Plenary 02: Changing the Landscape of Endometrial Cancer

AS04. Endometrial/Uterine corpus cancers

PO006LBA/#1520 SELINEXOR MAINTENANCE FOR PATIENTS WITH TP53WT ADVANCED OR RECURRENT ENDOMETRIAL CANCER: LONG-TERM FOLLOW UP OF EFFICACY AND SAFETY SUBGROUP ANALYSIS OF THE ENGOT-EN5/GOG-3055/SIENDO STUDY

[1]Giovanni Scambia*, [2]Ignace Vergote, [3]Erika Hamilton, [4]Jose Perez Fidalgo, [5]Toon Van Gorp, [6]Jalid Sehouli, [7]Jaroslav Klat, [8]Tally Levy, [9]Stephen Welch, [10]Debra Richardson, [11]Eva Guerra Alía, [12]Stéphanie Henry, [13]Pauline Wimberger, [14]David Miller, [15]Jerónimo Martínez, [16]Bradley Monk, [17]Pratheek Kalyanapu, [18]Mansoor Raza Mirza, [19]Vicky Makker. *[1]MITO and Fondazione Policlinico Universitario A. Gemelli IRCCS Università Cattolica del S. Cuore, Obstetric and Gynecology, Rome, Italy; [2]BGOG and University Hospitals Leuven, Leuven Cancer Institute, Leuven, Belgium; [3]Sarah Cannon Research Institute, Tennessee Oncology, Breast and Gynecologic Cancer Research, Nashville, USA; [4]GEICO and Hospital Clinico Universitario de Valencia, Incliva. Ciberonc., Valencia, Spain; [5]University Hospitals Leuven, Leuven Cancer Institute, Oncology, Leuven, Belgium; [6]NOGGO and European Competence Center for Ovarian Cancer, Charité Comprehensive Cancer Center, Charité-Berlin University of Medicine, Department of Gynecology, Berlin, Germany; [7]CEEGOG and University Hospital Ostrava, Oncology, Ostrava, Czech Republic; [8]ISGO and Wolfson Medical Center, Holon, affiliated with Sackler Faculty of Medicine, Tel Aviv University, Gynecologic Oncology Unit, Department of Obstetrics and Gynecology, Tel Aviv, Israel; [9]London Health Sciences Centre, Department of Oncology, London, Canada; [10]Stephenson Cancer Center, University of Oklahoma Health Sciences Center, Department of Oncology, Oklahoma City, USA; [11]GEICO and Hospital Universitario Ramón y Cajal, Department of Oncology, Madrid, Spain; [12]BGOG and Université Catholique de Louvain, CHU UCL Namur Site Ste Elisabeth, Service d'onco-hématologie (SORMN), Department of Oncology, Namur, Belgium; [13]NOGGO and Technische Universität Carl Gustav Carus Dresden, Department of Gynecology and Obstetrics, Dresden, Germany; [14]Harold C. Simmons Comprehensive Cancer Center, University of Texas Southwestern Medical Center, Department of Obstetrics and Gynecology, Dallas, USA; [15]GEICO and Hospital Universitario Virgen de la Arrixaca, Department of Oncology, Murica, Spain; [16]GOG-Foundation and HonorHealth University of Arizona College of Medicine and Creighton University School of Medicine, Division of Gynecologic Oncology, Phoenix, USA; [17]Karyopharm Therapeutics, Research, Newton, USA; [18]Rigshospitalet – Copenhagen University Hospital, Oncology, Copenhagen, Denmark; [19]Memorial Sloan Kettering Cancer Center, Department of Medicine, New York, USA*

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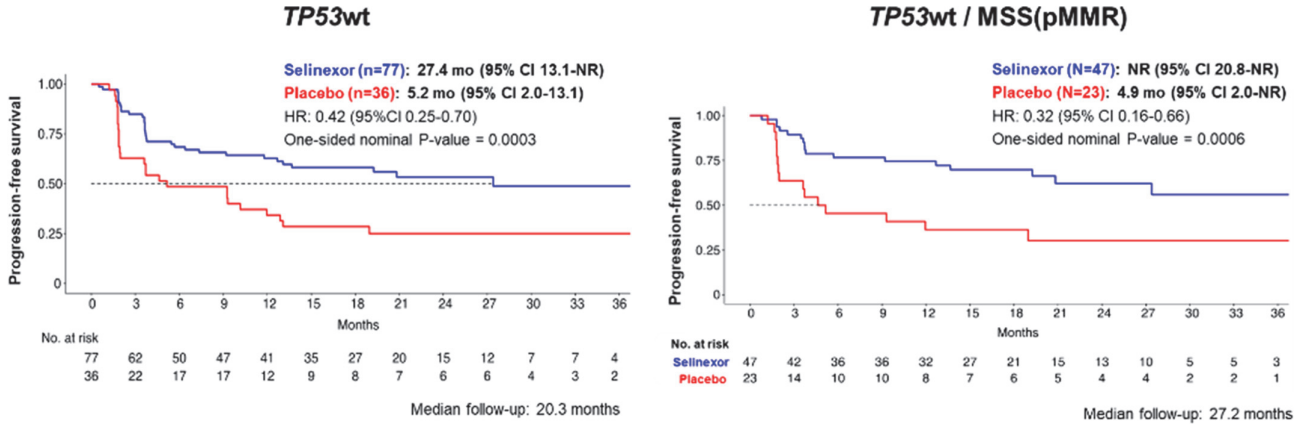
Introduction Molecular characterization is important to inform treatment decisions for patients with endometrial cancer (EC). Wild type TP53 (TP53wt) is found in ~50% of advanced/recurrent EC and of those, ~70% are microsatellite stable (MSS/pMMR).

Methods ENGOT-EN5/GOG-3055/SIENDO (NCT03555422) is a randomized double-blind, phase 3 trial evaluating selinexor vs placebo as a maintenance treatment for advanced/recurrent EC following response to prior systemic therapy. Here we report the updated efficacy and safety of a prespecified exploratory subgroup analysis of patients with TP53wt EC.

Results 113 patients with TP53wt EC received selinexor (n=77) or placebo (n=36) as maintenance therapy. As of March 2023, the median follow-up was 25.3 months, and 26 patients remain on treatment. Median PFS (mPFS) was 27.4 months with selinexor vs 5.2 months with placebo (HR 0.42; 95% CI [0.25–0.70], nominal one-sided p=0.0003). PFS improvement was observed regardless of microsatellite instability status; in the TP53wt/MSS(pMMR) subgroup, the mPFS was not reached with selinexor vs 4.9 months with placebo. In patients with TP53wt, the most common adverse events (AEs) were nausea, vomiting, and diarrhea; most common grade ≥3 AEs were neutropenia, thrombocytopenia, and nausea; 16% of patients discontinued selinexor due to AEs. No grade 5 AEs occurred. No immune-related AEs were observed.

Conclusion/Implications TP53wt status may represent a robust predictive biomarker for selinexor efficacy in EC. Additionally, a strong PFS signal was observed in the TP53wt/MSS(pMMR) subgroup, a patient population with high unmet need. Both additional data and updated data will be presented at the conference.



Abstract PO006LBA/#1520 Figure 1