ENGOT
European Network of Gynaecological Oncological Trial groups

GEICO
Grupo Español de Investigación en Cáncer de Ovario

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

ANITA

Atezolizumab and NIraparib Treatment Association in patients with recurrent ovarian cancer and platinum as option

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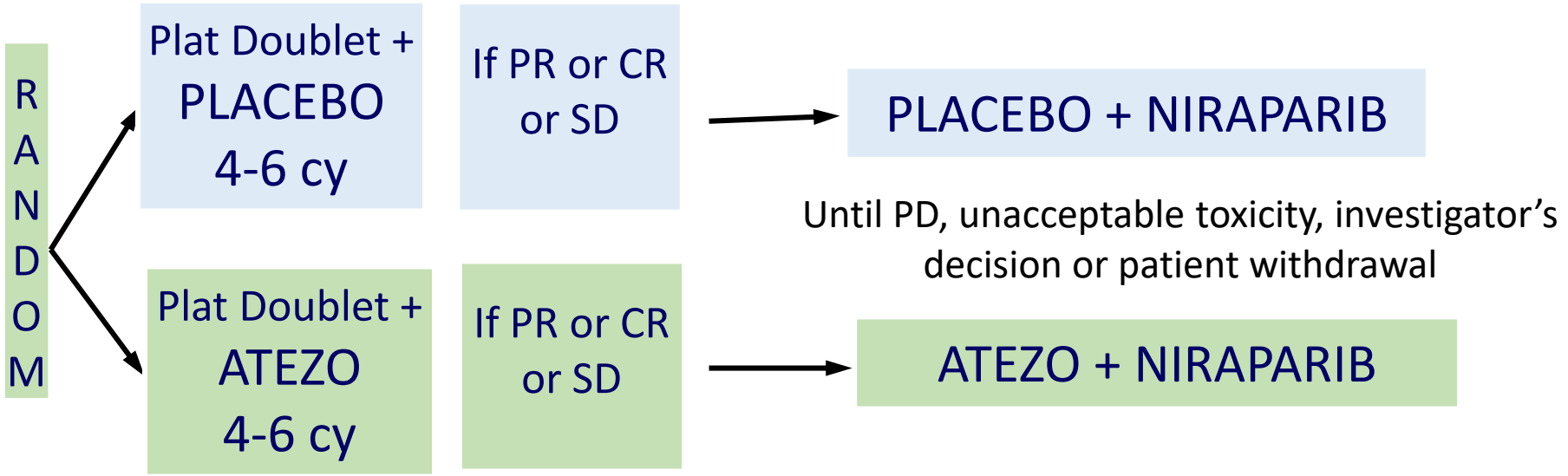
on behalf of GEICO

ENGOT MODEL B

ANITA Design

- High-grade serous or endometrid
- Known gBRCA status
- TFIp > 6 months after the last platinum regimen
- 1-2 prior lines
- Platinum is still an option
- 1 measurable lesion



Until PD, unacceptable toxicity, investigator's decision or patient withdrawal

Stratification
- TFIp 6-12 vs >12 months
- BRCAmut (germline or somaticif known) vs BRCAwt
- Platinum based regimen selected (paclitaxel-carboplatin vs gemcitabine-carboplatin vs PLD-carboplatin)

ANITA Endpoints

- **Primary Endpoint:**
- Progression-free survival (PFS1) based on investigator assessment determined by RECIST (version 1.1.
- **Secondary Endpoints:**
- PFS according to irRECIST criteria
- Time from randomization to first subsequent therapy or death (TFST)
- Time from randomization to second subsequent therapy or death (TSST)
- Time from randomization to progression after first subsequent therapy or death (PFS2)
- Frequency and severity of adverse events as assessed by CTCAE version 4.03
- Patient reported outcomes (PROs) as measured by EORTC QLQ-C30, OV28 and EQ-5D-5L plus the visual scale EQ-5D VAS.
- Overall survival (OS)
- Objective Response Rate (ORR) as assessed by RECIST v1.1 and Immune related RECIST (irRECIST)
- PFS from the beginning of maintenance phase.
- PFS of patients with CR or PR at the end of chemotherapy from the beginning of the maintenance phase.
- PFS of patients with stable disease at the end of chemotherapy from the beginning of the maintenance phase.
- Assessment of primary and secondary endpoints according to stratification factors.

ANITA Inclusion Criteria

- High grade serous or endometrioid ovarian, primary peritoneal or tubal cancer.
- BRCA status is known (germline or somatic).
- Relapsed disease more than 6 months after the last platinum dose.
- No other cytotoxic agent is allowed from last platinum dose, but maintenance with a biological agent is allowed if it is interrupted 21 days before randomization
- No more than 2 prior lines of chemotherapy are allowed, and the last one must contain a platinum-based regimen.
- At least one measurable lesion by RECIST criteria
- Archival tumor sample must be available.
- Performance status determined by ECOG score of 0-1
- Patients must have normal organ and bone marrow function

ANITA Exclusion Criteria

- Patient has received prior treatment with a known PARP inhibitor or has participated in a study where any treatment arm included administration of a known PARP inhibitor in the recurrent setting.