NItCHE (MITO 33)

Randomized phase III trial on Niraparib-Dostarlimab vs physician's choice CHEmotherapy in recurrent, ovarian, fallopian tube or primary peritoneal cancer patients not candidate for platinum retreatment

Randomized, open-label, phase III multicenter. Primary endpoint: OS

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Study Drug Ke: Niraparib (PARPi) + dostarlimab (anti-PD-1) versus standard of care (PLD, PTX, gemcitabina, topotecan)

Eligibility Criteri:

• Patients with recurrent ovarian, Fallopian tube or primary peritoneal cancer (any epithelial histology) not candidate for platinum retreatment: - platinum-resistant patients (PFI 1-6 months); - platinum is contraindicated (allergic reactions or residual toxicity)

• No more than 2 prior CHT lines (prior PARPi and/or immunotherapy allowed if maggiore/uguale 6 months from the last dose)

• Measurable or evaluable disease (RECIST 1.1)

• CS therapy is allowed if dosage has been stable for maggiore/uguale 4 weeks before start of therapy

• New biopsy should be performed (within 6 weeks/42 days prior to start of therapy), but not mandatory.