to assess changes in Quality of Life parameters in patients treated with olaparib maintenance compared to chemotherapy (EORTC QLQC30)**
- **to compare the two arms in terms of financial toxicity assessed with PROFFIT**

Inclusion criteria

- **patient must have received a first-line maintenance therapy with a PARPi for at least 6 months**
- **patients who experience disease relapse after the end of the 24 months maintenance therapy are eligible**
- **patients must have undergone secondary cytoreductive surgery. The cytoreduction must result in complete resection (absence of macroscopic residual tumor) or at least resection of the progressive lesion(s) occurring during maintenance**
- **documented BRCA1/2 status. Both mutated and wild type patients are eligible Patient with unknown status of BRCA genes agrees to undergo analysis of their germline and somatic BRCA status (testing must be completed prior to randomization in the study)**
- **patients must start the experimental treatments in the current study within 3 to 8 weeks from second surgery**
- **patient must provide archival tumor samples formalin fixed, paraffin embedded (FFPE) from both the primary and secondary surgeries for paired analysis. A quality control analysis of samples will be performed before patient's randomization**