Endometrial Cancer: Highlight Reel

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SYSTEMIC THERAPY FOR ENDOMETRIAL CARCINOMA

Primary or Adjuvant Treatment When Used for Uterine-Confined High-Risk Disease
Preferred Regimens • Carboplatin/paclitaxel

Recurrent or Metastatic Disease[a,b]		
	Preferred Regimens	**Other Recommended Regimens**
Systemic therapies[a,b]	• Carboplatin/paclitaxel (category 1 for carcinosarcoma)[1] • Carboplatin/paclitaxel/trastuzumab[c] (for stage III/IV or recurrent HER2-positive uterine serous carcinoma)[2]	• Carboplatin/docetaxel[d] • Cisplatin/doxorubicin[3] • Cisplatin/doxorubicin/paclitaxel[e,f,3] • Carboplatin/paclitaxel/bevacizumab[e,g,4] • Cisplatin • Carboplatin • Doxorubicin • Liposomal doxorubicin • Paclitaxel[5] • Albumin-bound paclitaxel[h] • Topotecan • Bevacizumab[g,i,6] • Temsirolimus[7] • Docetaxel[d] (category 2B) • Ifosfamide (for carcinosarcoma) • Ifosfamide/paclitaxel (for carcinosarcoma)[8] • Cisplatin/ifosfamide (for carcinosarcoma)
Biomarker-directed systemic therapy for second-line treatment	• Lenvatinib/pembrolizumab (category 1) for non–MSI-high [MSI-H]/non–MMR-deficient [dMMR] tumors[j,9] • Pembrolizumab[k] for TMB-H[10] or MSI-H/dMMR tumors[l,11]	• Nivolumab for dMMR/MSI-H tumors[12] • Dostarlimab-gxly for dMMR/MSI-H tumors[m,13] • Larotrectinib or entrectinib for *NTRK* gene fusion-positive tumors (category 2B)[e] • Avelumab for dMMR/MSI-H tumors • Cabozantinib

Footnotes on page ENDO-D 3 OF 4

Note: All recommendations are category 2A unless otherwise indicated.
Clinical Trials: NCCN believes that the best management of any patient with cancer is in a clinical trial. Participation in clinical trials is especially encouraged.

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SYSTEMIC THERAPY FOR ENDOMETRIAL CARCINOMA

Hormone Therapy[n]		
Preferred Regimens	**Other Recommended Regimens**	**Useful in Certain Circumstances**
• Medroxyprogesterone acetate/tamoxifen (alternating) • Megestrol acetate/tamoxifen (alternating) • Progestational agents ▸ Medroxyprogesterone acetate ▸ Megestrol acetate ▸ Levonorgestrel intrauterine device (IUD) (for select fertility-sparing cases) • Aromatase inhibitors • Tamoxifen • Fulvestrant	• Everolimus/letrozole (for endometrioid histology)	N/A

Footnotes on page ENDO-D 3 OF 4

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Continued

GOG Highlight Reel

A multicenter, open-label, randomized, phase 3 study to compare the efficacy and safety of lenvatinib in **combination with pembrolizumab vs treatment of physician's choice in patients with advanced endometrial cancer: Study 309/KEYNOTE-775**

Vicky Makker[1]; Nicoletta Colombo[2]; Antonio Casado Herráez[3]; Alessandro D. Santin[4]; Emeline Colomba[5]; David S. Miller[6]; Keiichi Fujiwara[7]; Sandro Pignata[8]; Sally Baron-Hay[9]; Isabelle Ray-Coquard[10]; Ronnie Shapira-Frommer[11]; Kimio Ushijima[12]; Jun Sakata[13]; Kan Yonemori[14]; Yong Man Kim[15]; Eva M. Guerra[16]; Ulus A. Sanli[17]; Mary M. McCormack[18]; Jie Huang[19]; Alan D. Smith[20]; Stephen Keefe[21]; Lea Dutta[19]; Robert J. Orlowski[21]; Domenica Lorusso[22]

[1]Memorial Sloan Kettering Cancer Center, New York, NY, USA; [2]University of Milan-Bicocca, European Institute of Oncology IRCCS, Milan, Italy; [3]San Carlos University Teaching Hospital, Madrid, Spain; [4]Yale University School of Medicine, New Haven, CT, USA; [5]Gustave Roussy Cancerology Institute, Villejuif, GINECO group, France; [6]University of Texas Southwestern Medical Center, Dallas, TX, USA; [7]Saitama Medical University International Medical Center, Hidaka, Japan; [8]Istituto Nazionale Tumori IRCCS-Fondazione G. Pascale, Naples, Italy; [9]Royal North Shore Hospital, St. Leonards, Australia; [10]Centre Léon-Bérard, University Claude Bernard, Lyon, GINECO group, France; [11]Sheba Medical Center, Ramat, Israel; [12]Kurume University School of Medicine, Kurume, Japan; [13]Aichi Cancer Center Hospital, Nagoya, Japan; [14]National Cancer Center Hospital: Kokuritsu Gan Kenkyu Center Chuo Byoin, Tokyo, Japan; [15]Asan Medical Center, University of Ulsan, Seoul, Korea; [16]Hospital Universitario Ramón y Cajal, Madrid, Spain; [17]Ege University, Izmir, Turkey; [18]University College London Hospitals NHS Foundation Trust, London, United Kingdom; [19]Eisai Inc., Woodcliff Lake, NJ, USA; [20]Eisai Ltd., Hatfield, United Kingdom; [21]Merck & Co., Inc., Kenilworth, NJ, USA; [22]Fondazione Policlinico Universitario Agostino Gemelli IRCCS, Rome, Italy

SGO 2021 VIRTUAL ANNUAL MEETING ON WOMEN'S CANCER®

SGO Society of Gynecologic Oncology

Study Design

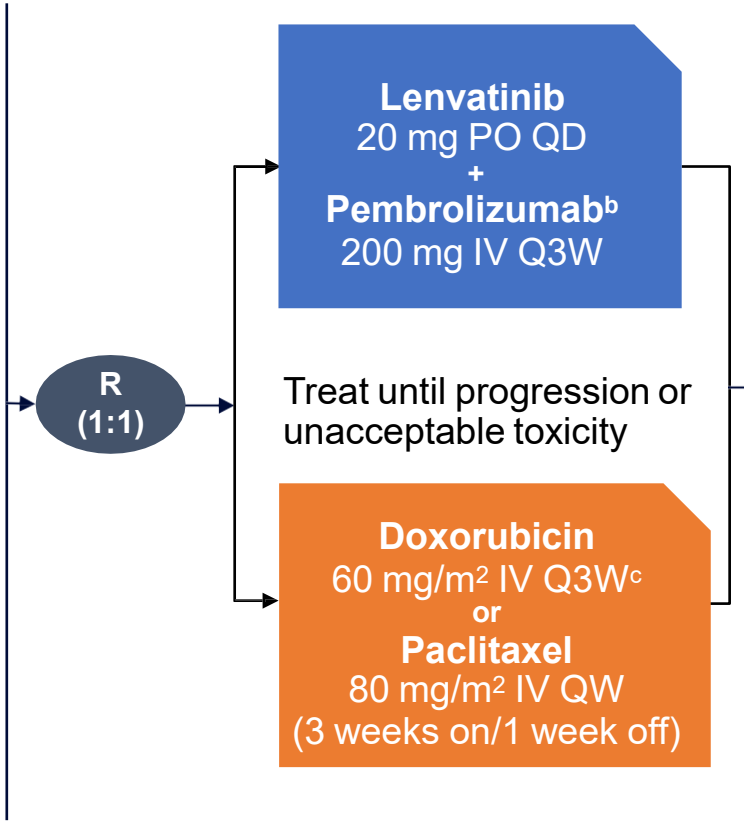
Key eligibility criteria

- Advanced, metastatic, or recurrent endometrial cancer
- Measurable disease by BICR
- 1 Prior platinum-based CT[a]
- ECOG PS 0-1
- Tissue available for MMR testing

Stratification factors

MMR status (pMMR vs dMMR) and further stratification within pMMR by:

- Region (R1: Europe, USA, Canada, Australia, New Zealand, and Israel, vs R2: rest of the world)
- ECOG PS (0 vs 1)
- Prior history of pelvic radiation (Y vs N)



Primary endpoints

- PFS by BICR
- Overall survival

Secondary endpoints

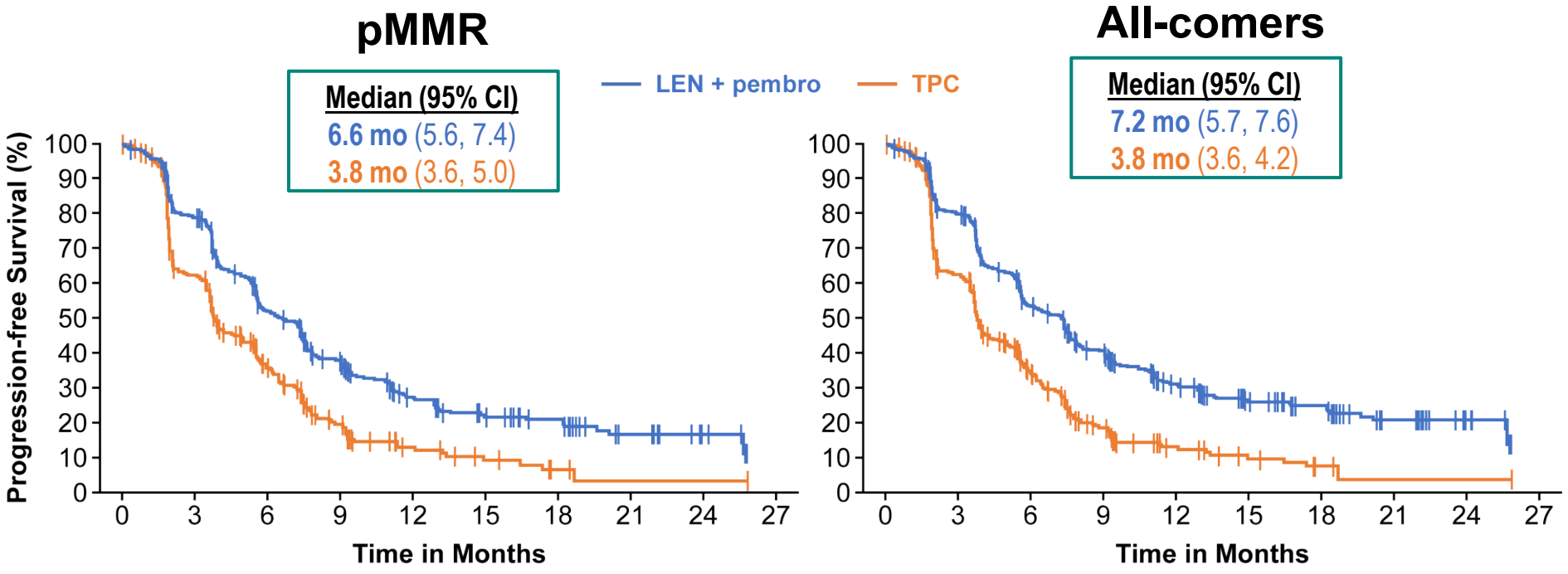
- ORR
- HRQoL
- Pharmacokinetics
- Safety

Key exploratory endpoint

- Duration of response

[a]Patients may have received up to 2 prior platinum-based CT regimens if 1 is given in the neoadjuvant or adjuvant treatment setting. [b]Maximum of 35 doses. [c]Maximum cumulative dose of 500 mg/m^2.
BICR, blinded independent central review; ECOG PS, Eastern Cooperative Oncology Group performance status; HRQoL, health-related quality of life; IV, intravenous; PFS, progression-free survival; pMMR, mismatch repair-proficient; ORR, objective response rate; PO, per os (by mouth); QD, once daily; Q3W, every 3 weeks; QW, once weekly.

Progression-free Survival[a]



	Events	HR (95% CI)	*P*-value
LEN + pembro	247	**0.60** (0.50, 0.72)	< 0.0001
TPC	238		

	Events	HR (95% CI)	*P*-value
LEN + pembro	281	**0.56** (0.47, 0.66)	< 0.0001
TPC	286		

[a]By BICR per Response Evaluation Criteria in Solid Tumors version 1.1.

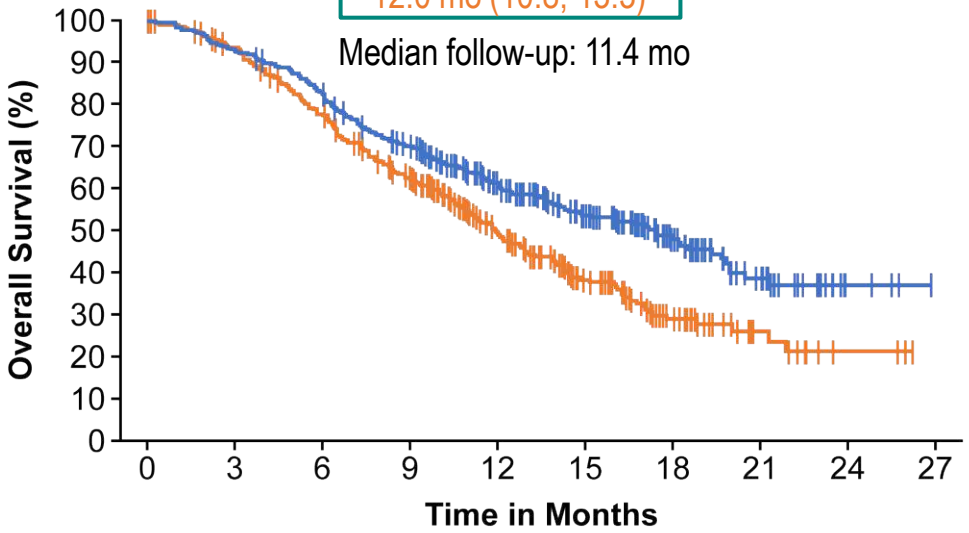
Overall Survival

pMMR

Median (95% CI)
17.4 mo (14.2, 19.9)
12.0 mo (10.8, 13.3)

LEN + pembro — TPC

Median follow-up: 11.4 mo



No. at risk

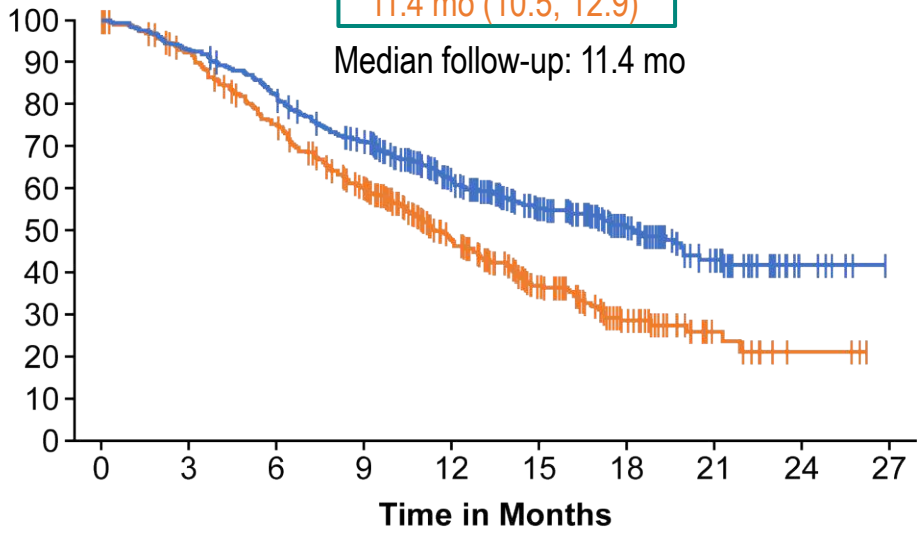
346	322	285	232	160	109	62	28	5	0
351	319	262	201	120	70	33	11	3	0

	Events	HR (95% CI)	*P*-value
LEN + pembro	165	**0.68** (0.56, 0.84)	0.0001
TPC	203		

All-comers

Median (95% CI)
18.3 mo (15.2, 20.5)
11.4 mo (10.5, 12.9)

Median follow-up: 11.4 mo



No. at risk

411	383	337	282	198	136	81	40	7	0
416	373	300	228	138	80	40	11	3	0

	Events	HR (95% CI)	*P*-value
LEN + pembro	188	**0.62** (0.51, 0.75)	< 0.0001
TPC	245		

Treatment Exposure, Safety, and Discontinuation in All-comers

	LEN + pembro (n = 406)	TPC (n = 388)
Median duration of treatment (range), days	231 (1-817)	104.5 (1-785)
Patients with any TEAEs, %	99.8	99.5
Grade ≥ 3	88.9	72.7
Patients with any TEAEs leading to dose reductions, %[a]	66.5	12.9
Patients with any-grade TEAEs leading to interruption, %[b]	69.2	27.1
LEN[c]	58.6	--
Pembro[c]	50.0	--
LEN + pembro	30.8	--
Patients with any-grade TEAEs leading to discontinuation, %[b]	33.0	8.0
LEN[c]	30.8	--
Pembro[c]	18.7	--
LEN + pembro	14.0	--

[a]Includes LEN only or TPC. [b]Includes LEN or pembro or LEN + pembro or TPC. [c]Regardless of action taken with the other drug in the combination arm.

Outcomes by Histology and Prior Therapy With Lenvatinib Plus Pembrolizumab vs Treatment of Physician's Choice in Patients With Advanced Endometrial Cancer (Study 309/KEYNOTE-775)

Nicoletta Colombo[1]; Domenica Lorusso[2]; Antonio Casado Herráez[3]; Alessandro D. Santin[4]; Emeline Colomba[5]; David S. Miller[6]; Keiichi Fujiwara[7]; Sandro Pignata[8]; Anne Floquet[9]; Bradley J. Monk[10]; Susana Banerjee[11]; Richard T. Penson[12]; Rebecca Kristeleit[13]; Michel Fabbro[14]; Mauro Orlando[15]; Helen Mackay[16]; Erin Jensen[17]; Lea Dutta[18]; Robert Orlowski[17]; Vicky Makker[19]

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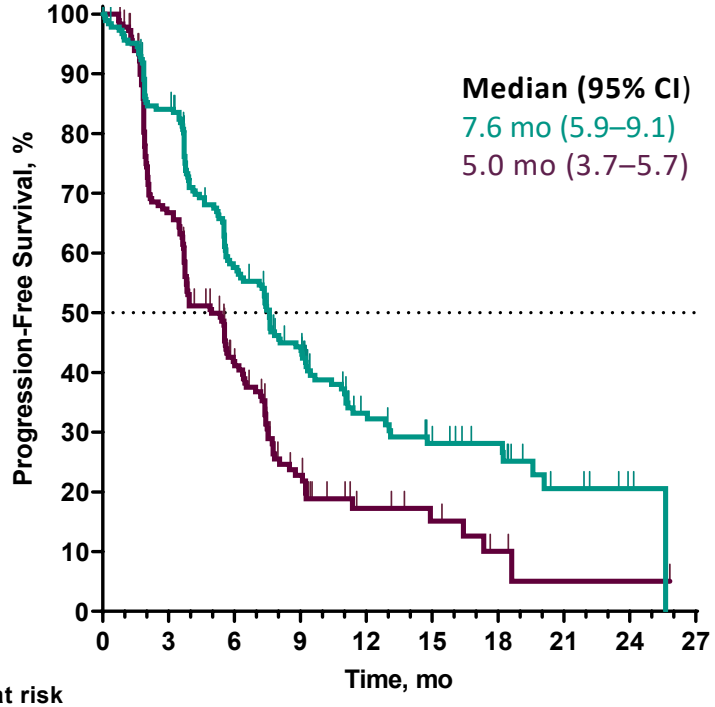
Progression-Free Survival[a] by Histology: pMMR

Endometrioid

	N	Events, n (%)	HR (95% CI)
Len + pembro	188	122 (64.9)	0.59 (0.46–0.76)
TPC	198	131 (66.2)	

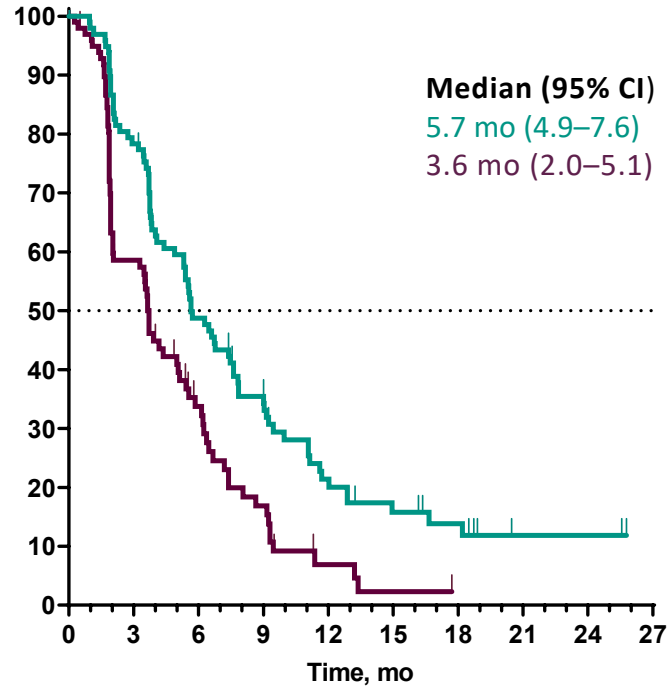


No. at risk

len + pembro	188	152	98	70	34	25	19	7	2	0
TPC	198	113	59	24	10	7	3	1	1	0

Serous

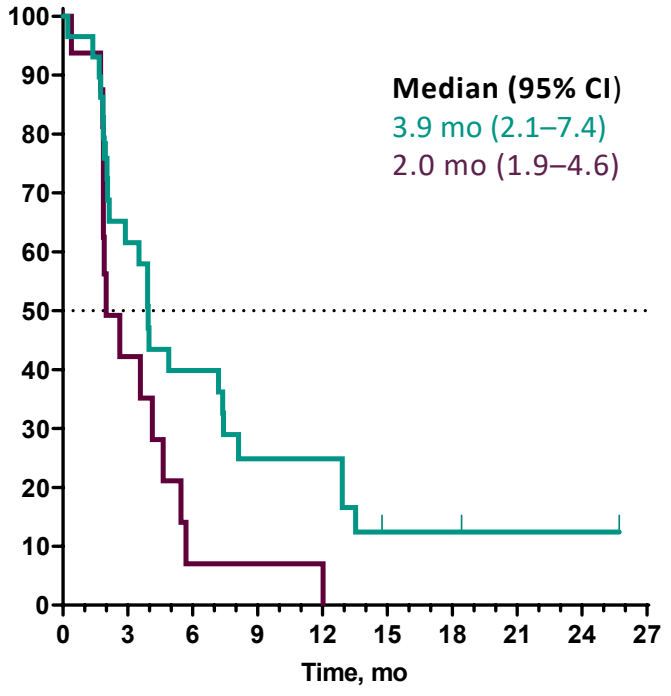
	N	Events, n (%)	HR (95% CI)
Len + pembro	99	78 (78.8)	0.54 (0.39–0.75)
TPC	112	77 (68.8)	



	99	76	45	31	16	10	7	2	2	0
	112	48	22	11	3	1	0	0	0	0

Clear cell

	N	Events, n (%)	HR (95% CI)
Len + pembro	29	24 (82.8)	0.49 (0.25–0.97)
TPC	17	15 (88.2)	



	29	17	11	6	6	2	2	1	1	0
	17	6	1	1	1	0	0	0	0	0

[a]Per RECIST v1.1 by BICR. Randomization was stratified by MMR status.
HRs for other histologic types: mixed cell (n = 31): HR (95% CI), 0.90 (0.35–2.29); other (n = 23): HR (95% CI), 0.38 (0.12–1.19).
Data cutoff: Oct 26, 2020.

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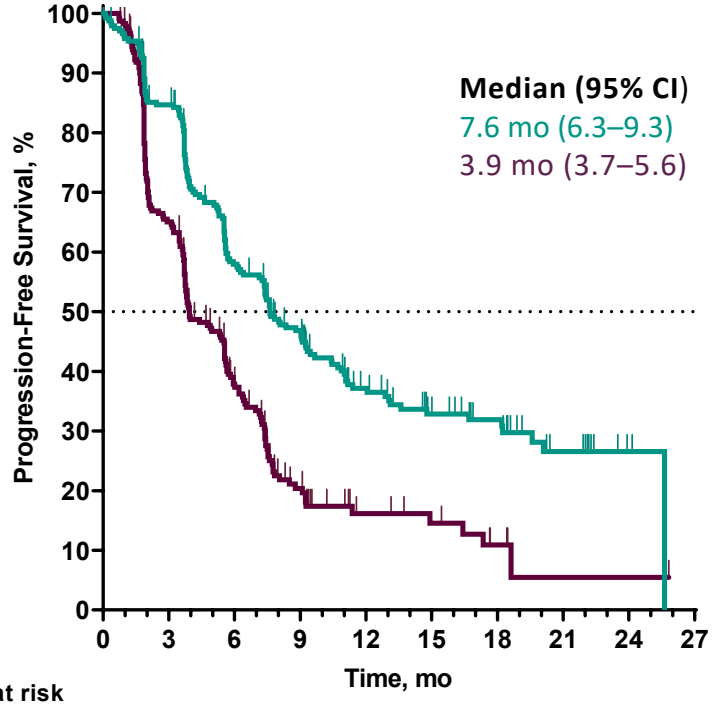
Progression-Free Survival[a] by Histology: All-Comers

Endometrioid

	N	Events, n (%)	HR (95% CI)
Len + pembro	243	150 (61.7)	0.52 (0.41–0.65)
TPC	254	173 (68.1)	

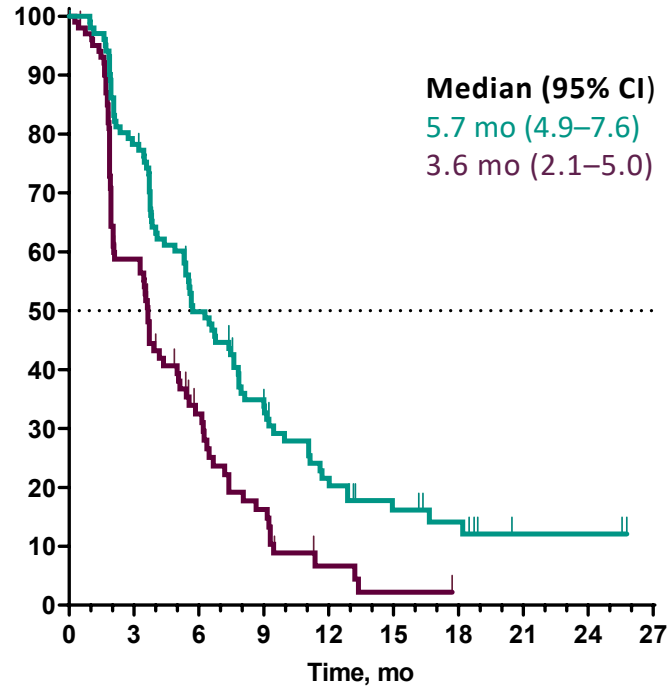


No. at risk

len + pembro	243	196	128	98	56	39	29	12	3	0
TPC	254	142	69	28	12	9	4	1	1	0

Serous

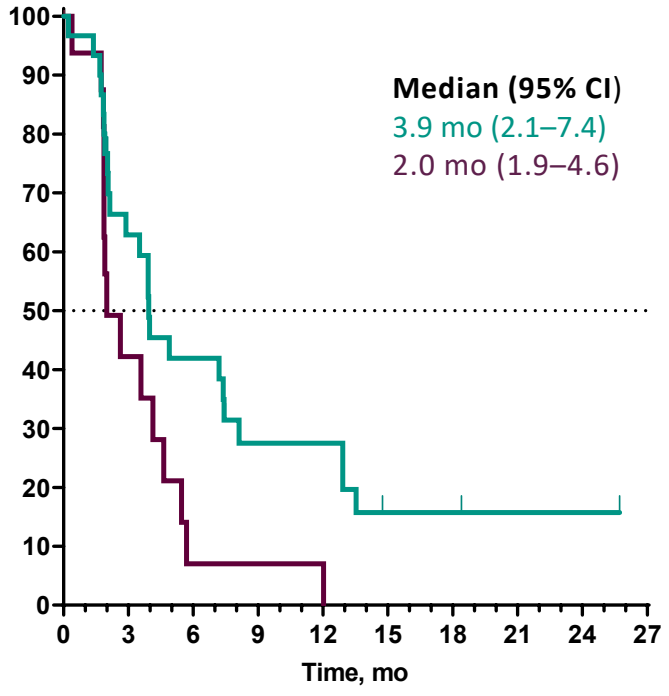
	N	Events, n (%)	HR (95% CI)
Len + pembro	103	81 (78.6)	0.53 (0.38–0.72)
TPC	115	80 (69.6)	



	103	79	48	32	17	10	7	2	2	0
	115	50	22	11	3	1	0	0	0	0

Clear cell

	N	Events, n (%)	HR (95% CI)
Len + pembro	30	24 (80.0)	0.47 (0.24–0.92)
TPC	17	15 (88.2)	



	30	18	12	7	7	3	3	1	1	0
	17	6	1	1	1	0	0	0	0	0

[a]Per RECIST v1.1 by BICR.
HRs for other histologic types: mixed cell (n = 38): HR (95% CI), 0.90 (0.38–2.17); other (n = 27): HR (95% CI), 0.57 (0.21–1.54).
Data cutoff: Oct 26, 2020.

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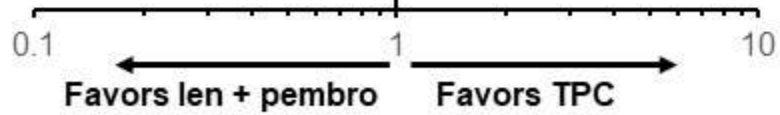
PFS[a] by Prior Therapy and PFI: pMMR and All-Comers

Subgroup	Events/N	HR for OS (95% CI)
1 prior line of platinum		
pMMR	370/526	0.54 (0.44−0.67)
All-comer	446/641	0.50 (0.41−0.61)
>1 prior line of platinum		
pMMR	114/170	0.75 (0.52−1.09)
All-comer	120/185	0.69 (0.48−0.99)
Received (neo)adjuvant therapy		
pMMR	190/258	0.58 (0.43−0.78)
All-comer	217/303	0.55 (0.42−0.73)
No (neo)adjuvant therapy		
pMMR	295/439	0.60 (0.47−0.76)
All-comer	350/524	0.54 (0.44−0.67)

Subgroup	Events/N	HR for OS (95% CI)
PFI ≥6 months		
pMMR	158/240	0.59 (0.43−0.81)
All-comer	173/270	0.55 (0.41−0.75)
PFI <6 months		
pMMR	323/451	0.57 (0.45−0.71)
All-comer	390/550	0.51 (0.42−0.63)
PFI ≥12 months		
pMMR	67/99	0.74 (0.45–1.20)
All-comer	70/111	0.72 (0.45–1.16)
PFI <12 months		
pMMR	414/592	0.56 (0.46–0.68)
All-comer	493/709	0.50 (0.42–0.60)



PFI, platinum-free interval from most recent platinum-containing regimen. [a]Per RECIST v1.1 by BICR.
Data cutoff: Oct 26, 2020.

Summary

- Lenvatinib + pembrolizumab provided a PFS and OS benefit compared with TPC in patients with previously treated, advanced endometrial cancer, including in patients with pMMR status and all-comers and regardless of
  - Histology, including difficult-to-treat histologies (i.e., clear cell carcinoma)
  - Prior (neo)adjuvant treatment
  - PFI
- Patients with 1 prior line of platinum therapy had more favorable HRs for OS and PFS than those with >1 prior line of platinum therapy, supporting earlier use of lenvatinib + pembrolizumab
- Because these were post hoc analyses, the results should be interpreted with caution

Randomized Phase 3 Study of Lenvatinib Plus Pembrolizumab for Advanced Endometrial Cancer: Subgroup Analysis of Patients with DNA Mismatch Repair-Deficient Tumors

Vicky Makker[1], Nicoletta Colombo[2], Antonio Casado Herráez[3], Alessandro D. Santin[4], Emeline Colomba[5], David S. Miller[6], Keiichi Fujiwara[7], Sandro Pignata[8], Susana Banerjee[9], Bradley J. Monk[10], Kimio Ushijima[11], Richard T. Penson[12], Rebecca Kristeleit[13], Michel Fabbro[14], Mauro Orlando[15], Helen Mackay[16], Min Ren[17], Robert J. Orlowski[18], Lea Dutta[19], and Domenica Lorusso[20]

[1]Department of Medicine, Memorial Sloan Kettering Cancer Center; Weill Cornell Medical Center, New York, NY, USA; [2]Gynecologic Oncology Program, University of Milan-Bicocca, European Institute of Oncology IRCCS, Milan, Italy; [3]Department of Medical Oncology, San Carlos University Teaching Hospital, Madrid, Spain; [4]Department of Obstetrics, Gynecology & Reproductive Sciences, Yale University School of Medicine, New Haven, CT, USA; [5]Department of Cancer Medicine, Gustave Roussy Cancerology Institute, Villejuif, GINECO group, France; [6]Gynecologic Oncology, University of Texas Southwestern Medical Center, Dallas, TX, USA; [7]Department of Gynecologic Oncology, Saitama Medical University International Medical Center, Hidaka, Japan; [8]Department of Urology & Gynecology, Istituto Nazionale Tumori IRCCS-Fondazione G. Pascale, Naples, Italy; [9]Gynaecology Unit, The Royal Marsden NHS Foundation Trust, London, UK; [10]Gynecologic Oncology, Obstetrics and Gynecology, Arizona Oncology, Phoenix, AZ, USA; [11]Department of Obstetrics and Gynecology, Kurume University School of Medicine, Kurume, Japan; [12]Division of Hematology and Oncology, Harvard Medical School, Massachusetts General Hospital, Boston, MA, USA; [13]Department of Oncology, Guy's and St Thomas' NHS Foundation Trust, London, UK; [14]Service de radiothérapie, Institut Régional du Cancer de Montpellier, Montpellier, France; [15]Oncologo Medico, Instituto Alexander Fleming, Buenos Aires, Argentina; [16]Medical Oncology, Odette Cancer Centre, Sunnybrook Health Sciences Centre, Toronto, Canada; [17]Biostatistics, Oncology Business Group, Eisai Inc., Woodcliff Lake, NJ, USA; [18]Late Stage Clinical Development, Merck & Co., Inc., Kenilworth, NJ, USA; [19]Clinical Research, Eisai Inc., Woodcliff Lake, NJ, USA; [20]Division of Gynecologic Oncology, Fondazione Policlinico Universitario Agostino Gemelli IRCCS, Rome, Italy.

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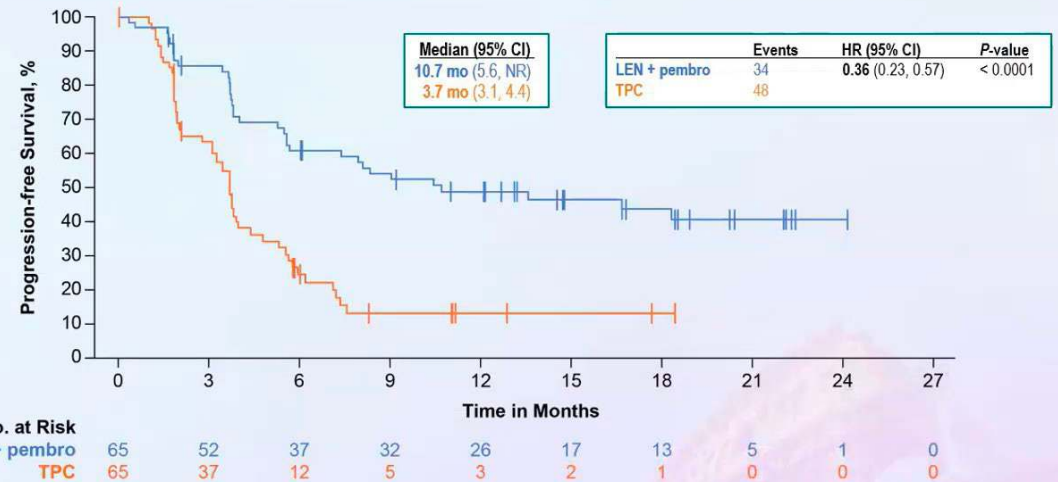
ANNUAL GLOBAL MEETING

Progression-free Survival[a] of the dMMR Population



[a]By blinded independent central review per RECIST version 1.1.

dMMR, DNA mismatch repair-deficient; LEN + pembro, lenvatinib plus pembrolizumab; NR, not reached; TPC, treatment of physician's choice.

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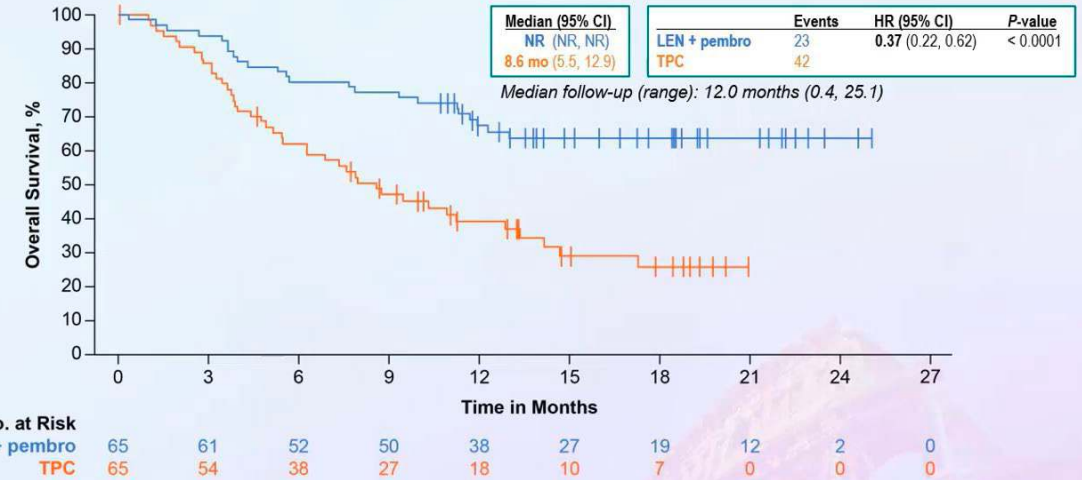
Overall Survival of the dMMR Population



dMMR, DNA mismatch repair-deficient; LEN + pembro, lenvatinib plus pembrolizumab; NR, not reached; TPC, treatment of physician's choice.

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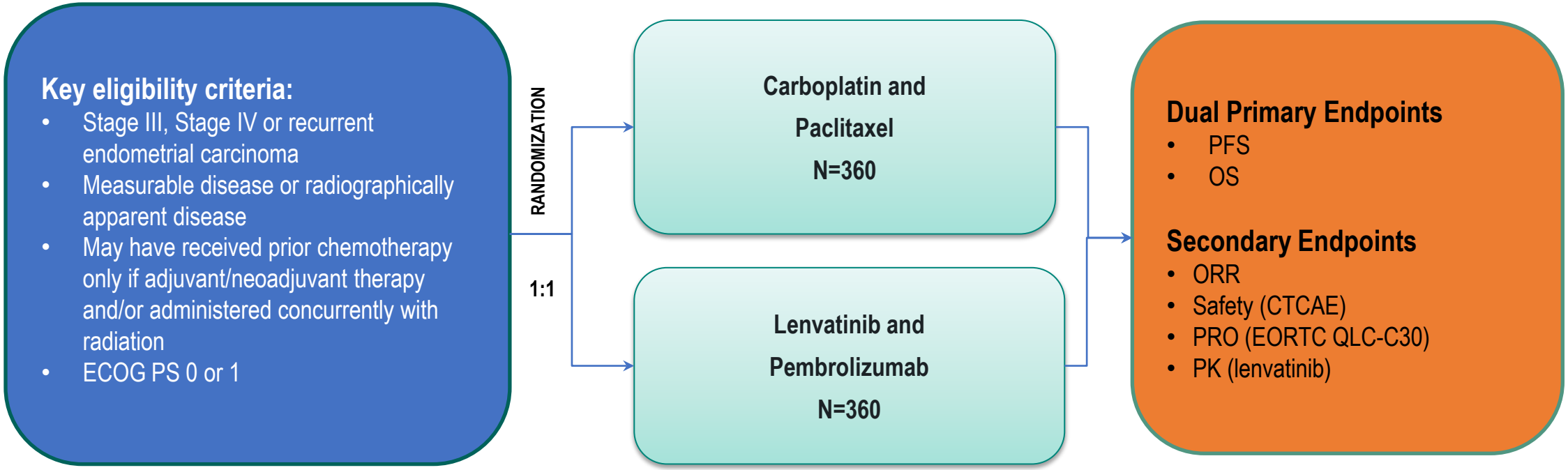
Conclusions

- Efficacy in the dMMR population of patients with aEC appeared to improve with LEN + pembro, at least consistent with that of patients in both the pMMR and all-comers populations previously reported[1]
  - PFS, OS, and ORR were improved with LEN + pembro compared to treatment of physician's choice
  - Notably, ~14% of patients treated with LEN + pembro had a complete response
- LEN + pembro had a manageable safety profile in the dMMR population and was generally consistent with that observed in the all-comers population and the established safety profiles of the individual monotherapies[1]

aEC, advanced endometrial cancer; dMMR, DNA mismatch repair-deficient; LEN + pembro, lenvatinib plus pembrolizumab; ORR, objective response rate; OS, overall survival; PFS, progression-free survival; pMMR, DNA mismatch repair-proficient.

1. Makker V et al. *SGO Virtual Annual Meeting on Women's Cancer*. 2021.

What's Next for Lenvatinib/Pembrolizumab: LEAP-001: First-line metastatic recurrent Phase 3



Stratification factors:

- MMR status (pMMR v dMMR), if pMMRR:
  - Measurable disease (yes or no)
  - ECOG (0 vs 1)
  - Prior chemotherapy and/or chemoradiation (yes or no)

PI: C. Marth

ClinicalTrials.gov: NCT04865289

Activated October 22, 2019

Accrual complete except for China expansion

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Analysis of Antitumor Activity of Dostarlimab by Tumor Mutational Burden in Patients with Endometrial Cancer in the GARNET Trial

Ana Oaknin, Lucy Gilbert, Anna V. Tinker, Jubilee Brown, Cara Mathews, Joshua Z. Press, Renaud Sabatier, David M. O'Malley, Vanessa Samouëlian, Valentina Boni, Linda Duska, Sharad Ghamande, Prafull Ghatage, Rebecca Kristeleit, Charles Leath III, Xinwei Han, Sujatha Kumar, Tao Duan, Ellie Im, Bhavana Pothuri

Objective:

To examine the antitumor activity of dostarlimab in patients with dMMR/MSI-H or MMRp/microsatellite stable (MSS) EC by TMB status

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Conclusions

- TMB-high (TMB-H) status and dMMR/MSI-H status show substantial overlap in the patient populations with EC
- TMB-H and dMMR/MSI-H EC have similar response rates
- Notably, the objective response rate (ORR) ofpatients with mismatch repair proficient (MMRp) and TMB-H EC was comparable to the ORR of patients with dMMR/MSI-H and TMB-H EC
- TMB-H status in the patients with MMRp EC was not due to MSI-H (hypermutated) or POLε-mutated (ultramutated) status
- The study was not powered to assess antitumor activity by TMB status, and interpretation is limited by the small

Pembrolizumab in Patients With Microsatellite Instability-High (MSI-H) Advanced Endometrial Cancer: Updated Results From KEYNOTE-158

David M. O'Malley[1]; Giovanni Mendonca Bariani[2]; Philippe A. Cassier[3]; Aurelien Marabelle[4]; Aaron R. Hansen[5]; Ana De Jesus Acosta[6]; Wilson H. Miller, Jr[7]; Tamar Safra[8]; Antoine Italiano[9]; Linda Mileshkin[10]; Lei Xu[11]; Fan Jin[11]; Kevin Norwood[11]; Michele Maio[12]

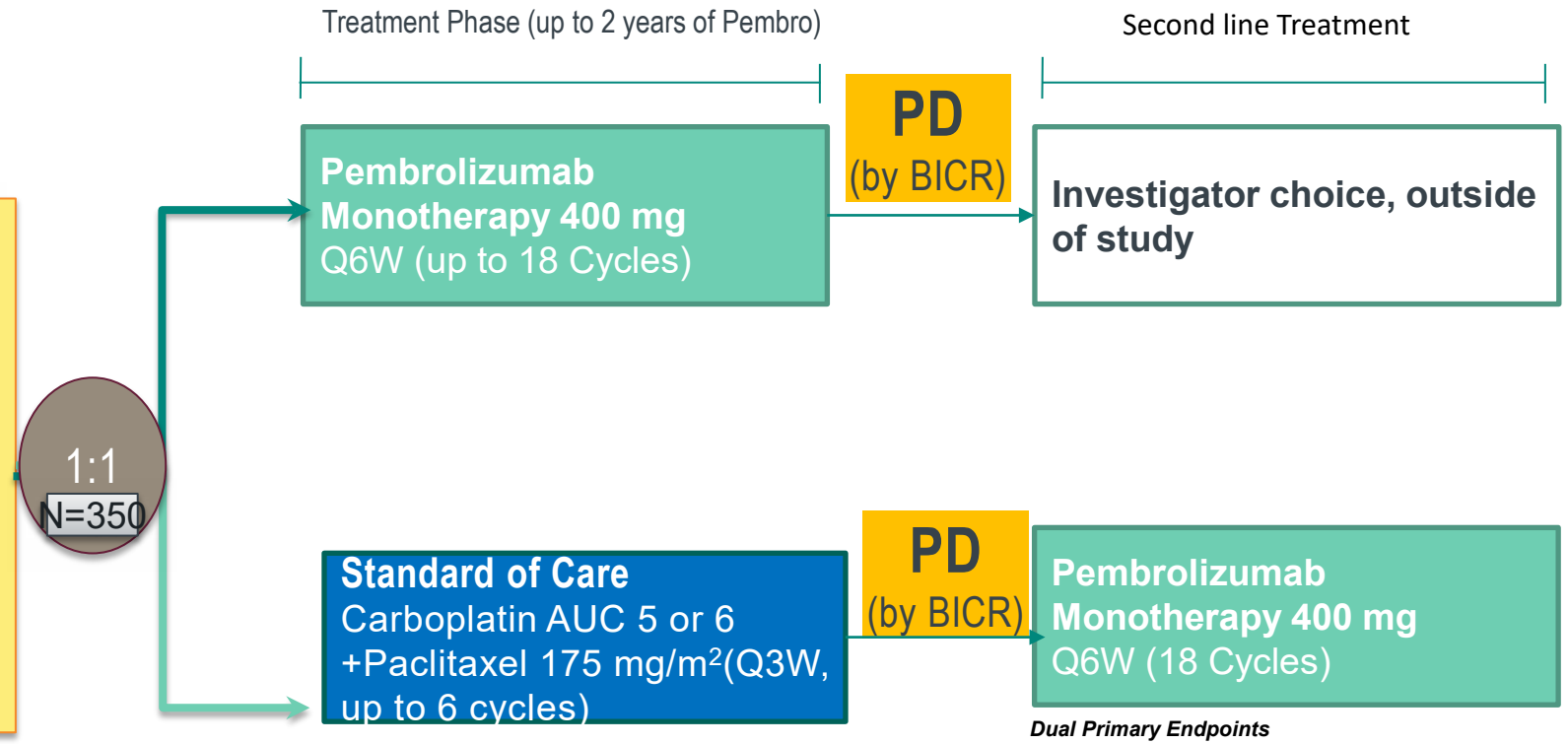
[1]The Ohio State University Wexner Medical Center and The James Comprehensive Cancer Center, Columbus, OH, USA; [2]Instituto do Câncer do Estado de São Paulo, Universidade de São Paulo, São Paulo, Brazil; [3]Centre Léon Bérard, Lyon, France; [4]Gustave Roussy, Institut National de la Santé et de la Recherche Médicale U1015, Villejuif, France; [5]Princess Margaret Cancer Centre, Toronto, ON, Canada; [6]Sidney Kimmel Comprehensive Cancer Center at Johns Hopkins, Baltimore, MD, USA; [7]Segal Cancer Centre, Jewish General Hospital, Rossy Cancer Network, and McGill University, Montreal, QC, Canada; [8]Tel Aviv Medical Center, Tel Aviv and Sackler School of Medicine, Tel Aviv University, Tel Aviv, Israel; [9]Early Phase Trials and Sarcoma Units, Institut Bergonie, Bordeaux, France; [10]Peter MacCallum Cancer Centre, Melbourne, VIC, Australia; [11]Merck & Co., Inc., Kenilworth, NJ, USA; [12]Center for Immuno-Oncology, University Hospital of Siena, Siena, Italy

Summary

- Pembrolizumab demonstrated robust and clinically meaningful antitumor activity in patients with previously treated MSI-H/dMMR advanced endometrial cancer
  - ORR, 48%
  - Estimated DOR ≥3 years, 68%
- Survival outcomes after treatment with pembrolizumab were encouraging, with 60% estimated to be alive at 4 years
- Toxicity was manageable and consistent with that previously observed for pembrolizumab in patients with advanced solid tumors
- Pembrolizumab monotherapy represents a promising treatment option for patients with previously treated MSI-H/dMMR advanced endometrial cancer

What's Next for dMMR:
GOG 3064/ ENGOT–en15/MK KN-C93 Proposed Study Design 1L dMMR platinum doublet chemotherapy vs pembro (with formal cross over)

Phase 3, multi-center, randomized, open-label



Key Eligibility Criteria:

- Stage III or IV, persistent/ recurrent, or metastatic EC
- Measurable/non-measurable disease (radiologically apparent)
- dMMR
- No previous chemo for adjuvant or first line except as part of radiosensitizing
- ECOG 0-1

Stratification factors:

- Newly diagnosed advanced EC vs Recurrent EC
- Histology – endometrioid vs. non-endometrioid

*Participants who were randomized to Arm 2 (chemotherapy) and experience BICR-assessed disease progression per RECIST 1.1, will have an opportunity to participate in the Crossover Phase to receive up to 18 cycles of pembrolizumab 400 mg Q6W, upon Sponsor consultation

Dual Primary Endpoints

- *PFS (by BICR)*
- *OS*

Secondary Endpoints

- *ORR (by BICR)*
- *DCR*
- *DOR*
- *PFS by investigator*
- *PFS2*
- *QOL*
- *Safety*

PI: B. Slomovitz
co-PI: F. Backes
Clinicaltrials.gov #: TBD
Shared with permission from sponsor

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INTENSIVE VERSUS MINIMALIST FOLLOW-UP IN PATIENTS TREATED FOR ENDOMETRIAL CANCER: A MULTICENTRIC RANDOMIZED CONTROLLED TRIAL *THE TOTEM STUDY - NCT00916708*

Paolo Zola,

TOTEM trial: aims

To compare with a randomized trial an intensive (INT) vs minimalist (MIN) 5-year follow-up regimen in endometrial cancer patients in terms of overall survival (OS)

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CONCLUSIONS

INTENSIVE FOLLOW-UP IN ENDOMETRIAL CANCER TREATED PATIENTS DOES NOT IMPROVE OS, EVEN IN HIR PATIENTS

THE HRQL, IN OUR STUDY, IS NOT INFLUENCED BY DIFFERENT REGIMENS OF FOLLOW-UP

ACCORDING TO OUR DATA THERE IS NO NEED TO ROUTINELY ADD VAGINAL CYTOLOGY, LABORATORY OR IMAGING INVESTIGATIONS TO THE MINIMALIST REGIMENS USED IN THIS TRIAL

“The best way to predict the future is to create it”

Abraham Lincoln

Endometrial Cancer: Active Trials

- 2 trials of immunotherapy in the adjuvant setting
- 5 first line trials
  - 3 trials chemo vs. chemo and I/O (and PARP)
  - LEAP trial: combination I/O vs chemotherapy
  - 3064/c93: single agent I/O vs chemotherapy
  - Selinexor maintenance trial
- Multiple I/O and biomarker second line trials

Current Standard of Care

- Adjuvant:
  - Chemotherapy +/- XRT
- First-line metastatic or recurrent:
  - Chemotherapy (+ trastuzumab for HER2 + USC)
- Second-line:
  - dMMR: single agent I/O
  - pMMR: pembrolizumab and Lenvatinib
- Third-line and beyond:
  - Hormonal therapy (mTOR, CDK 4/6)
  - 2nd line chemotherapy

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Predicting Future in First Line **Recurrent**

	Chemo + I/O +/- PARP	LEAP-001	B21 or GY020 – Adjuvant Pembro in HR	IMPACT
Scenario #1	Positive	Positive		I/O 1st line
	Positive	Negative		I/O 1st line
Scenario #3	Negative	Positive		I/O 1st line
Scenario #4	Negative	Negative		No change
Scenario #5	Positive or Negative	Positive or Negative	Positive	I/O adjuvant

- I/O after I/O?
- May move Biomarker/Hormonal therapy to 2nd line?
- MSI-H/dMMR in adjuvant setting
  - In MSI/dMMR, do we need chemo?

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The Future is Bright

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