ISTITUTO DI RICERCHE FARMACOLOGICHE MARIO NEGRI · IRCCS

ENGOT-en7/MaNGO/AtTEnd

Phase III double-blind randomized trial of atezolizumab in combination with paclitaxel and carboplatin in women with advanced/recurrent endometrial cancer

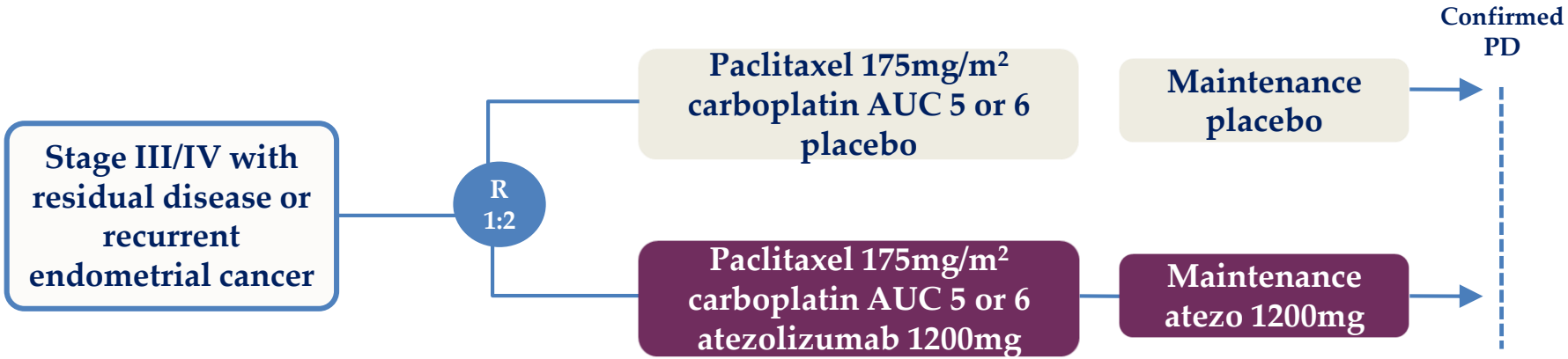
AtTEnd Study

XVI Assemblea MaNGO – Reggio Emilia 21-22 giugno 2019

Anna Roberto, Francesca Tettamanzi, Elena Biagioli, Roldano Fossati

Principal Investigator: Nicoletta Colombo, Istituto Europeo di Oncologia
Sponsor: MaNGO- Istituto di Ricerche Farmacologiche Mario Negri IRCCS

STUDY DESIGN



Stratified by:

- Country of the experimental center
- Histological type (endometrioid vs. other types)
- Disease (recurrent disease vs advanced disease at primary diagnosis)
- MS status (MSS vs MSI vs non-evaluable)

STUDY ENDPOINTS

PRIMARY ENDPOINTS

Overall survival and progression free survival (PFS)

SECONDARY ENDPOINTS

- PFS by micro satellite instability (MSI) status
- PFS2 by PD-L1 status
- Objective Response Rate
- Quality of life
- Safety

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 to detect HR of 0.7 in PFS (type 1 error 0.01 – two tails)

- Accrual 24 months; follow-up of 24 months; 10% not evaluable patients: **550 patients** are needed.

An interim analysis for OS is planned when 80% of the events are observed (approximately 260 events)

STUDY UPDATE

PARTICIPATING COUNTRIES

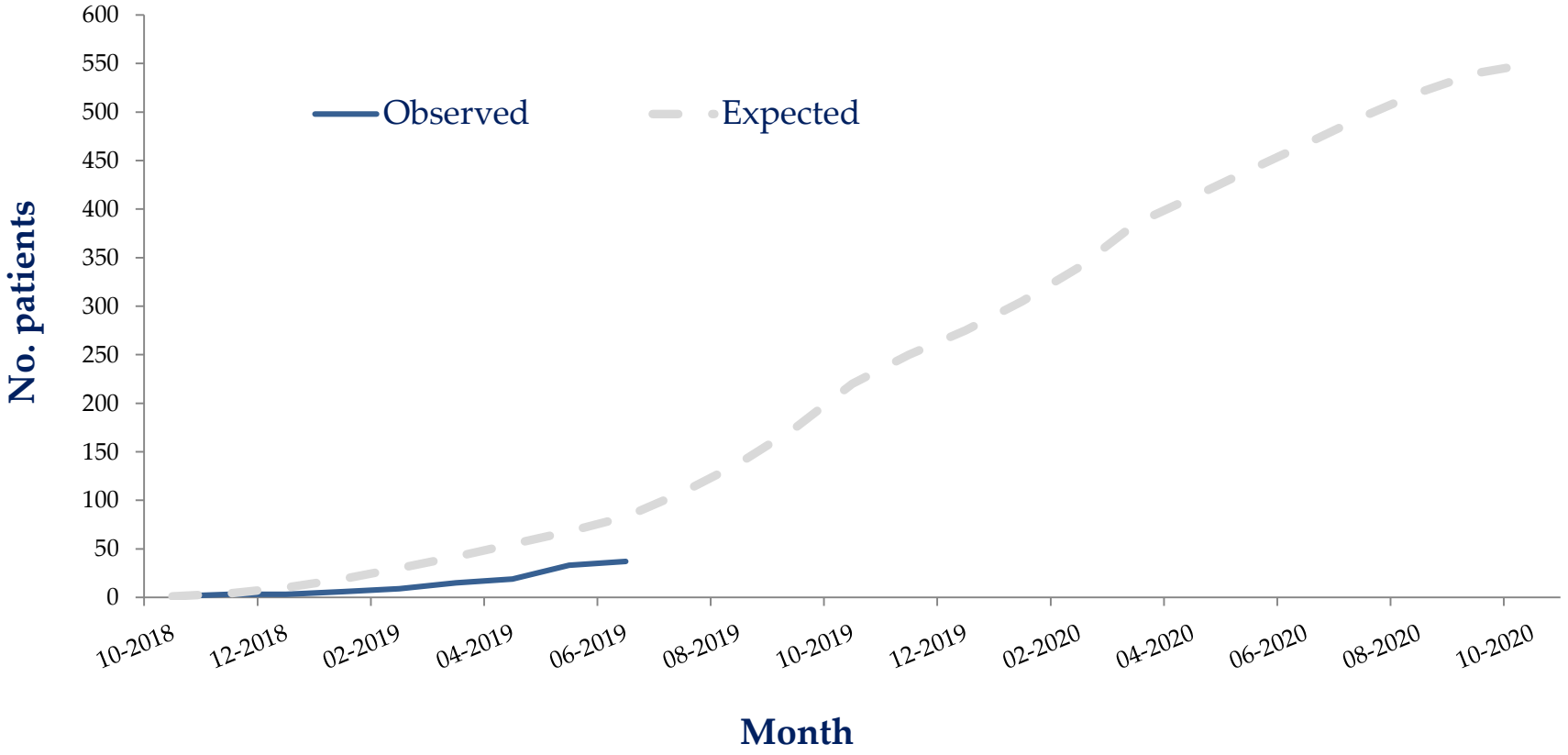
80% sites: August 2019
95 % sites: December 2019
100% sites: January 2020

EORTC
European Organisation for Research and Treatment of Cancer
The future of cancer therapy

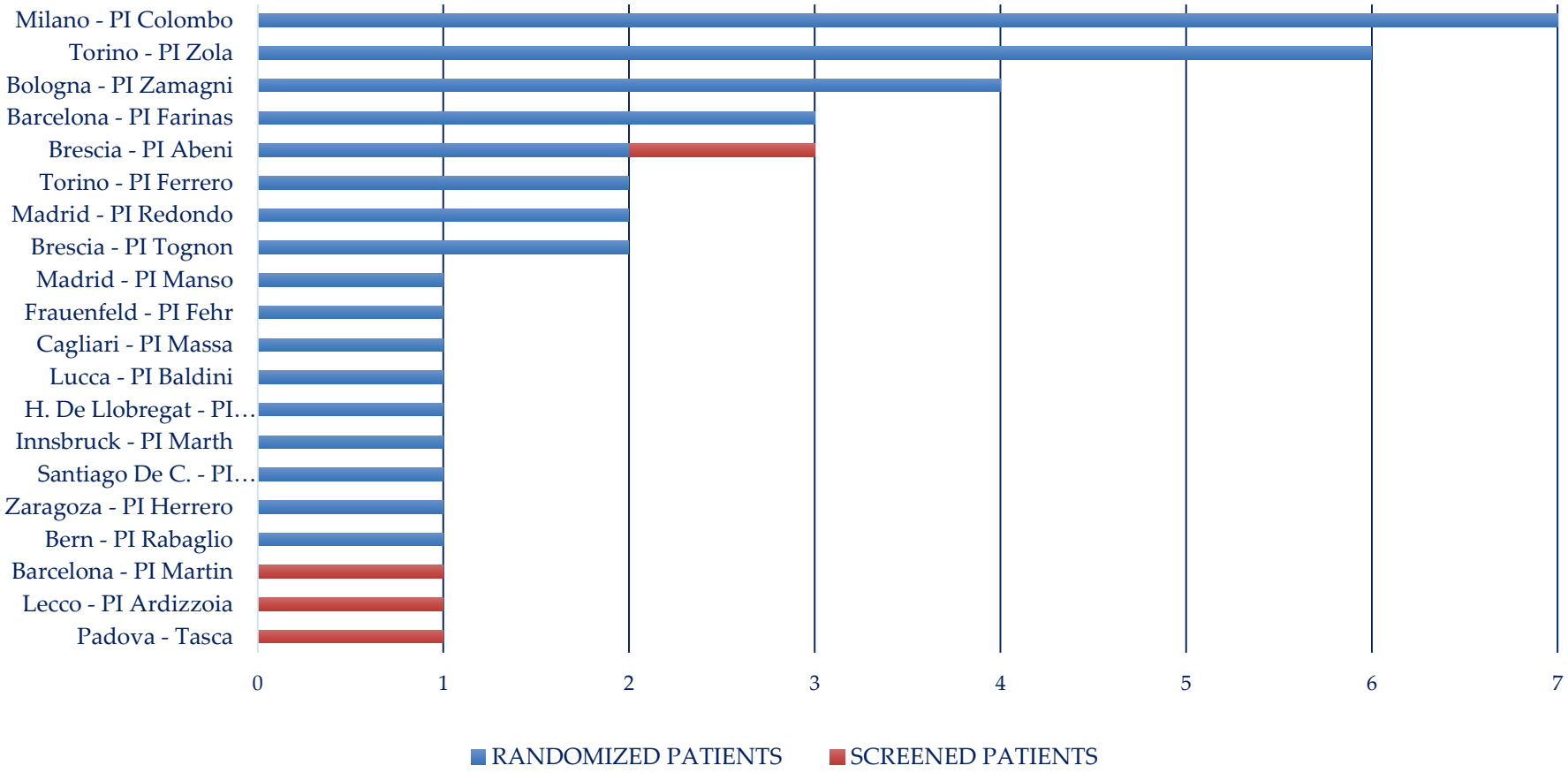
0/18 sites

ENROLLMENT

- No. of screened patients: 48
- No. of randomized patients: 37
- No. of screening failures: 7 (14%)



ENROLLMENT PER SITE



STEERING COMMITTEE

Steering Committee meeting in Chicago – june 2019

Discussion on

- Scientific background with a focus on competitive trials with immune-oncology agents in endometrial cancer
- Study update
- Action to speed-up recruitment

- The study has the advantage over the other competitive trials
- Patient fee as a possible action for enrollment increase (unbalance with other fully sponsored non IIS competitive trials, regain sites, facilitate sites' clinical management of patients)

INDIPENDENT DATA MONITORING COMMITTEE (IDMC)

Members

- Prof. Isabelle Ray-Coquard
- Prof. Ignace Vergote
- Prof. Vincenzo Bagnardi – Study Independent statistician

First safety Interim Analysis: **meeting planned for 19th of July**

Monitoring safety of first included patients in the study

Recommendations to Steering Committee

TRANSLATIONAL STUDY

- Proposal in collaboration with the Translational Genomic Unit of Mario Negri Institute, headed by Dr. Sergio Marchini
- Aim at characterizing the molecular profile of patients
- Genetic and epigenetic analyses on tumor samples already collected for Microsatellite instability evaluation
- Project presented to Roche for request of full/partial funding

GEICO
Grupo Español de Investigación en Cáncer de Ovario

JGOG
Japanese Gynecologic Oncology Group

NCRI
National Cancer Research Institute

GYNECOLOGIC CANCER INTERGROUP
An Organization of International Cooperative Groups for Clinical Trials in Gynecologic Cancers

MaNGO
Mario Negri Gynecologic Oncology

ENGOT
European Network of Gynaecological Oncological Trial groups

AGO Studiengruppe

AGO AUSTRIA

50 YEARS SAKK
WE BRING PROGRESS TO CANCER CARE

ANZGOG