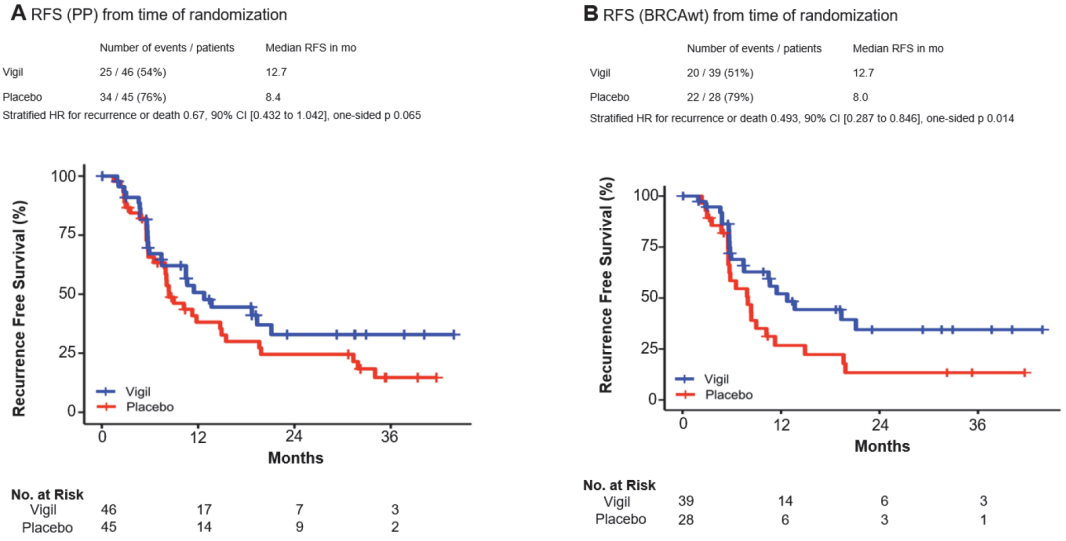


Abstract 15 Figure 1 RFS from randomization. **(A)** RFS of all PP. **(B)** RFS of *BRCA1/2-wt* population

Conclusion Vigil immunotherapy as 1L maintenance in Stage III/IV ovarian cancer is well tolerated and showed significant RFS clinical benefit, particularly in BRCA1/2-wt disease.

IGCS20_1101

16 QUALITY-ADJUSTED (QA) PROGRESSION-FREE SURVIVAL ANALYSES OF VELIPARIB + CARBOPLATIN/PACLITAXEL (CP) VS CP ALONE IN PATIENTS WITH NEWLY DIAGNOSED OVARIAN CANCER

[1]A Alvarez Secord*, [2]M Bookman, [3]R Coleman, [4]M Dinh, [4]N Khandelwal, [4]K Benjamin, [4]R Kamalakar, [4]D Sullivan, [5]D Cella. *[1]Department of Obstetrics and Gynecology, Duke University School of Medicine, Duke Cancer Institute, USA; [2]Department of Medicine, University of Arizona Health Sciences, USA; [3]Department of Gynecologic Oncology and Reproductive Medicine, Division of Surgery, MD Anderson Cancer Center, USA; [4]Abbvie Inc, USA; [5]Department of Medical Social Sciences, Northwestern University, USA*

10.1136/ijgc-2020-IGCS.16

Objective Veliparib, a poly (ADP-ribose) polymerase inhibitor, was evaluated in a Phase 3 trial (VELIA, NCT02470585) among patients with newly diagnosed stage III/IV high-grade serous epithelial ovarian/fallopian tube/primary peritoneal cancer. VELIA examined veliparib added to CP followed by veliparib maintenance compared to placebo added to CP followed by placebo maintenance. This analysis compared QA progression-free survival among patients enrolled in VELIA.

Methods Patient-centered outcomes were assessed in 344 Veliparib+ CP and 351 CP alone subjects. Progression-free survival (PFS) time was partitioned into two health states: time with toxicity (Tox) and time without Tox. Tox included three clinically meaningful adverse events (AEs) including nausea, vomiting and fatigue. QA-PFS was assessed for duration of good quality of life, incorporating PFS and health states. Q-TWiST (QA time without disease symptoms or treatment Tox) was calculated as utility-weighted sums of mean health state durations. Sensitivity analyses were conducted utilizing Grade 2+ or Grade 3+ AEs. Similar analyses were conducted on HRD and BRCA-deficient subgroups.

Results A significant difference in mean QA-PFS was seen in favor of Vel throughout compared to CP alone (19.5 months vs 16.5 months; 95% CI 1.42, 4.61; p<0.0001). Mean Q-TWiST was longer for patients in Vel throughout arm compared to CP alone (20.82 months vs 18.06 months; 95% CI 1.09, 4.47; p<0.001). Similar differences in mean Q-TWiST were observed for sensitivity and subgroup analyses.

Conclusion Compared to CP alone, Veliparib added to CP and continued as maintenance had significant patient-centered benefits in terms of QA-PFS and on-treatment Q-TWiST.

IGCS20_1131

17 SAFETY AND PATIENT-REPORTED OUTCOMES IN PATIENTS RECEIVING NIRAPARIB IN THE PRIMA/ENGOT-OV26/GOG-3012 TRIAL

[1]G Freyer*, [2]B Pothuri, [3]S Han, [4]D Chase, [4]B Monk, [5]F Heitz, [6]R Burger, [7]L Gaba, [8]L Van Le, [9]E Guerra, [10]D Bender, [11]J Korach, [12]N Cloven, [13]C Churruca, [14]P Follana, [15]P DiSilvestro, [16]JF Baurain, [17]K Jardon, [18]C Pisano, [19]U Peen, [20]J Maenpaa, [21]P Hoskins, [22]E Bacque, [22]Y Li, [22]L Eliason, [23]A González-Martín. *[1]Groupe d'Investigateurs Nationaux pour l'Etude des Cancers Ovariens and Service d'Oncologie Médicale, Centre Hospitalier Lyon-Sud, France; [2]Gynecologic Oncology Group (GOG) and the Department of Obstetrics/Gynecology, Perlmutter Cancer Center, NYU Langone Health, USA; [3]Department of Obstetrics and Gynecology, University Hospitals Leuven, Belgium; [4]Arizona Oncology (US Oncology Network), University of Arizona College of Medicine, USA; [5]Department for Gynecology and Gynecologic Oncology, Kliniken Essen-Mitte, Germany; [6]University of Pennsylvania, USA; [7]Medical Oncology Department, Hospital Clinic de Barcelona, Spain; [8]Department of Obstetrics and Gynecology, Division of Gynecologic Oncology, University of North Carolina at Chapel Hill, USA; [9]Medical Oncology Department, Breast and Gynecological Cancer Unit, Hospital Ramon y Cajal, USA; [10]Department of Obstetrics and Gynecology, University of Iowa, USA; [11]Department of Gynecologic Oncology, Chaim Sheba Medical Center, Israel; [12]Texas Oncology, USA; [13]Hospital Universitario Donostia, Spain; [14]GINECO and Centre Antoine Lacassagne, France; [15]Department of Obstetrics and Gynecology, Women and Infants Hospital/Alpert School of Medicine at Brown University, USA; [16]Université Catholique de Louvain and Cliniques Universitaires Saint-Luc, Belgium; [17]Department of Obstetrics and Gynecology, McGill University, Canada; [18]Department of Urology and Gynecology, Istituto Nazionale Tumori IRCCS Fondazione G. Pascale, Italy; [19]Herlev University Hospital, Denmark; [20]Tampere University Central Hospital, Finland; [21]British Columbia Cancer Agency, Vancouver Centre, Medical Oncology, Canada; [22]GlaxoSmithKline, USA; [23]Grupo Español de Investigación en Cáncer de Ovario (GEICO) and Medical Oncology Department, Clínica Universidad de Navarra, Spain*

10.1136/ijgc-2020-IGCS.17

Abstract 17 Table 1

Grade ≥3 TEAE, n (%)	Niraparib FSD n=315	Niraparib ISD n=169	Placebo FSD n=158	Placebo ISD n=86
Thrombocytopenia event	152 (48)	36 (21)	0	1 (1)
Anemia event	112 (36)	38 (22)	3 (2)	1 (1)
Neutropenia event	75 (24)	25 (15)	2 (1)	1 (1)

FSD, fixed starting dose; ISD, individualized starting dose; TEAE, treatment-emergent adverse event.

Introduction Niraparib is a poly(ADP-ribose) polymerase inhibitor approved for treatment in heavily pretreated patients and maintenance of patients with newly diagnosed or recurrent ovarian cancer following a response to platinum-based chemotherapy. Here we report safety and patient-reported outcomes (PROs) in the overall population and subgroups from PRIMA/ENGOT-OV26/GOG-3012 (NCT02655016).

Methods This double-blind, placebo-controlled, phase 3 study randomized 733 patients. Patients received a 300-mg QD fixed starting dose (FSD) of niraparib or placebo for 36 months or until progression/toxicity. A protocol amendment introduced an individualized starting dose (ISD): 200 mg in patients with body weight <77 kg or platelets <150,000/μL, or 300 mg in all others. The primary endpoint was PFS; safety and PROs were secondary endpoints. Safety data were collected at each visit and graded using CTCAE v4.03. PRO instruments (FOSI, EQ-5D-5L, EORTC-QLQ-C30, and EORTC-QLQ-OV28) were collected Q8W for 56 weeks, then Q12W while a patient received treatment.

Results In the overall population, the most common grade ≥3 treatment-emergent adverse events (TEAEs) were hematologic (table 1). In patients receiving ISD, these TEAEs decreased. No treatment-related deaths occurred. PRO analysis showed no difference in niraparib-treated patients versus placebo in the overall population or in the homologous recombination deficient, homologous recombination proficient, FSD, and ISD subgroups.

Conclusions ISD incorporation improved the safety profile of niraparib without compromising efficacy. Niraparib was well tolerated, with similar PRO scores across the treatment period. Hematologic toxicities were manageable through implementation of dose interruptions and reductions.

Funding GlaxoSmithKline

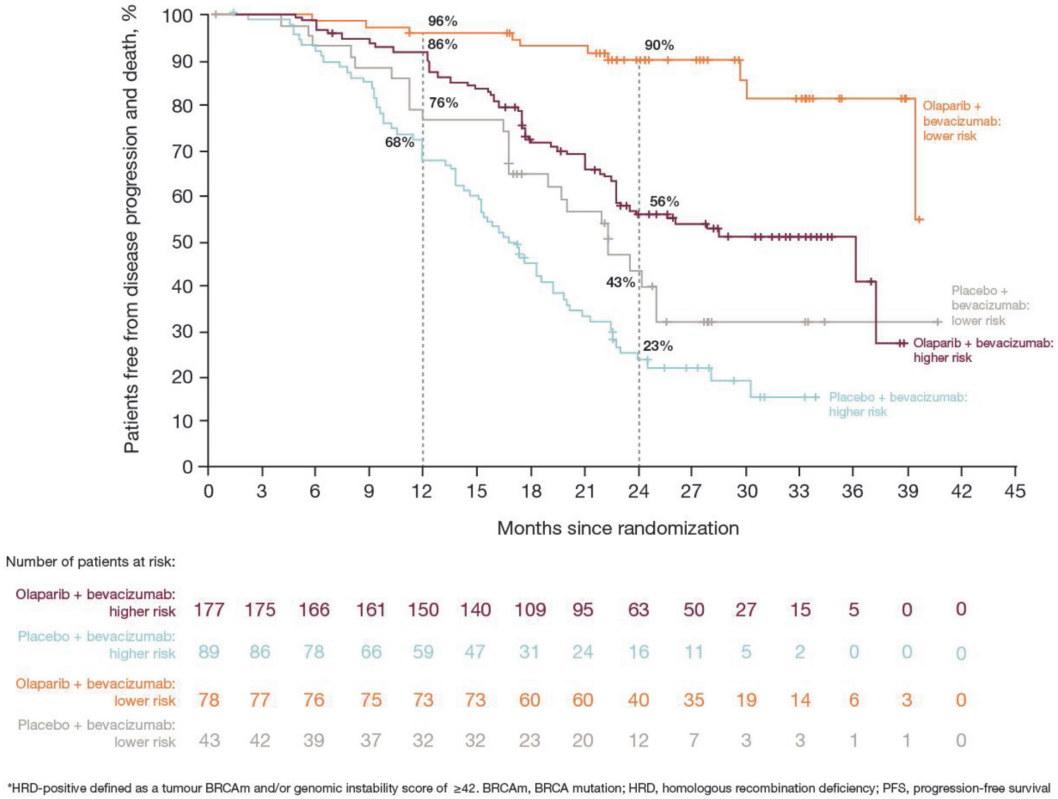
NCT: NCT02655016

IGCS20_1207

18 EFFICACY OF MAINTENANCE OLAPARIB PLUS BEVACIZUMAB BY BIOMARKER STATUS IN CLINICAL HIGHER- AND LOWER-RISK PATIENTS WITH NEWLY DIAGNOSED, ADVANCED OVARIAN CANCER IN THE PAOLA-1 TRIAL

[1]P Harter*, [2]D Petran, [3]G Scambia, [4]E Ortega, [5]I Tsibulak, [6]S Nagao, [7]I Vergote, [8]J Meunier, [9]F Priou, [10]R Sverdlin, [11]T Milenkova, [12]I Ray-Coquard, [12]I Ray-Coquard. *[1]Kliniken Essen Mitte, and AGO, Germany; [2]Centre Hospitalier Mont de Marsan, and GINECO, France; [3]Fondazione Policlinico Universitario A. Gemelli IRCCS Università Cattolica, and MITO, Italy; [4]Hospital Universitari Arnau de Vilanova, Spain; [5]Medical University of Innsbruck, and AGO-Austria, Austria; [6]Hyogo Cancer Center, and GOTIC, Japan; [7]University Hospital Leuven, Leuven Cancer Institute, and BGOG, Belgium; [8]Centre Hospitalier Régional d'Orléans, and GINECO, France; [9]Centre Hospitalier Départemental Les Oudairies, and GINECO, France; [10]GH Saint Joseph, and GINECO, France; [11]Centre Paul Strauss, and GINECO, France; [12]AstraZeneca, UK*

10.1136/ijgc-2020-IGCS.18



Abstract 18 Figure 1 Kaplan-Meier estimates of investigator-assessed PFS in higher-risk and lower-risk HRD-positive patients*