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Latest advancements in systemic treatment outcomes in patients with advanced or recurrent endometrial cancer: June 2023

Meeting summary

Summary of the MSD- and Eisai-sponsored symposium at the British Gynaecological Cancer Society (BGCS) Annual Scientific Meeting 2023

30 June 2023

Dr Rebecca Kristeleit
Consultant Medical Oncologist and Principal Investigator in the KEYNOTE-775/Study 309 trial

GB-KLE-00178 | Date of preparation: October 2023

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MSD and Eisai would like to thank Dr Rebecca Kristeleit, Consultant Medical Oncologist, for her informative session at the BGCS symposium on 30 June 2023

Following the findings of the KEYNOTE-775/Study 309 clinical trial, NICE guidelines recommend KEYTRUDA® (pembrolizumab) in combination with LENVIMA® (lenvatinib) in the treatment of previously treated advanced or recurrent endometrial carcinoma[1]

KEYTRUDA, in combination with LENVIMA, is indicated in the treatment of advanced or recurrent endometrial carcinoma in adults who have experienced disease progression on or following prior treatment with a platinum-containing therapy in any setting and who are not candidates for curative surgery or radiation therapy[2]

The objectives of this symposium were to:

- Discuss the data and rationale for IO and TKI combination therapy in patients with advanced and recurrent endometrial cancer
- Explore patient eligibility for KEYTRUDA + LENVIMA in this indication
- Discuss adverse event management for patients receiving treatment with IO and TKI combination therapy

Dr Rebecca Kristeleit opened the session by discussing the patient characteristics and study design of the KEYNOTE-775/Study 309 clinical trial. It was highlighted that patients receiving KEYTRUDA + LENVIMA, compared with chemotherapy alone, presented a 44% reduction in the risk of disease progression or death (HR: 0.56; 95% CI: 0.48–0.66; nominal p-value <0.0001) and a 35% reduction in the risk of death (HR: 0.65; 95% CI: 0.55–0.77; nominal p-value <0.0001).[3,4] 33.8% of patients achieved an objective response with KEYTRUDA + LENVIMA vs 14.7% of patients receiving chemotherapy. Median DOR was 12.9 months (95% CI: 1.6–39.5) with KEYTRUDA + LENVIMA vs 5.7 months (95% CI: 0.0–37.1) with chemotherapy.[3]

Click the buttons below to learn more about the KEYNOTE-775/Study 309 clinical trial

Study design | Patient characteristics | PFS
OS | ORR and DOR | Safety

BGCS, British Gynaecological Cancer Society; CI, confidence interval; CR, complete response; DOR, duration of response; HR, hazard ratio; IO, immuno-oncology; NICE, National Institute for Health and Care Excellence; ORR, objective response rate; OS overall survival; PFS, progression-free survival; PR, partial response; TKI, tyrosine kinase inhibitor.

1. NICE. Pembrolizumab with lenvatinib for previously treated advanced or recurrent endometrial carcinoma. Available at https://www.nice.org.uk/guidance/indevelopment/gid-ta10692. Accessed July 2023;
2. KEYTRUDA (pembrolizumab) Summary of Product Characteristics. Available at https://www.medicines.org.uk/emc/product/2498/smpc. Accessed July 2023; 3. Makker V et al. Presented at the European Society for Medical Oncology (ESMO) Virtual Annual Meeting 2022, 9–13 September; 4. MSD data on file.

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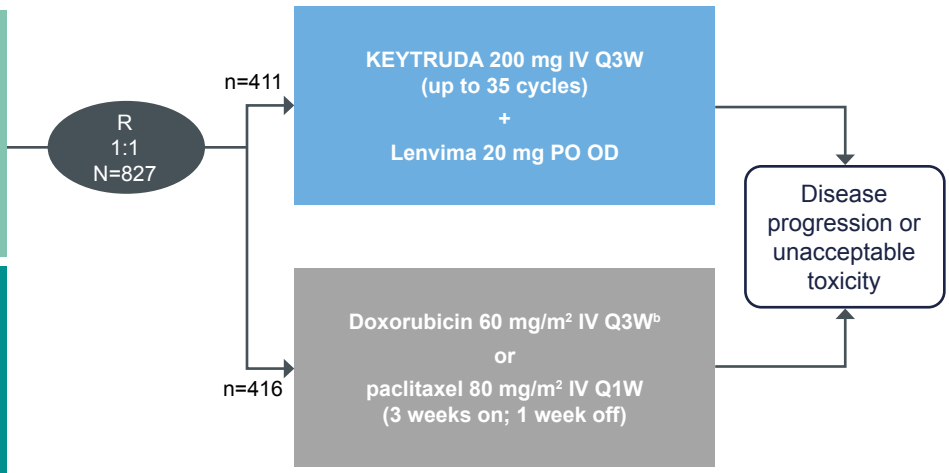
KEYNOTE-775/Study 309: Study design[1,2]

- **KEYNOTE-775 was a randomised, open-label, Phase 3 study**

Key eligibility criteria
- Advanced, metastatic or recurrent endometrial cancer
- One prior platinum-based chemotherapy[a]
- ECOG PS 0–1
- Measurable disease per BICR
- Tissue available for MMR testing

Stratification factors
- MMR status (pMMR vs dMMR) and further stratification within pMMR by:
  - Region 1: Europe, USA, Canada, Australia, New Zealand and Israel, Region 2: rest of world
  - ECOG PS (0 vs 1)
  - Prior history of pelvic radiation (yes vs no)

Endpoints
- Primary: PFS per BICR, OS
- Secondary: ORR, HRQoL, PK, safety
- Exploratory: DOR



Adapted from Makker V et al. N Engl J Med 2022 and Makker V et al. ESMO 2022.

[a]Patients could receive up to two prior platinum-based chemotherapy regimens if one was given in the neoadjuvant or adjuvant setting; [b]Maximum cumulative dose of 500 mg/m².

BICR, blinded independent central review; dMMR, mismatch repair deficient; DOR, duration of response; ECOG PS, Eastern Cooperative Oncology Group performance status; HRQoL, health-related quality of life; IV, intravenous; MMR, mismatch repair; ORR, objective response rate; OS, overall survival; PFS, progression-free survival; PK, pharmacokinetics; pMMR, mismatch repair proficient; PO, orally; Q1W, every week; Q3W, every 3 weeks; OD, once daily; R, randomisation.

1. Makker V et al. *N Engl J Med* 2022;386:437–448; 2. Makker V et al. Slide deck presented at: European Society for Medical Oncology (ESMO) Virtual Annual Meeting; September 9–13, 2022.

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KEYNOTE-775/Study 309: Patient characteristics in the ITT population

Characteristic, n (%)[a]	KEYTRUDA + LENVIMA (n=411)	Chemotherapy (n=416)
Age		
Median (range), years	64 (30–82)	65 (35–86)
<65 years	206 (50.1)	204 (49.0)
Race[b]		
White	261 (63.5)	246 (59.1)
Black	17 (4.1)	14 (3.4)
Asian	85 (20.7)	92 (22.1)
Geographic region		
Region 1[c]	234 (56.9)	240 (57.7)
Region 2[d]	177 (43.1)	176 (42.3)
MMR status		
pMMR	346 (84.2)	351 (84.4)
dMMR	65 (15.8)	65 (15.6)

Characteristic, n (%)	KEYTRUDA + LENVIMA (n=411)	Chemotherapy (n=416)
ECOG PS		
0	246 (59.9)	241 (57.9)
1	164 (39.9)	175 (42.1)
History of pelvic radiation	174 (42.3)	186 (44.7)
Histological features at initial diagnosis		
Endometrioid carcinoma	243 (59.1)	254 (61.1)
High grade	94 (22.9)	90 (21.6)
Low grade	59 (14.4)	54 (13.0)
Not specified[e]	90 (21.9)	110 (26.4)
Serous carcinoma	103 (25.1)	115 (27.6)
Clear cell carcinoma	30 (7.3)	17 (4.1)
Mixed features	22 (5.4)	16 (3.8)

Adapted from Makker V et al. N Engl J Med 2022.

[a]Unless stated otherwise; [b]Race was reported by the patient. Data on race were missing for 36 patients (8.8%) in the KEYTRUDA + LENVIMA group and 44 (10.6%) in the chemotherapy group. Other races or ethnic groups (reported by 12 patients [2.9%] in the KEYTRUDA + LENVIMA group and 20 [4.8%] in the chemotherapy group) included American Indian or Alaska Native, Native Hawaiian or other Pacific Islander and multiple; [c]Europe, USA, Canada, Australia, New Zealand and Israel; [d]Rest of world; [e]Including endometrioid carcinoma (grade not specified) and endometrioid carcinoma with squamous differentiation. dMMR, mismatch repair deficient; ECOG PS, Eastern Cooperative Oncology Group performance status; ITT, intention-to-treat; MMR, mismatch repair; pMMR, mismatch repair proficient.

Makker V et al. *N Engl J Med* 2022;386:437–448.

Study design | Patient characteristics | PFS
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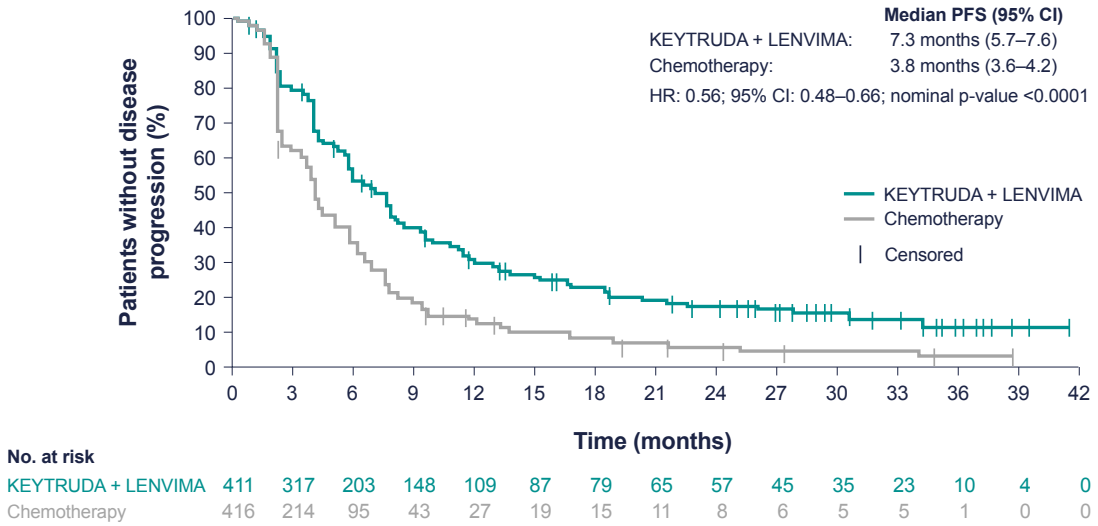
KEYNOTE-775/Study 309: PFS with KEYTRUDA + LENVIMA vs chemotherapy in all patients at the final analysis (nominal p-value)[a,1,2]



No. at risk														
KEYTRUDA + LENVIMA	411	317	203	148	109	87	79	65	57	45	35	23	10	4	0
Chemotherapy	416	214	95	43	27	19	15	11	8	6	5	5	1	0	0

Adapted from Makker V et al. Presented at ESMO 2022.

A 44% reduction in the risk of progression or death was presented with KEYTRUDA + LENVIMA vs chemotherapy in the ITT population (HR: 0.56; 95% CI: 0.48–0.66; nominal p-value <0.0001)

Analysis cut-off date: 1 March 2022.

[a]By BICR per RECIST v1.1.

BICR, blinded independent central review; CI, confidence interval; HR, hazard ratio; ITT, intention-to-treat; PFS, progression-free survival; RECIST v1.1, Response Evaluation Criteria in Solid Tumors Version 1.1.

1. Makker V et al. Slide deck presented at: European Society for Medical Oncology (ESMO) Virtual Annual Meeting; September 9–13, 2022;
2. MSD data on file.

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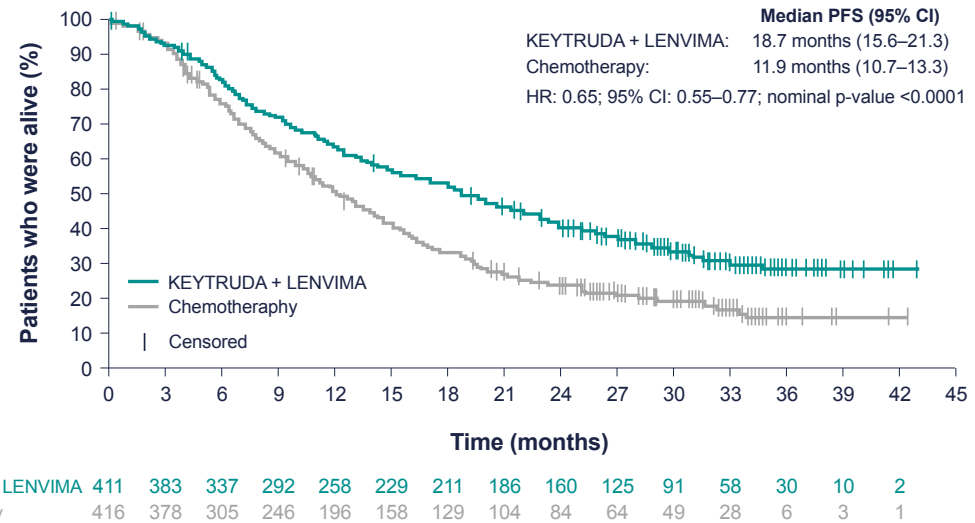
KEYNOTE-775/Study 309: OS with KEYTRUDA + LENVIMA vs chemotherapy in all patients at the final analysis (nominal p-value)[1,2]



No. at risk

KEYTRUDA + LENVIMA	411	383	337	292	258	229	211	186	160	125	91	58	30	10	2
Chemotherapy	416	378	305	246	196	158	129	104	84	64	49	28	6	3	1

Adapted from Makker V et al. Presented at ESMO 2022.

A 35% reduction in the risk of death was presented with KEYTRUDA + LENVIMA vs chemotherapy in the ITT population (HR: 0.65; 95% CI: 0.55–0.77; nominal p-value <0.0001)

Analysis cut-off date: 1 March 2022.

CI, confidence interval; CR, complete response; HR, hazard ratio; ITT, intention-to-treat; ORR, objective response rate; OS, overall survival; PR, partial response.

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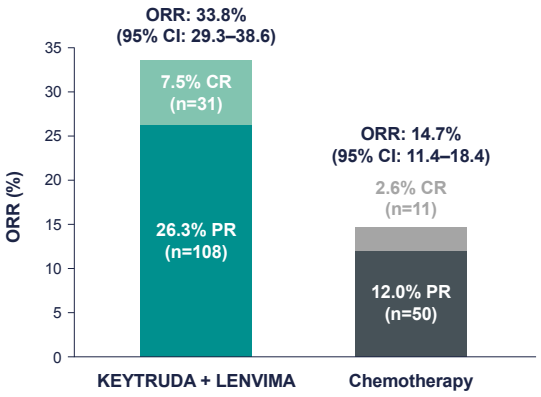

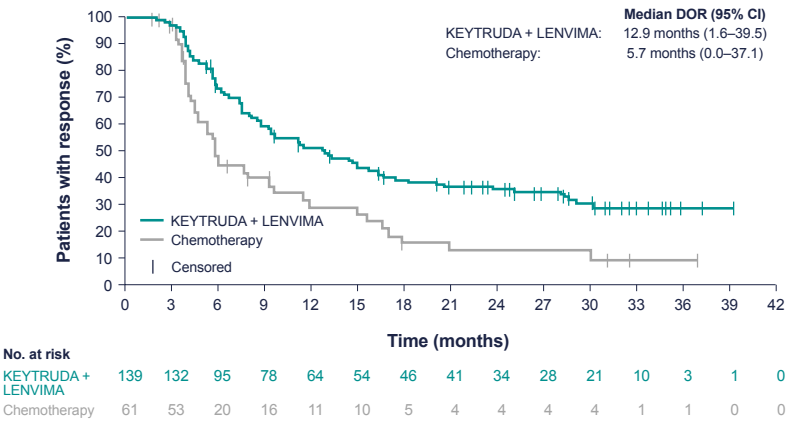

Adapted from Makker V et al. Presented at ESMO 2022.

33.8% of patients achieved an objective response with KEYTRUDA + LENVIMA vs 14.7% of patients receiving chemotherapy. Median DOR was 12.9 months (95% CI: 1.6–39.5) with KEYTRUDA + LENVIMA vs 5.7 months (95% CI: 0.0–37.1) with chemotherapy[1]

Analysis cut-off date: 1 March 2022.

CI, confidence interval; HR, hazard ratio; ITT, intention-to-treat; OS, overall survival.

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KEYNOTE-775/Study 309: Summary of AEs in all treated patients

AE, n (%)	KEYTRUDA + LENVIMA (n=406)	Chemotherapy (n=388)
Any AE	405 (99.8)	386 (99.5)
Grade ≥3	361 (88.9)	282 (72.7)
Serious AEs	214 (52.7)	118 (30.4)
AE leading to dose reduction[a]	270 (66.5)	50 (12.9)
AE leading to treatment interruption[b]	281 (69.2)	105 (27.1)
KEYTRUDA[c]	203 (50.0)	–
LENVIMA[c]	238 (58.6)	–
KEYTRUDA + LENVIMA	125 (30.8)	–
AE leading to discontinuation	134 (33.0)	31 (8.0)
KEYTRUDA[c]	76 (18.7)	–
LENVIMA[c]	125 (30.8)	–
KEYTRUDA + LENVIMA	57 (14.0)	–
AE leading to death	23 (5.7)	19 (4.9)

Adapted from Makker V et al. N Engl J Med 2022 (and supplementary appendix)

Analysis cut-off date: 26 October 2020.

[a]Includes LENVIMA only or chemotherapy; [b]Includes KEYTRUDA or LENVIMA; [c]Regardless of the action taken with the other drug in the combination arm.

AE, adverse event.

Makker V et al. *N Engl J Med* 2022;386:437–448 (and supplementary appendix).

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Following discussion on the outcomes of the KEYNOTE-775/Study 309 clinical trial, Dr Rebecca Kristelait presented the treatment journeys of two patients with endometrial carcinoma, including presentation, diagnosis, treatment options and adverse event management

Patient WB

Diagnosis

Treatment

Initial examination of patient WB demonstrated multiple abdomen and pelvic fibroids and a soft mass filling the endometrial cavity with myometrial invasion. p53 overexpression was apparent as well as moderate PR and weak ER expression. Following primary debulking surgery for Stage IIIC1 high-grade serous endometrial cancer, bilateral pelvic lymph node metastases were observed but no distant disease. The patient demonstrated poor tolerance of carboplatin/paclitaxel in the first and second line, but maintained a continued PR. Third-line KEYTRUDA + LENVIMA was initiated and symptoms improved as the patient maintained SD. One dose reduction was necessary for LENVIMA from 20 mg daily to 14 mg daily.

Patient HJ

Diagnosis

Treatment

Patient HJ presented with Stage II endometrial high-grade serous carcinoma with no LVSI, pMMR and low expression of ER and PR. The patient received surgery followed by carboplatin/paclitaxel, which was stopped due to AEs, before completing pelvic radiotherapy. Recurrence was found after several months, which significantly quickly progressed. For second-line therapy, the patient was given KEYTRUDA + LENVIMA via the expanded access programme and the patient experienced a deepening PR over 9/12 cycles of treatment, experiencing around 1 year of benefit. Toxicites were manageable with LENVIMA dose reduction from 20 mg to 14 mg and thyroxine replacement.

Please note that these are individual cases and patient experience may vary

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AE, adverse event; ER, oestrogen receptor; LSVI, lymph-vascular space invasion; pMMR, proficient mismatch repair; PR, progesterone receptor; SD, stable disease.

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Nov 2019	Patient presented with PMB (menopausal for 10 years) and bladder instability
Jan 2020	TVUS showed fibroid uterus, thickened endometrium and R adnexal cystic swelling. Patient had hysterescopy, resection of fibroids and polyp and endometrial curettage- p53 aberrant overexpression were observed. ER expression was weak and PR expression was moderate. pMMR. Germline BRCA wild type
Feb 2020	MRI of abdomen/pelvis revealed multiple fibroids. There was a soft tissue mass filling the endometrial cavity. Myometrial invasion, R hydrosalpinx. No extra-pelvic disease

ER, oestrogen receptor; MRI, magnetic resonance imaging; pMMR, proficient mismatch repair; PMB, post-menopausal bleeding; R, right; TVUS, transvaginal ultrasound.

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Apr 2020	Patient had primary debulking surgery for Stage IIIC1 high-grade serous endometrial cancer. There was no involvement of the omentum. Bilateral pelvic lymph node metastases were observed. CTTAP in May 2020 revealed post-operative change. No distant disease
Jun 2020	Carboplatin/paclitaxel was poorly tolerated by the patient and they declined to continue with this treatment
Sep 2020	Completed EBRT 45 Gy in 25# and VBT 8 Gy in 2#
Dec 2020	CTTAP was suggestive of right retrocrural adenopathy. MDM review of PET/CT and CTTAP confirm mediastinal and right SCF lymphadenopathy – highly suggestive of recurrent disease
Mar 2021	Patient presented with bowel obstruction. CTTAP demonstrated no evidence of intro-abdominal disease on scan. Multiple loops of dilated small bowel with collapse of the distal ileum, ileo-caecal junction and large bowel
Apr 2021	A defunctioning loop ileostomy was formed. Metastatic high-grade serous carcinoma was found in resected peritoneal nodule. ER–, PR–, p53 aberrant overexpression
Apr 2021	Patient had a TIA and was subsequently switched to apixaban
May 2021	C1D1 12 May: 6# carboplatin/paclitaxel. Treatment was continued until September 2021
Oct 2021	At EOT, CTTAP showed VGPR
Jan 2022	CTTAP showed maintained partial response
May 2022	PD lung metastasis/nodule, right paratracheal node, right pelvic mass increase, peritoneal thickening of right paracolic gutter. 7/12 interval

C1D1, Cycle 1, Day 1; CT, computed tomography; CTTAP, computed tomography of the thorax, abdomen and pelvis; EBRT, external beam radiation therapy; EOT, end of treatment; ER, oestrogen receptor; Gy, gray; MDM, multidisciplinary meeting; PD, progressive disease; PET, positron emission tomography; PR, progesterone receptor; SCF, supraclavicular fossa node; TIA, transient ischaemic attack; VGPR, very good partial response.

CONTINUE

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Patient was considered for KEYTRUDA + LENVIMA treatment based on KEYNOTE-775/Study 309 data. WB had a PS of 1, Grade 1 R lower leg swelling, R hip pain and a high output stoma. They were on regular loperamide and IV Mg.

Jun 2022	**HepB cAb+ and HepB DNA negative. Patient was started on entecavir. Patient initiated treatment with 200 mg KEYTRUDA IV Q21d + 20 mg oral LENVIMA daily. 2# R hip pain and leg swelling improved. TSH was raised**
July 2022	**For 3#, LENVIMA dose was reduced to 14 mg daily. Patient experienced Grade 1 neutropenia 1.1×109/L (baseline 2.0×109/L), Grade 1 thrombocytopenia 130×109/L (baseline 192×109/L) and Grade 1 thyroid disruption (increased TSH). Hip pain resolved. R leg selling continued to improve**
Aug 2022	**CTTAP was performed after 3# SD. Patient was feeling much better and reported reduced pelvis/hip pain**
Aug 2022	**CTTAP post-3# showed SD**
Sep 2022	**Patient presented with bowel obstruction. CTTAP demonstrated no evidence of intro-abdominal disease on scan. Multiple loops of dilated small bowel with collapse of the distal ileum, ileo-caecal junction and large bowel**
Oct 2022	**7# administered. Patient remains well, with ongoing Grade 1 fatigue**
Nov 2022	**CTTAP observed after 7#: PD (new disease). Grade 1 abdomen distention, Grade 1 peripheral oedema**

Stabilisation of disease with symptomatic improvement

Dec 2022	**Patient was switched to 3L treatment- carboplatin/PLD**

3L, third-line; cAB, circulating antibody; CTTAP, computed tomography of the thorax, abdomen and pelvis; HepB, hepatitis B; IV, intravenous; Mg, magnesium; PD, progressive disease; PLD, pegylated liposomal doxorubicin; PS, performance status; R, right; SD, stable disease; TSH, thyroid-stimulating hormone.

PREVIOUS

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Speaker insight.

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in endometrial carcinoma. Let's keep talking

PREVIOUS PAGE

Following discussion on the outcomes of the KEYNOTE-775/Study 309 clinical trial, Dr Rebecca Kristelait presented the treatment journeys of two patients with endometrial carcinoma, including presentation, diagnosis, treatment options and adverse event management

X

Dec 2020	**TAH/BSO/omental biopsy/adhesiolysis for Stage II endometrial high-grade serous carcinoma No LVSI pMMR ER- and PR-**
Jan 2021	**CTTAP was performed; results: Nil residual CA-125: 23 U/mL (not raised during treatment)**
Mar 2021	**Patient completed 4# post-operative carboplatin/paclitaxel Treatment was stopped due to progressive sensory neuropathy**
Jun 2021	**Patient completed pelvic radiotherapy**

Metastatic high-grade serous recurrence, chemotherapy poorly tolerated, interval of 8/12 from completion of 1L treatment (<1 year from curtailed chemotherapy), pMMR

Feb 2022	**CTTAP revealed pelvic recurrence of 6x5x6cm at hysterectomy bed, pelvic peritoneal thickening and small bowel mesenteric stranding**
Mar 2022	**HJ was referred to Guy's and St Thomas' NHS Foundation Trust. Biopsy revealed high-grade serous component**

1L, first-line; CA-125, cancer antigen 125; CTTAP, computed tomography of the thorax, abdomen and pelvis; ER, oestrogen receptor; LVSI, lymph-vascular space invasion; pMMR, proficient mismatch repair; PR, progesterone receptor.

patient maintained SD. One dose reduction was necessary for LENVIMA from 20 mg daily to 14 mg daily.

Toxicites were manageable with LENVIMA dose reduction from 20 mg to 14 mg and thyroxine replacement.

Please note that these are individual cases and patient experience may vary

If you would like to access more MSD resources on endometrial carcinoma, click here.
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AE, adverse event; ER, oestrogen receptor; LSVI, lymph-vascular space invasion; pMMR, proficient mismatch repair; PR, progesterone receptor; SD, stable disease.

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May 2022	Patient commenced first cycle of 200 mg KEYTRUDA + 20 mg LENVIMA
Jul 2022	CTTAP post-3#: PR
Aug 2022	LENVIMA reduced to 14 mg daily for C4 following PS2: Grade 3 nausea and vomiting, Grade 2 thyroid dysfunction, Grade 1 neutropenia, Grade 1 raised ALT and hoarse voice
Oct 2022	CTTAP post-6#: deepening PR. Hoarse voice was resolved. PS 1
Nov 2022	LENVIMA reduced to 10 mg daily for 8#. Patient experienced Grade 1 fatigue, Grade 2 ALT ride and Grade 2 neutropenia. In Dec 2022, patient tested positive for COVID and RSV. PS 1–2 due to Grade 2 fatigue. Appetite less good
Feb 2023	CTTAP and MRI post-11#: deepening PR, pelvic mass no longer easy to delineate Patient had a gas-filled cavity with vaginal vault, with no fistulation
Mar 2023	Patient commenced 12#
Apr 2023	An MRI scan of the abdomen/pelvis revealed fluid and recurrent soft tissue at the site of previous pelvic mass Gas locules had resolved PD

ALT, alanine transaminase; CTTAP, computed tomography of the thorax, abdomen and pelvis; MRI, magnetic resonance imaging; PD, progressive disease; PR, partial response; PS, performance status; RSV, respiratory syncytial virus.

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