demonstrate a statistically significant OS benefit in pts with pA/rEC and supports the use of dostarlimab+CP as a standard of care in the 1L setting.

Clinical trial identification: NCT03981796.

Editorial acknowledgement: Writing and editorial support, funded and coordinated by GSK (Waltham, MA, USA), was provided by Shannon Morgan-Pelosi, PhD, CMPP, and Kathleen Blake, PhD, of Ashfield MedComms, an Inizio company. Portions of this data were previously presented at the Society of Gynecologic Oncology (SGO) 2024 Congress; March 16—18, 2024; San Diego, California and are presented on behalf of the original authors with their permission. Reused with permission.

Legal entity responsible for the study: GSK.

Funding: GSK.

Disclosure: M.A. Powell: Financial Interests, Personal, Research Grant: GSK; Financial Interests, Personal, Other, honoraria/consultation fees: AstraZeneca, Clovis Oncology, Eisai, GSK, Immunogen, Merck. A. Auranen: Financial Interests, Personal, Advisory Board: GSK, MSD. L.J. Willmott: Financial Interests, Personal, Speaker's Bureau: AstraZeneca, Eisai, Immunogen, Merck, Seagen; Financial Interests, Personal, Advisory Board: AstraZeneca, Immunogen, Seagen. L. Gilbert: Financial Interests, Institutional, Other, Grants: Alkermes, AstraZeneca, Clovis, Esperas, ImmunoGen Inc, IMV, Karyopharm, Merck Sharp & Dohme, Mersana, Novocure GmbH, OncoQuest Pharmaceuticals, Pfizer, Roche, Tesaro; Financial Interests, Personal, Other, consulting fees: Merck; Financial Interests, Personal, Other, honoraria: Alkermes, AstraZeneca, Eisai, Eisai-Merck, GSK. D. Black: Financial Interests, Institutional, Other, grants: GSK; Financial Interests, Personal, Other, member: GOG Partners Investigational Council; Financial Interests, Personal, Other, medical director/owner: Trials365, LLC. D. Cibula: Financial Interests, Personal, Advisory Board: Akesobio, AstraZeneca, GSK, MSD, Novocure, Roche, Seagen, Sotio. G. Valabrega: Financial Interests, Personal, Other, consulting/advisory fees: Amgen, AstraZeneca, Clovis Oncology, GSK, PharmaMar, Roche, Tesaro. L.C. Hanker: Financial Interests, Personal, Other, consulting/advisory fees: Amgen, AstraZeneca, Clovis, Eisai, GSK, Intuitive Surgery, Janssen, MSD, Novartis, Pfizer, Pharma Mar, Roche, Tesaro. A. Stuckey: Financial Interests, Personal, Other, royalties: UptoDate reviewer. I.A. Boere: Financial Interests, Institutional, Research Grant: GSK; Financial Interests, Institutional, Advisory Board: AstraZeneca, GSK. M.S. Shahin: Financial Interests, Institutional, Other, grants: AstraZeneca, GSK, Merck; Financial Interests, Personal, Other, honoraria: AstraZeneca, GSK, Merck, Seagen; Financial Interests, Personal, Expert Testimony: Robindon & Havens PSC, Lexington KY; Financial Interests, Personal, Advisory Board: Seagen; Financial Interests, Personal, Other, board member: Unite for Her. B. Pothuri: Financial Interests, Institutional, Other, grant support: AstraZeneca, Celsion, Clovis Oncology, Eisai, Genentech/Roche, Karyopharm, Merck, Mersana, SeaGen, Sutro Biopharma, Takeda Pharmaceuticals, Tesaro/GSK, Toray, VBL Therapeutics; Financial Interests, Personal, Other, consulting fees: AstraZeneca, Atossa, Clovis Oncology, Deciphera, Elevar Therapeutics, Imab, Merck, Mersana, Sutro Biopharma, Tesaro/GSK, Toray; Other, Personal, Other, support for attending meetings: GOG Foundation; Financial Interests, Personal, Advisory Board: Arquer Diagnostics, AstraZeneca, Atossa, Clovis Oncology, Deciphera, Eisai, Elevar Therapeutics, GOGFoundation, Imab, Eli Lilly, Merck, Mersana, Seagen, Sutro Biopharma, Tesaro/GSK, Toray, VBL Therapeutics; Non-Financial Interests, Personal, Invited Speaker, leadership: NYOB Society Secretary, SGO Clinical Practice Committee Chair, SGO COVID-19 Taskforce Co-Chair. B.M. Slomovitz: Financial Interests, Personal, Advisory Board: AstraZeneca, Clovis, Genentech, GSK, GOG Foundation, Merck, Myriad, Jazz Pharma, Onconova, Nuvation Bio, EQRX, Regeneron, Eisai, Incyte; Financial Interests, Personal, Member of Board of Directors: GOG Foundation, HOW: Hearing Ovarian Cancer Whispers. M. Grimshaw, S. Stevens: Financial Interests, Personal, Full or part-time Employment: GSK. R.L. Coleman: Financial Interests, Personal, Other, grants or contracts: AstraZeneca, Clovis, Genelux, Genmab, Merck, Immunogen, Roche/Genentech; Financial Interests, Personal, Other, consulting fees: AbbVie, Agenus, Alkermes, AstraZeneca, Clovis, Deciphera, Genelux, Genmab, GSK, Immunogen, Novocure, Merck, OncoQuest, Onxerna, Regeneron, Roche/Genentech; Financial Interests, Personal, Other, participation on a data safety monitoring board or advisory board: Eisai/BMS, VBL Therapeutics. M.R. Mirza: Financial Interests, Institutional, Research Grant: Allarity, Apexigen, AstraZeneca, Boehringer Ingelheim, Clovis, GSK, Novartis, Ultimovacs; Financial Interests, Personal, Other, trial chair: Deciphera, Mersana, NuvationBio; Financial Interests, Personal, Invited Speaker: AstraZeneca, GenMab, GSK, Mersana, Seagen, Takeda; Financial Interests, Personal, Member of Board of Directors, and holds stocks and shares: Karyopharm, Sera Prognostics. All other authors have declared no conflicts of interest.

https://doi.org/10.1016/j.esmoop.2024.103537

38MO Progression-free survival (PFS) in primary advanced or recurrent endometrial cancer (pA/rEC) in the overall and mismatch repair proficient (MMR/MSS) populations and in histological and molecular subgroups: Results from part 2 of the RUBY trial

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Background: In Part 1 of the phase 3 RUBY trial (NCT03981796) in pA/rEC, patients (pts) receiving dostarlimab (dostar)/carboplatin-paclitaxel (CP) exhibited significant benefits in PFS and overall survival versus CP alone. Outcomes may be further improved by adding a poly(ADP-ribose) polymerase inhibitor (PARPi). Here we report results from Part 2 of RUBY of dostar/CP followed by dostar/niraparib (nira; a PARPi) maintenance therapy in pts with pA/rEC.

Methods: Pts were randomized 2:1 to dostar 500 mg IV + CP Q3W for 6 cycles followed by dostar 1000 mg IV Q6W + nira (individualized starting dose of 200 or 300 mg) PO daily for ≤3 years from randomization or to placebo (PBO) + CP Q3W for 6 cycles followed by PBOs for ≤3 years. The primary endpoint was PFS in the overall and MMRp/MSS populations.

Results: 291 pts were randomized (192 dostar/CP + dostar/nira; 99 PBO/CP). PFS was significantly improved in pts receiving dostar/CP + dostar/nira vs PBO/CP in the overall and MMRp/MSS populations (Table). In pts with endometrioid carcinoma, pts with other histologies, and across most biomarker subgroups (eg, TP53mut), the hazard ratio (HR) directionally favored dostar/CP + dostar/nira in the overall and MMRp/MSS populations. The safety profile observed was consistent with those of the individual agents.

Table: 38MO PFS

	Dostar/ CP+dostar/nira	PBO/CP+PBO	HR (95% CI)
Overall, n	192	99	0.60 (0.43—0.82) P=0.0007
Median (95% CI), mo	14.5 (11.8—17.4)	8.3 (7.6—9.8)	-
MMRp/MSS, n	142	74	0.63 (0.44—0.91) P=0.0060
Median (95% CI), mo	14.3 (9.7—16.9)	8.3 (7.6-9.8)	-
Pre-specified exploratory analyses			
	No. of pts with events/No. of pts		
All pts	95/192	69/99	-
Endometrioid carcinoma	52/114	46/67	0.58 (0.39—0.87)
Other histologies	42/76	23/32	0.53 (0.32—0.88)
Molecular subgroup[b]			
POLεmut	0/3	1/2	-[a]
dMMR/MSI-H	12/37	10/17	0.45 (0.20—1.05)
TP53mut	27/39	10/10	0.29 (0.13—0.63)
No specific molecular profile	37/75	31/46	0.61 (0.38—0.99)
Not evaluable	19/38	17/24	0.71 (0.37—1.37)

[a]<20 events. [b]Based on whole exome sequencing.

Conclusions: RUBY Part 2 met its primary endpoint and is the first study to show significant and clinically meaningful improvement in PFS in the MMRp/MSS and overall populations. The trial is ongoing for OS follow-up. The safety profile observed was generally consistent with the known safety profiles of the individual agents.

These data demonstrate a potential role for PARPi maintenance in pts receiving dostar/CP, especially for MMRp/MSS tumors.

Clinical trial identification: NCT03981796.

Editorial acknowledgement: Writing and editorial support, funded and coordinated by GSK (Waltham, MA, USA), was provided by Charlette Tiloke, PhD, Kristoffer Myczek, PhD, and Kathleen Blake, PhD, of Ashfield MedComms, an Inizio company. Encore Statement: Portions of this data were previously presented at the Society of Gynecologic Oncology (SGO) 2024 Congress; March 16—18, 2024; San Diego, California and are presented on behalf of the original authors with their permission. Reused with permission.

Legal entity responsible for the study: GSK.

Funding: GSK.

Disclosure: M.R. Mirza: Financial Interests, Personal, Other, consulting fees: AstraZeneca, Biocad, GSK, Karyopharm, Merck, Roche, Zailab; Financial Interests, Personal, Speaker's Bureau: AstraZeneca, GSK; Financial Interests, Institutional, Funding, research: Apexigen, AstraZeneca, Deciphera (trial chair), GSK, Ultimovacs; Financial Interests, Personal, Member of Board of Directors, stocks/shares: Karyopharm . S. Ghamande: Financial Interests, Institutional, Other, institutional fees: Georgia Cancer Center; Financial Interests, Personal, Speaker's Bureau, consulting: Eisai, GSK. L.C. Hanker: Financial Interests, Personal, Other, consulting/advisory fees: Amgen, AstraZeneca, Clovis, Eisai, GSK, Intuitive Surgery, Janssen, MSD, Novartis, Pfizer, PharmaMar, Roche, Tesaro. D. 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Oaknin: Financial Interests, Institutional, Other, grants: AbbVie Deutschland, Advaxis, Aeterna Zentaris, Amgen, Aprea Therapeutics AB, Bristol Myers Squibb, Clovis Oncology, Eisai, F. Hoffmann—La Roche, Immunogen, Merck Sharp & Dohme de España, Millennium Pharmaceuticals, PharmaMar, Regeneron Pharmaceuticals, Tesaro; Financial Interests, Personal, Other, consulting fees: Agenus, AstraZeneca, Clovis Oncology, Corcept Therapeutics, Deciphera Pharmaceuticals, Eisai, EMD Serono, Exelixis, F. 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Secord: Financial Interests, Institutional, Other, presenting an IGCS abstract: GSK; Financial Interests, Institutional, Other, grant support: AbbVie, Aravive, AstraZeneca, Biopharma, Clovis, Eisai, Ellipses, I-Mab, Immunogen, Merck, Oncoquest/Canaria Bio, Roche/Genentech, Seagen, TapImmune, Tesaro/GSK, VBL Therapeutics; Financial Interests, Personal, Other, honoraria: Bio Ascend, Curio Science, GOGFoundation (highlight reel), GOGFoundation Symposium, PeerView, @Point of Care Clinical Care Options, RTP; Financial Interests, Personal, Other, patent issued: "Blood based biomarkers in ovarian cancer"; Non-Financial Interests, Personal, Other, participation on a data safety monitoring board/advisory board: AstraZeneca, Clovis, Gilead, Immunogen, Imvax, Merck, Mersana, Natera, Onconova, OncoQuest; Non-Financial Interests, Personal, Leadership Role: AAOGF, NRG, SGO; Financial Interests, Personal, Leadership Role: GOG; Other, Personal, Other, receipt of medical writing support: AstraZeneca; Non-Financial Interests, Personal, Other, clinical trial steering committees: AXLerate trial (Aravive); Non-Financial Interests, Personal, Invited Speaker, clinical trial steering committees: AtTEnd trial (Hoffman-LaRoche), Oval trial (VBL Therapeutics), FLORA-5 trial (CanariaBio), QPT-ORE-004 (CanariaBio). A. Savarese: Financial Interests, Institutional, Other, funding and provision of study materials: GSK, MSD; Financial Interests, Institutional, Other, institutional funding and provision of study material for other clinical trials: GSK, MSD; Financial Interests, Personal, Other, honoraria: GSK, MSK; Financial Interests, Personal, Other, support for attending meetings and/or travel: GSK, MSK, PharmaMar; Financial Interests, Personal, Advisory Board, honoraria: Eisai, MSD. R.W. Holloway: Financial Interests, Personal, Other, honoraria: AstraZeneca, Clovis, Eisai, GSK, Merck. R. Kristeleit: Financial Interests, Personal, Other, grants: Clovis, MSD; Financial Interests, Personal, Other, honoraria and consultancy fees: AstraZeneca, Basilea Pharmaceutica, Clovis, Eisai, Incyte, MSD, PharmaMar; Financial Interests, Personal, Other, personal fees: GSK. J. Buscema: Financial Interests, Personal, Other, honoraria: GSK. I.A. Boere: Financial Interests, Institutional, Research Grant: GSK; Financial Interests, Institutional, Advisory Board: AstraZeneca, GSK. C. Gennigens: Financial Interests, Personal, Other, grants/contracts: AstraZeneca, GSK; Financial Interests, Personal, Other, consulting fees: GSK, Ipsen, MSD; Financial Interests, Personal, Other, honoraria: AstraZeneca, BMS, Ipsen, MSD, Pfizer, PharmaMar; Other, Personal, Other, support for attending meetings: GSK, Ipsen, MSD, Pfizer, PharmaMar; Other, Personal, Other, participation on a data safety monitoring or advisory board: AstraZeneca, BMS, Eisai, GSK, Ipsen, MSD. K. Yablonski: Other, Personal, Full or part-time Employment: GSK. S. Stevens: Financial Interests, Personal, Full or part-time Employment: GSK. M.A. Powell: Financial Interests, Personal, Other, consulting fees: AstraZeneca, Clovis Oncology, Eisai, GSK, Merck, Seagen, Tesaro. All other authors have declared no conflicts of interest.

https://doi.org/10.1016/j.esmoop.2024.103538

39MO Phase III ENGOT-En9/LEAP-001 study: Lenvatinib + pembrolizumab (LEN/PEMBRO) vs chemotherapy (chemo) as first-line (1L) therapy for advanced or recurrent endometrial cancer

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Background: LEN/PEMBRO following prior systemic therapy in any setting, including neo/adjuvant, is a standard of care for advanced endometrial cancer (EC). The phase 3 ENGOT-en9/LEAP-001 trial (NCT03884101) compared 1L LEN/PEMBRO vs chemo in patients (pts) with advanced/recurrent EC.

Methods: Eligible pts had stage III—IV or recurrent, measurable/non-measurable, radiographically apparent EC, with no prior chemo or PD ≥6 mo after neo/adjuvant platinum-based chemo. Pts were randomized 1:1 (stratified by proficient vs deficient mismatch repair status [pMMR/dMMR] and, in the pMMR stratum, by ECOG PS [0/1], measurable disease [yes/no], and chemo/chemoradiation [yes/no]) to lenvatinib 20 mg QD plus pembrolizumab 200 mg Q3W or paclitaxel 175 mg/m^2 Q3W plus carboplatin AUC 6 Q3W. Dual primary endpoints were PFS (RECIST v1.1, blinded independent central review) and OS in the pMMR population and among all-comers. Secondary endpoints included ORR and safety; duration of response (DOR) was an exploratory endpoint; and efficacy outcomes assessed by tumor histology was a prespecified exploratory analysis.

Results: 842 pts were randomized. At final analysis (data cutoff, 2 Oct 2023), after median follow-up of 38.4 (range, 30.3—52.9) mo, statistical significance for non-inferiority (NI) OS endpoint was not achieved for LEN/PEMBRO vs chemo in the pMMR population (HR, 1.02 [95% CI, 0.83—1.26]; NI P = 0.2459875; Table). PFS and OS results for LEN/PEMBRO vs chemo by histological subtype will be presented for the pMMR population and all-comers. Treatment-related AEs occurred in 411/420 (97.9%) vs 398/411 (96.8%) treated pts in the LEN/PEMBRO vs chemo groups.

Table: 39MO

	pMMR		All-comers	
	LEN/PEMBRO n = 320	Chemo n = 322	LEN/PEMBRO n = 420	Chemo n = 422
OS HR (95% CI)	1.02 (0.83—1.26)[a]		0.93 (0.77—1.12)	
PFS HR (95% CI)	0.99 (0.82—1.21)		0.91 (0.76—1.09)	
ORR (95% CI), %	50.6 (45.0—56.2)	54.7 (49.0—60.2)	55.7 (50.8—60.5)	55.5 (50.6—60.3)
Median DOR (range), mo	16.1 (1.0+ to 48.7+)	10.6 (1.1+ to 43.8+)	23.2 (1.0+ to 49.0+)	10.9 (1.1+ to 46.9+)

[a]1-sided NI P = 0.2459875 (nonsignificant), not crossing prespecified OS NI boundary, P = 0.0158890, so no further statistical testing of efficacy endpoints was performed per prespecified multiplicity strategy for type 1 error control.