AtTEnd/MaNGO

PHASE III DOUBLE-BLIND RANDOMIZED TRIAL OF ATEZOLIZUMAB IN COMBINATION WITH PACLITAXEL AND CARBOPLATIN IN WOMEN WITH ADVANCED/RECURRENT ENDOMETRIAL CANCER

Principal Investigator**:** Nicoletta Colombo, IEO – Milano

Trial setting: advanced/recurrent endometrial cancer

Study Design: randomized, double blind parallel arms

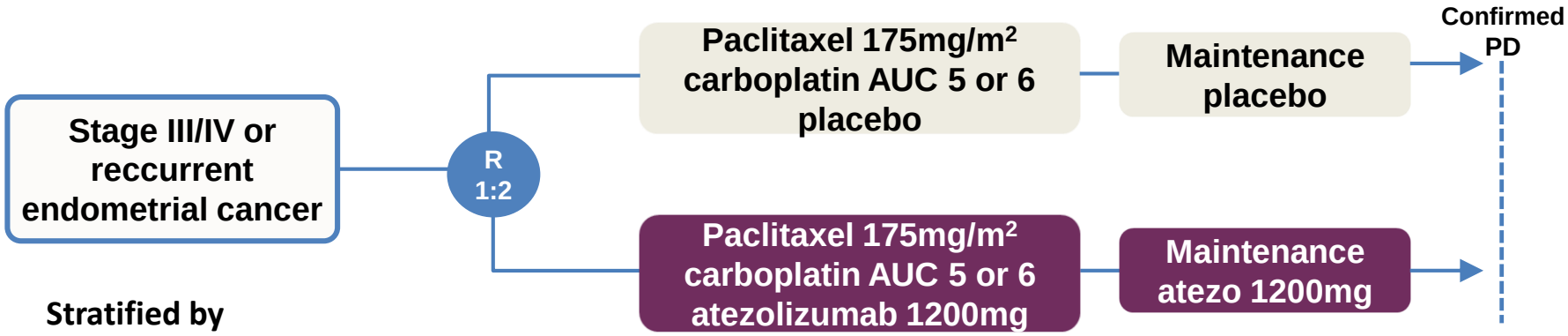
Sponsor(s): MaNGO- Istituto di Ricerche Farmacologiche Mario Negri, Milano

Planned No. of patients: 496

Current accrual: not yet recruiting

First patient-in is planned for Q1 2018

Study design



Stratified by

- Prior RT
- Recurrent disease
- MSI

Atezolizumab\Placebo will be administered:
as I.V. infusion **every 21 days** until **progression confirmed at least 4 weeks after the first evidence of progression according to RECIST v 1.1.**

Primary Endpoint: OS and PFS

Secondary Endpoints: PFS in MSI, PFS2, RR, QoL, safety

Translational Endpoints: PD1, PDL1, TILs, blood based biomarkers

Study Duration: accrual 2 years; **Follow-up**: 2 years

Main Inclusion Criteria

- Newly diagnosed advanced stage (III/IV) endometrial cancer with residual disease, if surgically debulked, or recurrent endometrial cancer, that has not been treated with systemic therapy in the advanced/recurrent setting.
- ECOG $\leq$ 2
- Age $\geq$ 18 years
- Platinum-based chemotherapy in the adjuvant setting is permitted if platinum-free interval > 6 months
- Adequate bone marrow, renal, and hepatic function
- Prior radiation allowed

Sample Size

- Median OS control group: 18 months
- HR for OS: 0.70; median survival gain 8 months
- type 1 error: 0.04 - two tails
- Power: 83%
- 326 death events
- Similarly powered for PFS

496 patients needed to be enrolled

Study Time-Line

- Accrual length: 24 months
- Follow-up: 24 months
- OS interim at 37 months from First Patient In (FPI)
  - type 1 error: 0.018 according to alpha spending function defined by the O'Brien-Fleming boundary.
  - Power 64%.
- OS and PFS final analysis at 48 months from FPI
- FPI is planned for Q1 2018