MSD Oncology

KEYTRUDA® (pembrolizumab) + Lenvima® (lenvatinib) in the treatment of adults with advanced/recurrent endometrial cancer that has progressed on or following prior treatment with platinum-containing therapy in any setting, and who are not candidates for curative surgery or radiation

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Please refer to the full Summary of Product Characteristics for KEYTRUDA, and patient-targeted Risk Minimisation Materials, before prescribing KEYTRUDA.

Adverse events should be reported. Reporting forms and information can be found at https://yellowcard.mhra.gov.uk/ or search for MHRA Yellow Card in the Google Play or Apple App Store. Adverse events should also be reported to Merck Sharp & Dohme (UK) Limited (Tel: 020 8 154 8000). By clicking the above link, you will be taken to the MHRA website.

FOR UK HEALTHCARE PROFESSIONALS ONLY

Please click here for the UK KEYTRUDA Prescribing Information.
Please click here for the UK Lenvima Prescribing Information.

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Prescribing Information: KEYTRUDA UK ; Lenvima UK

KEYNOTE-775: Overview

Click the links below to navigate to the section of interest

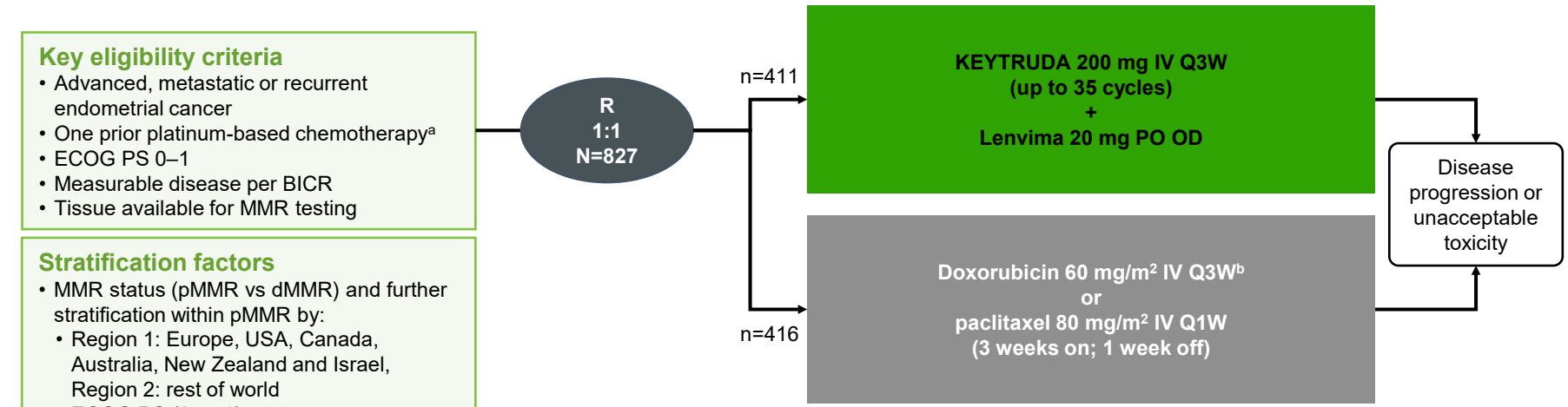
Study design

Baseline characteristics in the ITT population

ITT, intention-to-treat.

KEYNOTE-775: Study design

Randomised, open-label, Phase 3 study



[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.

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

Prescribing Information: KEYTRUDA UK ; Lenvima UK

KEYNOTE-775: Baseline 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)

[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 by 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]Included endometrioid carcinoma (grade not specified) and endometrioid carcinoma with squamous differentiation. Table adapted from Makker V et al. *N Engl J Med* 2022.

dMMR, mismatch repair deficient; ECOG PS, Eastern Cooperative Oncology Group performance status; ITT, intention-to-treat; pMMR, mismatch repair proficient.

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

Prescribing Information: KEYTRUDA UK ; Lenvima UK

KEYNOTE-775: Results (interim analysis)

Click the links below to navigate to the section of interest

KEYTRUDA + Lenvima demonstrated superior PFS vs chemotherapy in all patients

KEYTRUDA + Lenvima demonstrated superior PFS vs chemotherapy in patients who were pMMR

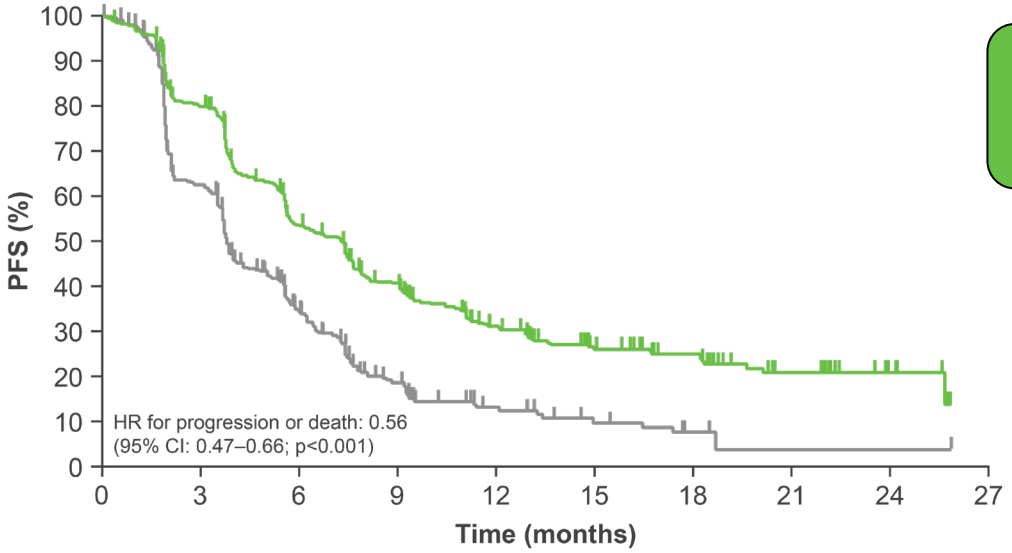
KEYTRUDA + Lenvima demonstrated superior OS vs chemotherapy in all patients

KEYTRUDA + Lenvima demonstrated superior OS vs chemotherapy in patients who were pMMR

OS, overall survival; PFS, progression-free survival; pMMR, mismatch repair proficient.

KEYNOTE-775: KEYTRUDA + Lenvima demonstrated superior PFS vs chemotherapy in all patients (interim analysis)[a,1,2]

Treatment arm	Median (95% CI), months	HR (95% CI)	p value
KEYTRUDA + Lenvima	7.2 (5.7–7.6)	0.56 (0.47–0.66)	<0.001
Chemotherapy	3.8 (3.6–4.2)	–	–



No. at risk										
KEYTRUDA + Lenvima	411	316	202	144	86	56	43	17	6	0
Chemotherapy	416	214	95	42	18	10	4	1	1	0

A **44% reduction in the risk of progression or death** was observed with KEYTRUDA + Lenvima vs chemotherapy in the ITT population (HR 0.56, 95% CI: 0.47–0.66; p<0.001)

The forest plot for PFS in patients who were pMMR and in key subgroups is shown in the appendix. Click here to view.

Analysis cut-off date: 26 October 2020.

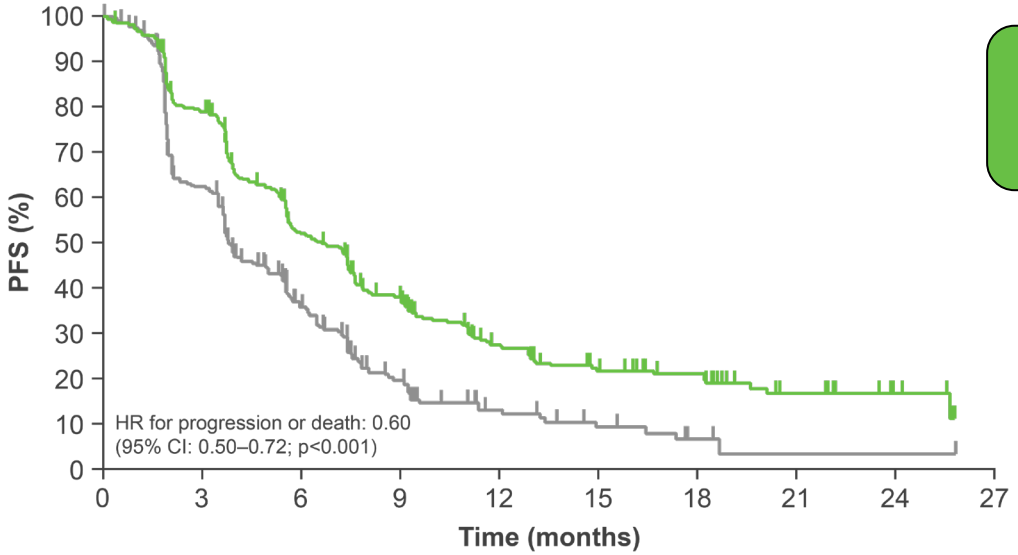
[a]By BICR per RECIST v1.1. Figure adapted from Makker V et al. *N Engl J Med* 2022. Tick marks indicate censored data.

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

1. Makker V et al. *N Engl J Med* 2022;386:437–448; 2. KEYTRUDA (pembrolizumab) SmPC. Available at: https://www.medicines.org.uk/emc/product/2498/smpc. Accessed January 2025.

KEYNOTE-775: KEYTRUDA + Lenvima demonstrated superior PFS vs chemotherapy in patients who were pMMR (interim analysis)[a,1,2]

Treatment arm	Median (95% CI), months	HR (95% CI)	p value
KEYTRUDA + Lenvima	6.6 (5.6–7.4)	0.60 (0.50–0.72)	<0.001
Chemotherapy	3.8 (3.6–5.0)	–	–



No. at risk										
KEYTRUDA + Lenvima	346	264	165	112	60	39	30	12	5	0
Chemotherapy	351	177	83	37	15	8	3	1	1	0

A **40% reduction in the risk of progression or death** was observed with KEYTRUDA + Lenvima vs chemotherapy in the pMMR population (HR 0.60, 95% CI: 0.50–0.72; p<0.001)

Analysis cut-off date: 26 October 2020.

[a]By BICR per RECIST v1.1. Figure adapted from Makker V et al. *N Engl J Med* 2022. Tick marks indicate censored data.

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

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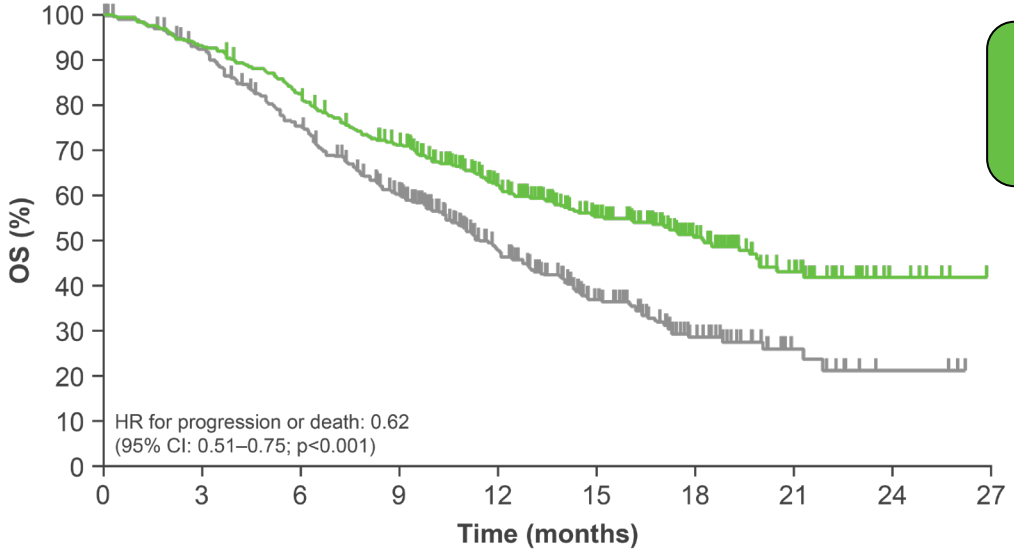
KEYNOTE-775: KEYTRUDA + Lenvima demonstrated superior OS vs chemotherapy in all patients (interim analysis)[1,2]

Treatment arm	Median (95% CI), months	HR (95% CI)	p value
KEYTRUDA + Lenvima	18.3 (15.2–20.5)	0.62 (0.51–0.75)	<0.001
Chemotherapy	11.4 (10.5–12.9)	–	–



No. at risk										
KEYTRUDA + Lenvima	411	383	337	282	198	136	81	40	7	0
Chemotherapy	416	373	300	228	138	80	40	11	3	0

A **38% reduction in the risk of death** was observed with KEYTRUDA + Lenvima vs chemotherapy in the ITT population (HR 0.62, 95% CI: 0.51–0.75; p<0.001)

The forest plot for OS in patients who were pMMR and in key subgroups is shown in the appendix. Click here to view.

Analysis cut-off date: 26 October 2020.

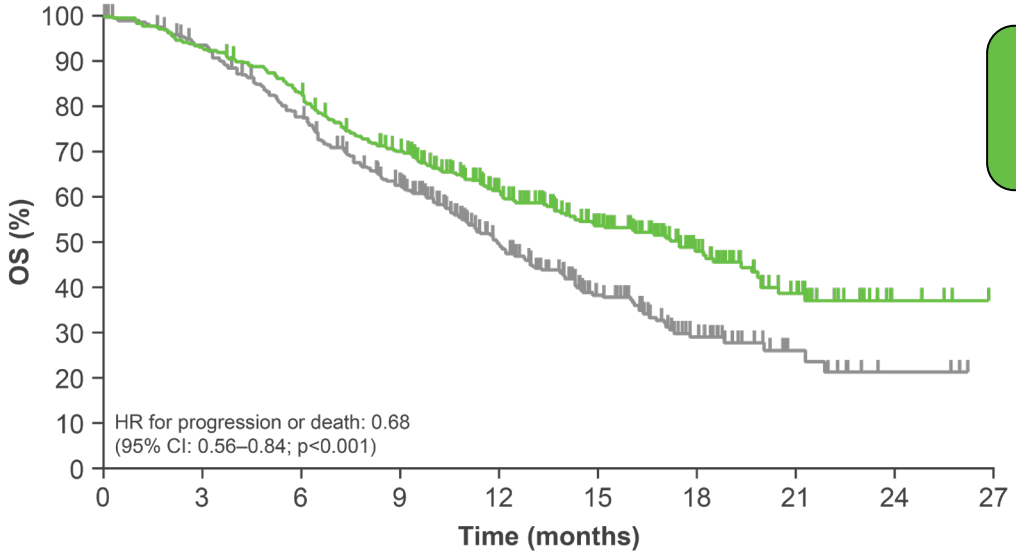
Figure adapted from Makker V et al. *N Engl J Med* 2022. Tick marks indicate censored data.

CI, confidence interval; HR, hazard ratio; ITT, intention-to-treat; mo, month; OS, overall survival; pMMR, mismatch repair proficient.

1. Makker V et al. *N Engl J Med* 2022;386:437–448; 2. KEYTRUDA (pembrolizumab) SmPC. Available at: https://www.medicines.org.uk/emc/product/2498/smpc. Accessed January 2025.

KEYNOTE-775: KEYTRUDA + Lenvima demonstrated superior OS vs chemotherapy in patients who were pMMR (interim analysis)[1,2]

Treatment arm	Median (95% CI), months	HR (95% CI)	p value
KEYTRUDA + Lenvima	17.4 (14.2–19.9)	0.68 (0.56–0.84)	<0.001
Chemotherapy	12.0 (10.8–13.3)	–	–



No. at risk										
KEYTRUDA + Lenvima	346	322	285	232	160	109	62	28	5	0
Chemotherapy	351	319	262	201	120	70	33	11	3	0

A **32% reduction in the risk of death** was observed with KEYTRUDA + Lenvima vs chemotherapy in the pMMR population (HR 0.68, 95% CI: 0.56–0.84; p<0.001)

Analysis cut-off date: 26 October 2020.

Figure adapted from Makker V et al. *N Engl J Med* 2022. Tick marks indicate censored data.

CI, confidence interval; HR, hazard ratio; ITT, intention-to-treat; mo, month; OS, overall survival; pMMR, mismatch repair proficient..

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KEYNOTE-775: Results (final analysis)

Click the links below to navigate to the section of interest

KEYTRUDA + Lenvima presented superior PFS vs chemotherapy in all patients

KEYTRUDA + Lenvima presented superior PFS vs chemotherapy in patients who were pMMR

KEYTRUDA + Lenvima presented superior OS vs chemotherapy in all patients

KEYTRUDA + Lenvima presented superior OS vs chemotherapy in patients who were pMMR

KEYTRUDA + Lenvima presented superior ORR and DOR vs chemotherapy in all patients

KEYTRUDA + Lenvima presented superior ORR and DOR vs chemotherapy in patients who were pMMR

Summary of AEs in all treated patients

AEs with ≥25% incidence in either arm

TEAEs with ≥10% incidence in either arm

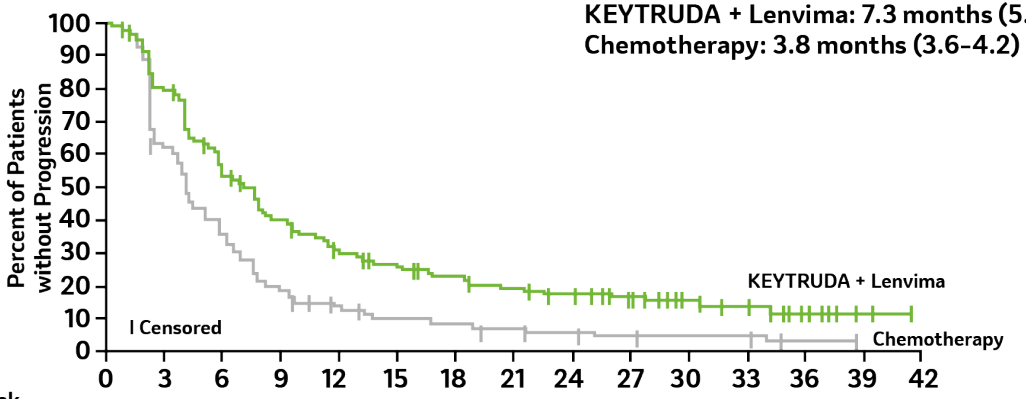
AE, adverse event; DOR, duration of response; ORR, objective response rate; OS, overall survival; PFS, progression-free survival; pMMR, mismatch repair proficient; TEAE, treatment-emergent adverse event.

Prescribing Information: KEYTRUDA UK ; Lenvima UK

KEYNOTE-775: KEYTRUDA + Lenvima presented superior PFS vs chemotherapy in all patients at the final analysis (nominal p-value)[a,1,2]

All-Comer Population

Median Progression-free Survival (95% CI)
KEYTRUDA + Lenvima: 7.3 months (5.7–7.6)
Chemotherapy: 3.8 months (3.6–4.2)



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

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. Figure adapted from Makker V et al. *Presented at ESMO* 2022. Tick marks indicate censored data.

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

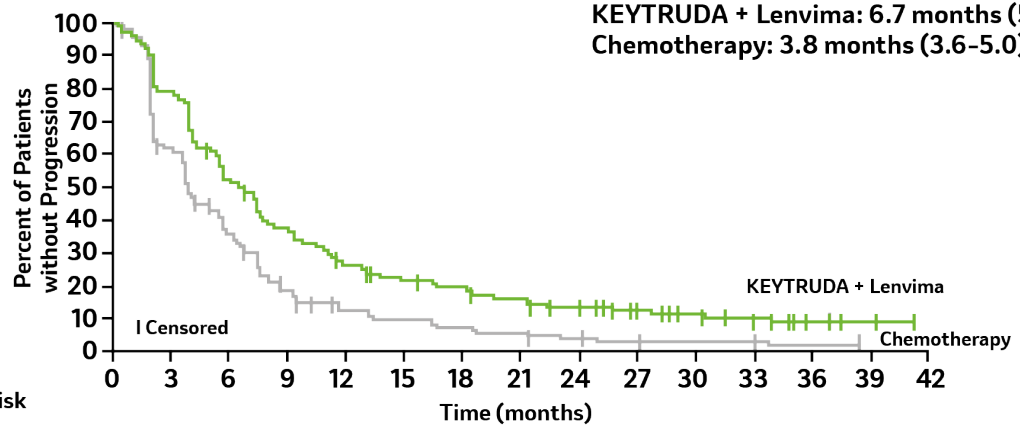
1. Makker V et al. Slide deck presented at: European Society for Medical Oncologists (ESMO) Virtual Annual Meeting; September 9-13, 2022; 2. MSD data on file.

Prescribing Information: KEYTRUDA UK ; Lenvima UK

KEYNOTE-775: KEYTRUDA + Lenvima presented superior PFS vs chemotherapy in patients who were pMMR at the final analysis (nominal p-value)[a,1,2]

pMMR Population

Median Progression-free Survival (95% CI)
KEYTRUDA + Lenvima: 6.7 months (5.6–7.4)
Chemotherapy: 3.8 months (3.6–5.0)



No. at risk														
KEYTRUDA + Lenvima	346	265	166	116	80	61	55	43	36	24	18	14	6	4	0
Chemotherapy	351	177	83	38	23	16	12	9	6	4	3	3	1	0	0

A **40% reduction in the risk of progression or death** was presented with KEYTRUDA + Lenvima vs chemotherapy in the pMMR population (HR 0.60, 95% CI: 0.50–0.72; **nomina**l p-value<0.0001)

Analysis cut-off date: 1 March 2022.

[a]By BICR per RECIST v1.1. Figure adapted from Makker V et al. *Presented at ESMO* 2022. Tick marks indicate censored data.

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

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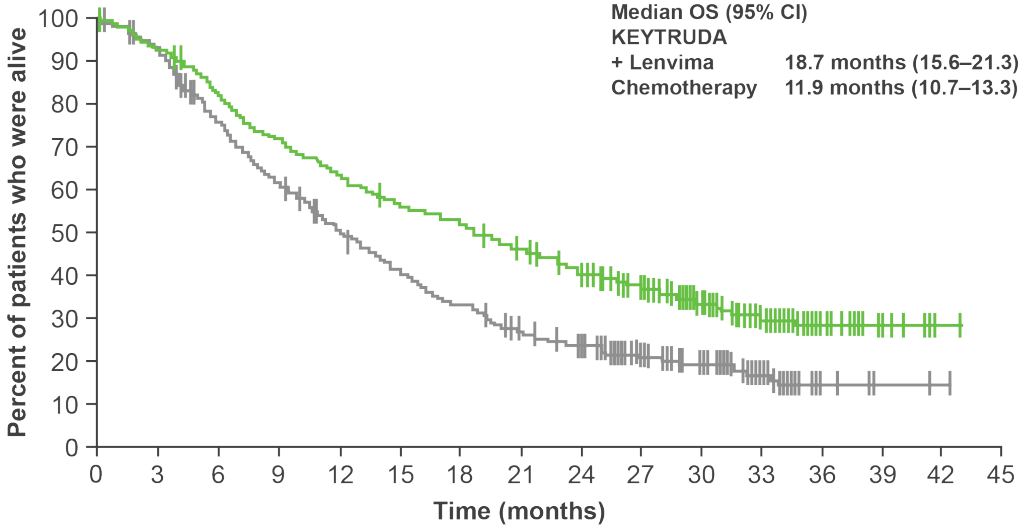
Prescribing Information: KEYTRUDA UK ; Lenvima UK

KEYNOTE-775: KEYTRUDA + Lenvima presented superior OS vs chemotherapy in all patients at the final analysis (nominal p-value)[1–3]



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

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.

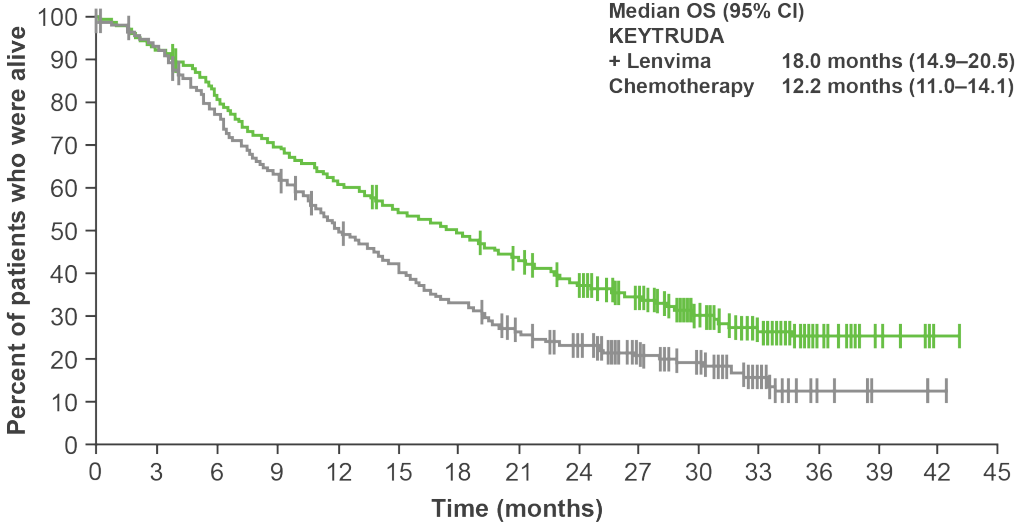
Figure adapted from Makker V et al. *Presented at ESMO* 2022. Tick marks indicate censored data.

CI, confidence interval; HR, hazard ratio; ITT, intention-to-treat; mo, month; OS, overall survival; pMMR, mismatch repair proficient.

1. Makker V et al. *N Engl J Med* 2022;386:437–448; 2. KEYTRUDA (pembrolizumab) SmPC. Available at: https://www.medicines.org.uk/emc/product/2498/smpc. Accessed January 2025; 3. MSD data on file.

Prescribing Information: KEYTRUDA UK ; Lenvima UK

KEYNOTE-775: KEYTRUDA + Lenvima presented superior OS vs chemotherapy in patients who were pMMR at the final analysis (nominal p-value)[1–3]



A **30% reduction in the risk of death** was presented with KEYTRUDA + Lenvima vs chemotherapy in the pMMR population (HR 0.70, 95% CI: 0.58–0.83; **nominal** p-value<0.0001)

Analysis cut-off date: 1 March 2022.

Figure adapted from Makker V et al. *Presented at ESMO* 2022. Tick marks indicate censored data.

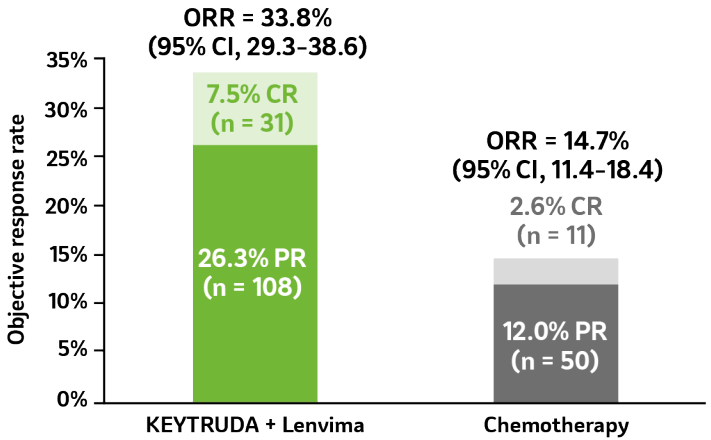
CI, confidence interval; HR, hazard ratio; ITT, intention-to-treat; mo, month; OS, overall survival; pMMR, mismatch repair proficient..

1. Makker V et al. *N Engl J Med* 2022;386:437–448; 2. KEYTRUDA (pembrolizumab) SmPC. Available at: https://www.medicines.org.uk/emc/product/2498/smpc. Accessed January 2025; 3. MSD data on file.

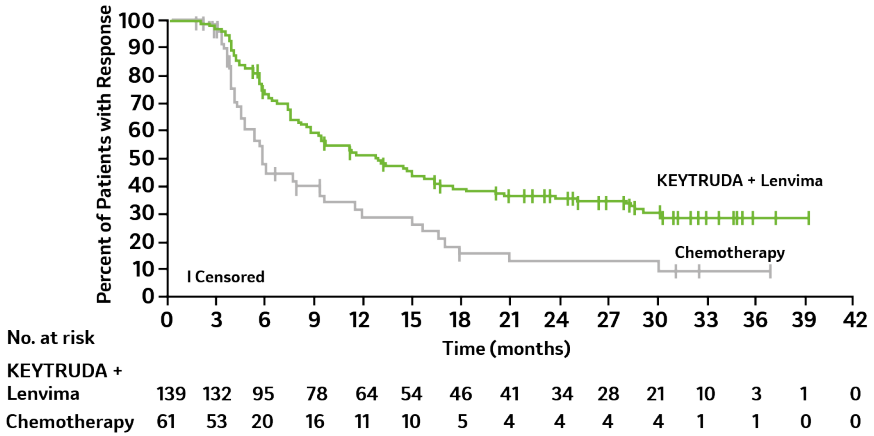
Prescribing Information: KEYTRUDA UK ; Lenvima UK

KEYNOTE-775: KEYTRUDA + Lenvima presented superior ORR and DOR vs chemotherapy in all patients (final analysis)

All-comer ORR[a]



All-comer DOR[b]



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

A tabular view of objective responses and duration of response is shown in the appendix. Click here to view.

Analysis cut-off date: 1 March 2022.

Figures adapted from Makker V et al. *Presented at ESMO* 2022. Tick marks indicate censored data.

[a]95% CI based on binomial exact CI method. Only confirmed CRs and PRs are included in ORR.. DCR: KEYTRUDA + Lenvima 72.3 (67.7–76.5), chemotherapy 46.6 (41.8–51.6). At the interim analysis, 18 (KEYTRUDA + Lenvima) and 9 (chemotherapy) patients with pMMR tumours had a CR of 27 (KEYTRUDA + Lenvima) and 11 (chemotherapy) patients in the all-comer population had a CR; [b]Median DOR is derived from product-limit KM method for censored data and includes patients with CR or PR. Median TTR (for patients with CR or PR): KEYTRUDA + Lenvima 2.1 (1.5–23.3), chemotherapy 2.1 (1.0–7.4).

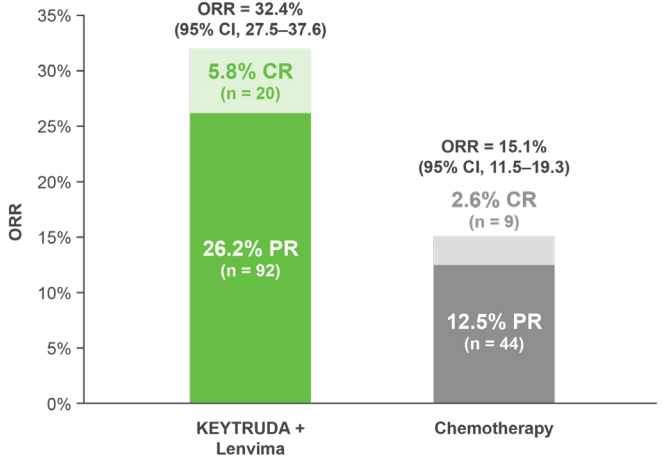
BOR, best objective response; CI, confidence interval; CR, complete response; DCR, sum of the complete, partial and stable disease rates; DOR, duration of response; ORR, objective response rate; PR, partial response; SD, stable disease; TTR, time to response.

Makker V et al. Slide deck presented at: European Society for Medical Oncologists (ESMO) Virtual Annual Meeting; September 9-13, 2022.

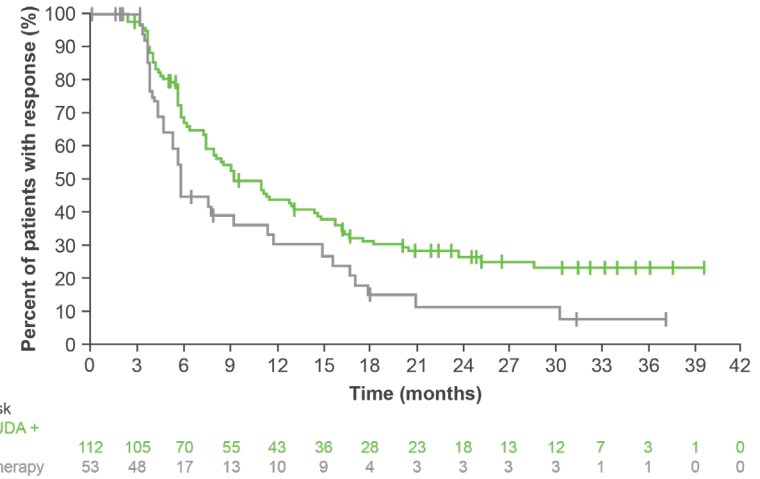
Prescribing Information: KEYTRUDA UK ; Lenvima UK

KEYNOTE-775: KEYTRUDA + Lenvima presented superior ORR and DOR vs chemotherapy in patients who were pMMR (final analysis)

pMMR ORR[a]



pMMR DOR[b]



32.4% of patients achieved an objective response with KEYTRUDA + Lenvima vs 15.1% of patients receiving chemotherapy

Median DOR was 9.3 months (95% CI: 1.6–39.5) with KEYTRUDA + Lenvima vs 5.7 months (95% CI: 0.0–37.1) with chemotherapy

A tabular view of objective responses and duration of response is shown in the appendix. Click here to view.

Analysis cut-off date: 1 March 2022.

Figures adapted from Makker V et al. *Presented at ESMO* 2022. Tick marks indicate censored data.

[a]95% CI based on binomial exact CI method. Only confirmed CRs and PRs are included in ORR. DCR (BOR of CR, PR or SD at 7 weeks or more after randomisation): KEYTRUDA + Lenvima ,72.0 (66.9–76.6), chemotherapy 46.4 (41.1–51.8). DCR: KEYTRUDA + Lenvima 72.3 (67.7–76.5), chemotherapy 46.6 (41.8–51.6) At the interim analysis, 18 (KEYTRUDA + Lenvima) and 9 (chemotherapy) patients with pMMR tumours had a CR of 27 (KEYTRUDA + Lenvima) and 11 (chemotherapy) patients in the all-comer population had a CR; [b]Median DOR is derived from product-limit KM method for censored data and includes patients with CR or PR. Median TTR (for patients with CR or PR): KEYTRUDA + Lenvima 2.1 (1.5–23.0), chemotherapy 3.5 (1.0–7.4).

CI, confidence interval; CR, complete response; DOR, duration of response; ORR, objective response rate; PR, partial response; SD, stable disease; TTR, time to response.

Makker V et al. Slide deck presented at: European Society for Medical Oncologists (ESMO) Virtual Annual Meeting; September 9-13, 2022.

Prescribing Information: KEYTRUDA UK ; Lenvima UK

KEYNOTE-775: 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 reductions[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)

For further information on the safety of KEYTRUDA + Lenvima, please refer to the SmPC: United Kingdom

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

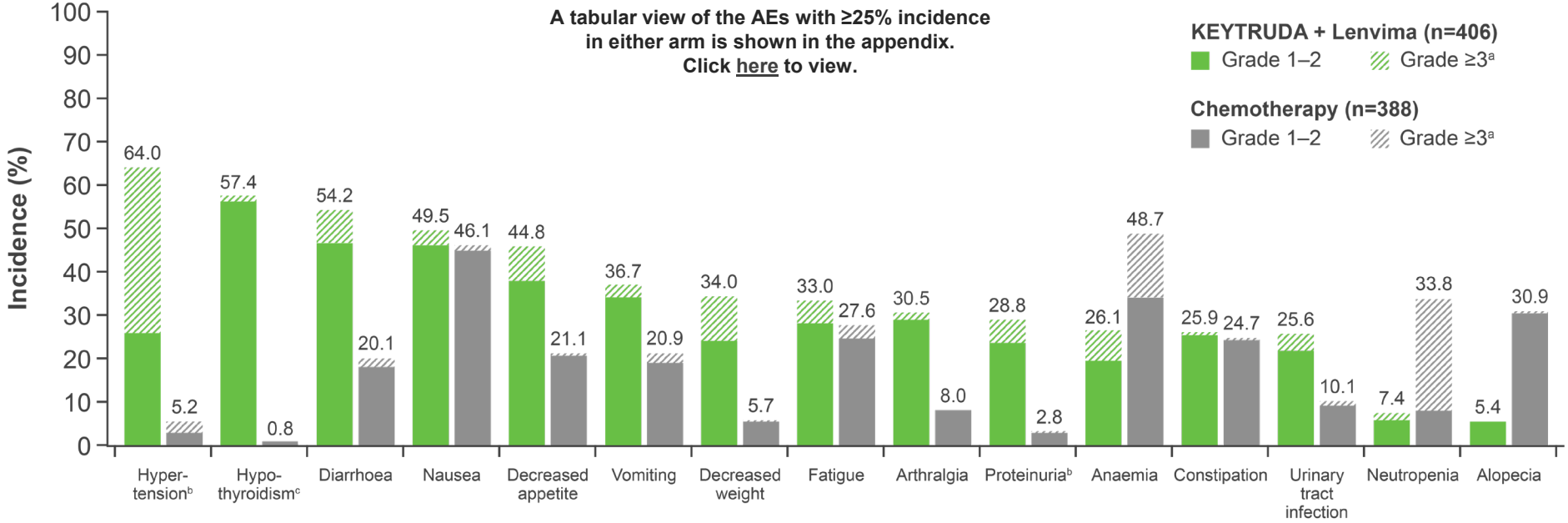
AE, adverse event; SmPC, Summary of Product Characteristics.

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

Prescribing Information: KEYTRUDA UK ; Lenvima UK

KEYNOTE-775: AEs with ≥25% incidence in either arm

A tabular view of the AEs with ≥25% incidence in either arm is shown in the appendix. Click here to view.

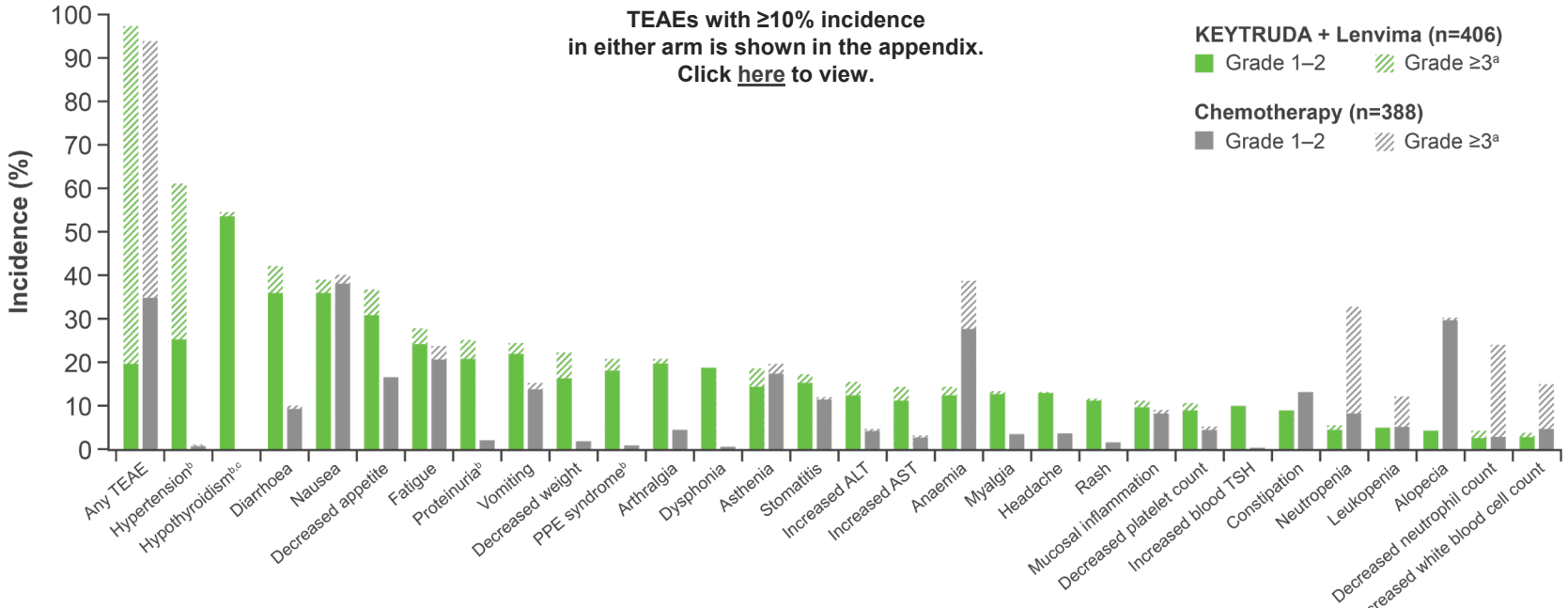


For further information on the safety of KEYTRUDA + Lenvima, please refer to the SmPC: United Kingdom

Analysis cut-off date: 26 October 2020. [a]Among patients who received KEYTRUDA + Lenvima, 5.7% died due to Grade 5 AEs (GI disorder in 1.2% of patients, cardiac disorder in 0.5%, general disorder in 1.5%, infection in 0.7%, decreased appetite in 0.2%, and neoplasms, nervous system disorder, psychiatric disorder, renal disorder, reproductive disorder or respiratory disorder in 0.2% each). Among patients who received chemotherapy, 4.9% died due to Grade 5 AEs (cardiac disorder in 1.0%, general disorder in 1.3%, infection in 1.5%, subdural haematoma in 0.3% and respiratory disorder in 0.8%); [b]Clinically significant AE with Lenvima; [c]AE of interest with KEYTRUDA.
Figure adapted from Makker V et al. *N Engl J Med* 2022.
AE, adverse event; GI, gastrointestinal; SmPC, Summary of Product Characteristics.
Makker V et al. *N Engl J Med* 2022;386:437–448.

Prescribing Information: KEYTRUDA UK ; Lenvima UK

KEYNOTE-775: Treatment-emergent adverse events with ≥10% incidence in either arm



For further information on the safety of KEYTRUDA + Lenvima, please refer to the SmPC: United Kingdom

Analysis cut-off date: 26 October 2020.

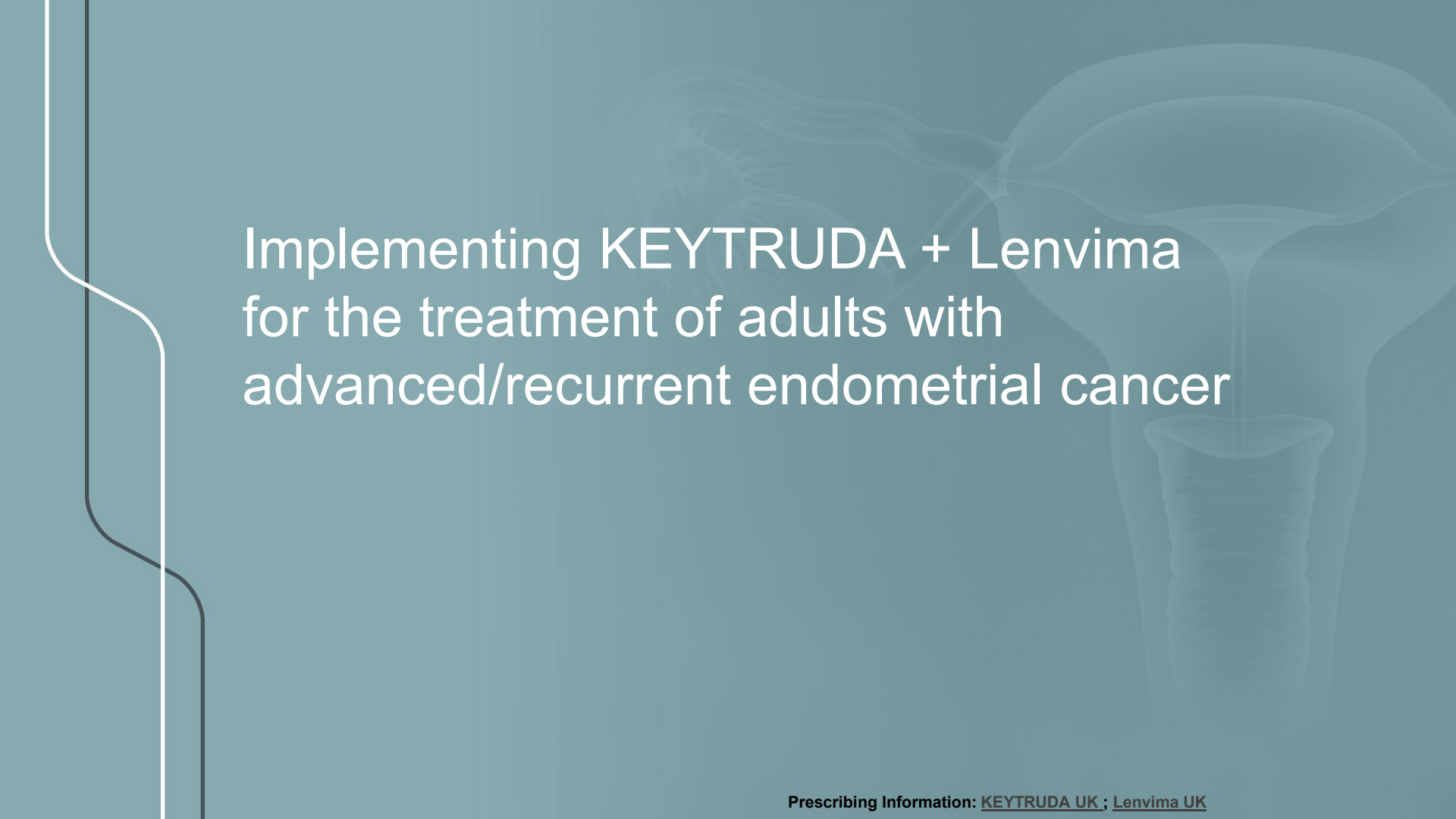
[a]TEAEs led to death in 1.5% of patients in the KEYTRUDA + Lenvima group (cardiac disorder [n=1]; gastrointestinal disorder [n=1]; general disorders and administration site conditions [n=2]; benign, malignant and unspecified neoplasms [n=1]; nervous system disorders [n=1]), and 2.1% of patients in the chemotherapy group (cardiac disorders [n=3]; infections and infestations [n=3]; respiratory, thoracic, mediastinal disorders [n=2]); [b]Clinically significant AEs for Lenvima in all patients; [c]AE of interest for KEYTRUDA in all patients. Figure adapted from Makker V et al. *N Engl J Med* 2022 (supplementary appendix).

AE, adverse event; ALT, alanine aminotransferase; AST, aspartate aminotransferase; PPE, palmar–plantar erythrodysesthesia; SmPC, Summary of Product Characteristics; TEAE, treatment-emergent adverse event; TSH, thyroid-stimulating hormone

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

Prescribing Information: KEYTRUDA UK ; Lenvima UK

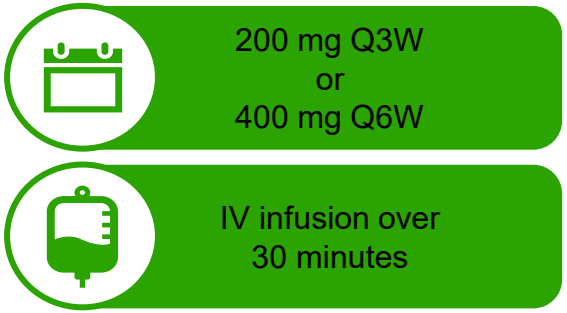
Implementing KEYTRUDA + Lenvima for the treatment of adults with advanced/recurrent endometrial cancer



Prescribing Information: KEYTRUDA UK ; Lenvima UK

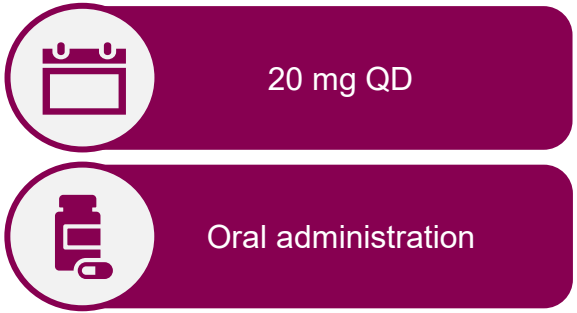
KEYTRUDA + Lenvima dosing

KEYTRUDA[1]



- Continue treatment with KEYTRUDA until disease progression or unacceptable toxicity occurs
- No dose reductions of KEYTRUDA are recommended. KEYTRUDA should be withheld or discontinued to manage AEs as described in the SmPC
- Immune-related AEs, including severe and fatal cases, have occurred in patients receiving KEYTRUDA
  - Please refer to the SmPC for further information on KEYTRUDA dosing: United Kingdom

Lenvima[2]



- Continue treatment with Lenvima for as long as there is clinical benefit or until unacceptable toxicity occurs
- For AEs thought to be related to Lenvima, upon resolution/improvement of an AE to Grade 0–1 or baseline, treatment should be resumed at a reduced dose of Lenvima
  - Please refer to the SmPC for further information on Lenvima dosing: United Kingdom

AE, adverse event; IV, intravenous; Q3W, every 3 weeks; Q6W, every 6 weeks; QD, once daily; SmPC, Summary of Product Characteristics.

1. KEYTRUDA (pembrolizumab) SmPC. Available at: https://www.medicines.org.uk/emc/product/2498/smpc. Accessed January 2025;
2. LENVIMA (lenvatinib) SmPC. Available at: https://www.medicines.org.uk/emc/product/6840/smpc. Accessed January 2025.

Prescribing Information: KEYTRUDA UK ; Lenvima UK

KEYNOTE-775: Summary

KEYNOTE-775: Summary of efficacy and safety in the ITT population

KEYTRUDA + Lenvima showed statistically significant (interim analysis), clinically meaningful improvements in PFS and OS vs chemotherapy in all patients with advanced, metastatic or recurrent endometrial cancer

KEYTRUDA + Lenvima presented a higher PFS vs chemotherapy (final analysis)

- Median (95% CI) PFS: 7.3 (5.7–7.6) months with KEYTRUDA + Lenvima vs 3.8 (3.6–4.2) months with chemotherapy (HR 0.56, 95% CI: 0.48–0.66; nominal p-value<0.0001)

KEYTRUDA + Lenvima presented a higher OS vs chemotherapy (final analysis)

- Median (95% CI) OS: 18.7 (15.6–21.3) months with KEYTRUDA + Lenvima vs 11.9 (10.7–13.3) months with chemotherapy (HR 0.65, 95% CI: 0.55–0.77; nominal p-value<0.0001)

Safety data were generally consistent with the known AE profiles of each agent (final analysis)

- Grade ≥3 AEs occurred in 88.9% of patients in the KEYTRUDA + Lenvima arm and 72.7% of patients in the chemotherapy arm
- Of those treated, patients in the KEYTRUDA + Lenvima arm had a higher proportion of discontinuations of any trial agent (33.0%) compared with patients in the chemotherapy arm (8.0%)
    - The main reason for discontinuation in both treatment arms was disease progression

AE, adverse event; CI, confidence interval; HR, hazard ratio; ITT, intention-to-treat; OS, overall survival; PFS, progression-free survival.

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

Prescribing Information: KEYTRUDA UK ; Lenvima UK

KEYNOTE-775: Appendix

Click the links below to navigate to the section of interest

- PFS in key subgroups (ITT population)
- PFS in key subgroups (pMMR population)
- OS in key subgroups (ITT population)
- OS in key subgroups (pMMR population)
- Objective responses in the ITT and pMRR populations
- Objective responses in the dMMR population
- AEs with ≥25% incidence in either arm
- TEAEs with ≥10% incidence in either arm (1)
- TEAEs with ≥10% incidence in either arm (2)
- QoL

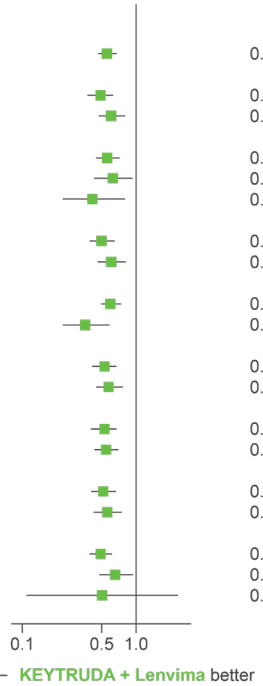
AE, adverse event; dMMR, mismatch repair deficient; ITT, intention-to-treat; OS, overall survival; PFS, progression-free survival; pMMR, mismatch repair proficient; QoL, quality of life.

Prescribing Information: KEYTRUDA UK ; Lenvima UK

KEYNOTE-775: PFS in key subgroups (ITT population)

No formal statistical analysis was performed for the subgroup analyses and no clinical conclusions can be drawn

Subgroup	KEYTRUDA + Lenvima No. of events/N	Chemotherapy No. of events/N	HR (95% CI)
Overall	281/411	286/416	0.56 (0.47–0.66)
Age, yr			
<65	138/206	146/204	0.49 (0.38–0.62)
≥65	143/205	140/212	0.61 (0.48–0.78)
Race			
White	177/261	163/246	0.56 (0.45–0.70)
Asian	59/85	62/92	0.63 (0.44–0.91)
Other	20/29	28/34	0.42 (0.23–0.78)
Region			
Region 1[a]	160/234	169/240	0.50 (0.40–0.63)
Region 2[b]	121/177	117/176	0.61 (0.47–0.79)
MMR status			
pMMR	247/346	238/351	0.60 (0.50–0.72)
dMMR	34/65	48/65	0.36 (0.23–0.57)
ECOG PS			
0	166/246	162/241	0.53 (0.42–0.66)
1	115/164	124/175	0.58 (0.45–0.75)
Prior history of pelvic radiation			
Yes	114/174	123/186	0.53 (0.41–0.69)
No	167/237	163/230	0.55 (0.44–0.68)
Histology			
Endometrioid	150/243	173/254	0.52 (0.41–0.65)
Non-endometrioid	131/168	113/162	0.56 (0.43–0.73)
Prior lines of therapy			
1	207/297	203/277	0.49 (0.40–0.60)
2	71/103	79/126	0.66 (0.48–0.92)
≥3	3/11	4/13	0.51 (0.11–2.30)



Analysis cut-off date: 26 October 2020.

[a]Europe, USA, Canada, Australia, New Zealand and Israel; [b]Rest of world. Figures adapted from Makker V et al. *N Engl J Med* 2022.

CI, confidence interval; dMMR, mismatch repair deficient; ECOG PS, Eastern Cooperative Oncology Group performance status; ITT, intention-to-treat; PFS, progression-free survival; MMR, mismatch repair; pMMR, mismatch repair proficient.

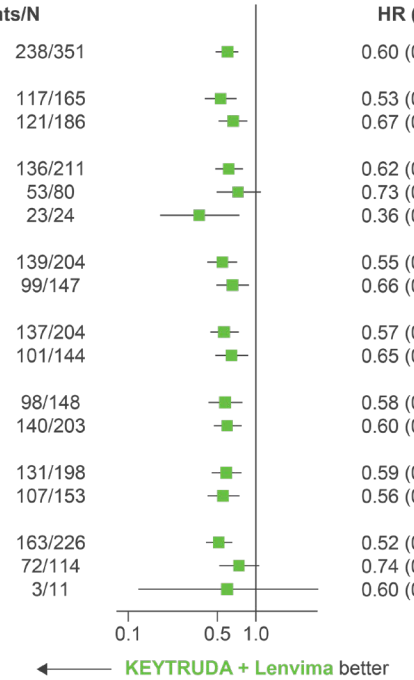
Makker V et al. *N Engl J Med* 2022;386:437–448 (supplementary appendix).

Prescribing Information: KEYTRUDA UK ; Lenvima UK

KEYNOTE-775: PFS in key subgroups (pMMR population)

No formal statistical analysis was performed for the subgroup analyses and no clinical conclusions can be drawn

Subgroup	KEYTRUDA + Lenvima No. of events/N	Chemotherapy No. of events/N	HR (95% CI)
Overall	247/346	238/351	0.60 (0.50–0.72)
Age, yr			
<65	118/171	117/165	0.53 (0.41–0.69)
≥65	129/175	121/186	0.67 (0.52–0.86)
Race			
White	154/220	136/211	0.62 (0.49–0.78)
Asian	55/74	53/80	0.73 (0.50–1.08)
Other	16/23	23/24	0.36 (0.18–0.73)
Region			
Region 1[a]	144/202	139/204	0.55 (0.43–0.70)
Region 2[b]	103/144	99/147	0.66 (0.50–0.87)
ECOG PS			
0	149/212	137/204	0.57 (0.45–0.72)
1	98/133	101/144	0.65 (0.49–0.86)
Prior history of pelvic radiation			
Yes	97/142	98/148	0.58 (0.43–0.77)
No	150/204	140/203	0.60 (0.48–0.76)
Histology			
Endometrioid	122/188	131/198	0.59 (0.46–0.76)
Non-endometrioid	125/158	107/153	0.56 (0.43–0.73)
Prior lines of therapy			
1	177/244	163/226	0.52 (0.42–0.65)
2	67/92	72/114	0.74 (0.53–1.04)
≥3	3/10	3/11	0.60 (0.12–3.07)



Analysis cut-off date: 26 October 2020.

[a]Europe, USA, Canada, Australia, New Zealand and Israel; [b]Rest of world. Figures adapted from Makker V et al. *N Engl J Med* 2022.

CI, confidence interval; ECOG PS, Eastern Cooperative Oncology Group performance status; PFS, progression-free survival; pMMR, mismatch repair proficient.

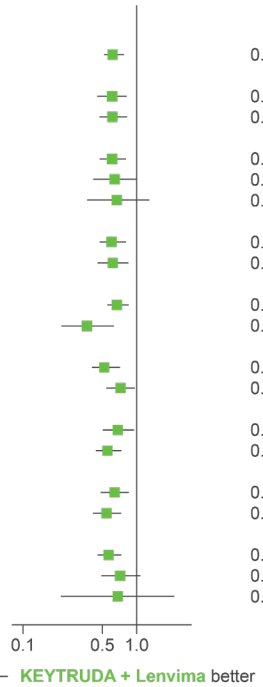
Makker V et al. *N Engl J Med* 2022;386:437–448 (supplementary appendix).

Prescribing Information: KEYTRUDA UK ; Lenvima UK

KEYNOTE-775: OS in key subgroups (ITT population)

No formal statistical analysis was performed for the subgroup analyses and no clinical conclusions can be drawn

Subgroup	KEYTRUDA + Lenvima No. of events/N	Chemotherapy No. of events/N	HR (95% CI)
Overall	188/411	245/416	0.62 (0.51–0.75)
Age, yr			
<65	89/206	116/204	0.61 (0.46–0.80)
≥65	99/205	129/212	0.62 (0.48–0.81)
Race			
White	117/261	141/246	0.61 (0.48–0.79)
Asian	36/85	51/92	0.65 (0.42–0.99)
Other	19/29	25/34	0.68 (0.37–1.26)
Region			
Region 1[a]	110/234	145/240	0.61 (0.48–0.79)
Region 2[b]	78/177	100/176	0.62 (0.46–0.84)
MMR status			
pMMR	165/346	203/351	0.68 (0.56–0.84)
dMMR	23/65	42/65	0.37 (0.22–0.62)
ECOG PS			
0	91/246	131/241	0.53 (0.41–0.70)
1	96/164	114/175	0.73 (0.55–0.95)
Prior history of pelvic radiation			
Yes	77/174	99186	0.69 (0.51–0.93)
No	111/237	146/230	0.56 (0.44–0.72)
Histology			
Endometrioid	95/243	127/254	0.65 (0.49–0.84)
Non-endometrioid	93/168	118/162	0.55 (0.42–0.72)
Prior lines of therapy			
1	136/297	172/277	0.57 (0.46–0.72)
2	47/103	65/126	0.72 (0.50–1.06)
≥3	5/11	8/13	0.69 (0.22–2.10)



Analysis cut-off date: 26 October 2020.

[a]Europe, USA, Canada, Australia, New Zealand and Israel. [b]Rest of world. Figures adapted from Makker V et al. *N Engl J Med* 2022.

CI, confidence interval; dMMR, mismatch repair deficient; ECOG PS, Eastern Cooperative Oncology Group performance status; ITT, intention-to-treat; MMR, mismatch repair; OS, overall survival; pMMR, mismatch repair proficient.

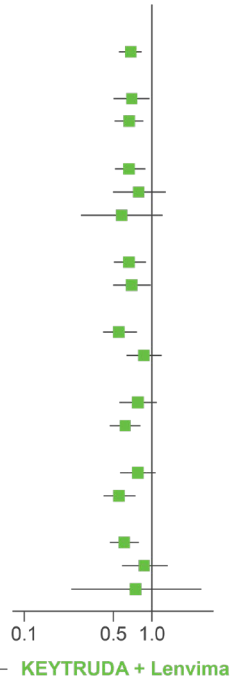
Makker V et al. *N Engl J Med* 2022;386:437–448 (supplementary appendix).

Prescribing Information: KEYTRUDA UK ; Lenvima UK

KEYNOTE-775: OS in key subgroups (pMMR population)

No formal statistical analysis was performed for the subgroup analyses and no clinical conclusions can be drawn

Subgroup	KEYTRUDA + Lenvima No. of events/N	Chemotherapy No. of events/N	HR (95% CI)
Overall	165/346	203/351	0.68 (0.56–0.84)
Age, yr			
<65	78/171	92/165	0.70 (0.51–0.94)
≥65	87/175	111/186	0.67 (0.51–0.89)
Race			
White	102/220	119/211	0.62 (0.52–0.88)
Asian	34/74	43/80	0.79 (0.50–1.24)
Other	15/23	19/24	0.58 (0.28–1.18)
Region			
Region 1[a]	98/202	121/204	0.67 (0.51–0.88)
Region 2[b]	67/144	82/147	0.70 (0.50–0.96)
ECOG PS			
0	82/212	114/207	0.56 (0.42–0.75)
1	82/133	89/144	0.87 (0.64–1.18)
Prior history of pelvic radiation			
Yes	66/142	78/148	0.78 (0.56–1.08)
No	99/204	125/203	0.62 (0.47–0.80)
Histology			
Endometrioid	76/188	91/198	0.78 (0.57–1.05)
Non-endometrioid	89/158	112/153	0.56 (0.42–0.74)
Prior lines of therapy			
1	114/244	140/226	0.61 (0.47–0.78)
2	46/92	56/114	0.88 (0.59–1.30)
≥3	5/10	7/11	0.75 (0.24–2.37)



Analysis cut-off date: 26 October 2020.

[a]Europe, USA, Canada, Australia, New Zealand and Israel. [b]Rest of world. Figures adapted from Makker V et al. *N Engl J Med* 2022.

CI, confidence interval; dMMR, mismatch repair deficient; ECOG PS, Eastern Cooperative Oncology Group performance status; ITT, intention-to-treat; OS, overall survival; pMMR, mismatch repair proficient.

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

Prescribing Information: KEYTRUDA UK ; Lenvima UK

KEYNOTE-775: Objective responses in the pMMR and all-comers populations (final analysis)

	pMMR population		All-comer population	
Endpoint	**KEYTRUDA + Lenvima (n=346)**	**Chemotherapy (n=351)**	**KEYTRUDA + Lenvima (n=411)**	**Chemotherapy (n=416)**
ORR difference %, (95% CI)[a]	17.2 (11.0–23.5)		19.2 (13.4–24.9)	
% (95% CI) [b]	32.4 (27.5–37.6)	15.1 (11.5–19.3)	33.8 (39.3–38.6)	14.7 (11.4–18.4)
BOR, % (95% CI) [a]				
CR[c]	5.8 (3.6–8.8)	2.6 (1.2–4.8)	7.5 (5.2–10.5)	2.6 (1.3–4.7)
PR[c]	26.6 (22.0–31.6)	12.5 (9.3–16.5)	26.3 (22.1–30.8)	12.0 (9.1–15.5)
SD	46.5 (41.2–51.9)	39.6 (34.4–44.9)	45.0 (40.1–50.0)	40.1 (35.4–45.0)
PD	15.6 (11.9–19.9)	30.8 (26.0–35.9)	14.8 (11.5–18.7)	29.6 (25.2–34.2)
NE[d]	0.6 (0.1–2.1)	2.0 (0.8–4.1)	1.2 (0.4–2.8)	1.9 (0.8–3.8)
NA[e]	4.9 (2.9–7.8)	12.5 (9.3–16.5)	5.1 (3.2–7.7)	13.7 (10.5–17.4)
Disease control rate, % (95% CI) [a,f]	72.0 (66.9–76.6)	46.4 (41.1–51.8)	72.3 (67.7–76.5)	46.6 (41.8–51.6)
Median DOR[g,h]	9.3 (1.6–39.5)	5.7 (0.0–37.1)	12.9 (1.6–39.5)	5.7 (0.0–37.1)
Median TTR[h]	2.1 (1.5–23.0)	3.5 (1.0–7.4)	2.1 (1.5–23.0)	2.1 (1.0–7.4)

Analysis cut-off date: 1 March 2022.

a95% CI based on binomial exact CI method; bbased on Miettinen & Nurminen method stratified by MMR status; ECOG PS, geographic region and prior history of pelvic radiation (for all-comer population and pMMR populations; cFor best OR of CR or PR, only confirmed responses are included; dPost-baseline assessment(s) available, but NE; eNo post-baseline assessment available for response evaluation; fDefined as BOR of CR, PR or SD at 7 weeks or more after randomisation; gFrom product-limit (Kaplan—Meier) method for censored data;hIncludes participants with CR or PR.

BOR, best overall response; CI, confidence interval; CR, complete response; DOR, duration of response; ITT, intention-to-treat; mo, months; MMR, mismatch repair; NA, not assessed; NE, not estimable; ORR, objective respor PD, progressive disease; PR, partial response; SD, stable disease; TTR, time to response.

Makker V et al. Slide deck presented at: European Society for Medical Oncologists (ESMO) Virtual Annual Meeting; September 9-13, 2022.

Prescribing Information: KEYTRUDA UK ; Lenvima UK

KEYNOTE-775: Objective responses in the dMMR population

Endpoint	KEYTRUDA + Lenvima (n=411)	Chemotherapy (n=416)
ORR		
n	26	8
% (95% CI)	40 (28–53)	12 (5–23)
BOR		
CR		
n	9	2
% (95% CI)	14 (7–25)	3 (<1–11)
PR		
n	17	6
% (95% CI)	26 (16–39)	9 (3–19)
SD		
n	25	28
% (95% CI)	38 (27–51)	43 (31–56)

Endpoint	KEYTRUDA + Lenvima (n=411)	Chemotherapy (n=416)
BOR (continued)		
PD		
n	7	15
% (95% CI)	11 (4–21)	23 (14–35)
NE		
n	3	1
% (95% CI)	5 (1–13)	2 (0–8)
NA		
n	4	13
% (95% CI)	6 (2–15)	20 (11–32)
Median DOR (range), mo	NR (2.1–20.4)	4.1 (1.9–15.6)
Median TTR (range), mo	2.9 (1.7–16.3)	1.9 (1.8–3.7)
Disease control		
n	48	31
% (95% CI)	74 (61–84)	48 (35–60)

Analysis cut-off date: 1 March 2022.

Table adapted from Makker V et al. *N Engl J Med* 2022.

BOR, best overall response; CI, confidence interval; CR, complete response; dMMR, mismatch repair deficient; DOR, duration of response; mo, months; NA, not assessed; NE, not estimable; NR, not reached; ORR, objective response rate; PD, progressive disease; PR, partial response; SD, stable disease; TTR, time to response.

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

Prescribing Information: KEYTRUDA UK ; Lenvima UK

KEYNOTE-775: AEs with ≥25% incidence in either arm

AE, n (%)	KEYTRUDA + Lenvima (n=406)		Chemotherapy (n=388)	
	Any grade	Grade ≥3[a]	Any grade	Grade ≥3[a]
Hypertension[b]	260 (64.0)	154 (37.9)	20 (5.2)	9 (2.3)
Hypothyroidism[c]	233 (57.4)	5 (1.2)	3 (0.8)	0
Diarrhoea	220 (54.2)	31 (7.6)	78 (20.1)	8 (2.1)
Nausea	201 (49.5)	14 (3.4)	179 (46.1)	5 (1.3)
Decreased appetite	182 (44.8)	32 (7.9)	82 (21.1)	2 (0.5)
Vomiting	149 (36.7)	11 (2.7)	81 (20.9)	9 (2.3)
Decreased weight	138 (34.0)	42 (10.3)	22 (5.7)	1 (0.3)
Fatigue	134 (33.0)	21 (5.2)	107 (27.6)	12 (3.1)
Arthralgia	124 (30.5)	7 (1.7)	31 (8.0)	0
Proteinuria[b]	117 (28.8)	22 (5.4)	11 (2.8)	1 (0.3)
Anaemia	106 (26.1)	25 (6.2)	189 (48.7)	57 (14.7)
Constipation	105 (25.9)	3 (0.7)	96 (24.7)	2 (0.5)
Urinary tract infection	104 (25.6)	16 (3.9)	39 (10.1)	4 (1.0)
Neutropenia	30 (7.4)	7 (1.7)	131 (33.8)	100 (25.8)
Alopecia	22 (5.4)	0	120 (30.9)	2 (0.5)

For further information on the safety of KEYTRUDA + Lenvima, please refer to the SmPC: United Kingdom

[a]Among patients who received KEYTRUDA + Lenvima, 5.7% died due to Grade 5 AEs (GI disorder in 1.2% of patients, cardiac disorder in 0.5%, general disorder in 1.5%, infection in 0.7%, decreased appetite in 0.2%, and neoplasms, nervous system disorder, psychiatric disorder, renal disorder, reproductive disorder or respiratory disorder in 0.2% each). Among patients who received chemotherapy, 4.9% died due to Grade 5 AEs (cardiac disorder in 1.0%, general disorder in 1.3%, infection in 1.5%, subdural haematoma in 0.3% and respiratory disorder in 0.8%); [b]Clinically significant AE with Lenvima; [c]AE of interest with KEYTRUDA. Table adapted from Makker V et al. *N Engl J Med* 2022.

AE, adverse event; GI, gastrointestinal; SmPC, Summary of Product Characteristics.

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

Prescribing Information: KEYTRUDA UK ; Lenvima UK

KEYNOTE-775: Treatment-emergent adverse events with ≥10% incidence in either arm (1)

AE, n (%)	KEYTRUDA + Lenvima (n=406)		Chemotherapy (n=388)	
	Any grade	Grade ≥3[a]	Any grade	Grade ≥3[a]
Any TEAE	395 (97.3)	316 (77.8)	364 (93.8)	229 (59.0)
Hypertension[b]	248 (61.1)	146 (35.9)	4 (1.0)	1 (0.3)
Hypothyroidism[b,c]	221 (54.4)	4 (1.0)	0	0
Diarrhoea	171 (42.1)	25 (6.2)	42 (10.8)	3 (0.8)
Nausea	158 (38.9)	12 (3.0)	157 (40.5)	4 (1.0)
Decreased appetite	149 (36.7)	24 (5.9)	64 (16.5)	0
Fatigue	113 (27.8)	15 (3.7)	92 (23.7)	12 (3.1)
Proteinuria[b]	102 (25.1)	18 (4.4)	4 (1.0)	0
Vomiting	99 (24.4)	10 (2.5)	59 (15.2)	6 (1.5)
Decreased weight	90 (22.2)	24 (5.9)	7 (1.8)	0
PPE syndrome[b]	84 (20.7)	11 (2.7)	3 (0.8)	0
Arthralgia	84 (20.7)	4 (1.0)	17 (4.4)	0
Dysphonia	76 (18.7)	0	2 (0.5)	0
Asthenia	75 (18.5)	17 (4.2)	76 (19.6)	9 (2.3)
Stomatitis	70 (17.2)	8 (2.0)	46 (11.9)	2 (0.5)

For further information on the safety of KEYTRUDA + Lenvima, please refer to the SmPC: United Kingdom

[a]TEAEs led to death in 1.5% of patients in the KEYTRUDA + Lenvima group (cardiac disorder [n=1]; gastrointestinal disorder [n=1]; general disorders and administration site conditions [n=2]; benign, malignant and unspecified neoplasms [n=1]; nervous system disorders [n=1]), and 2.1% of patients in the chemotherapy group (cardiac disorders [n=3]; infections and infestations [n=3]; respiratory, thoracic, mediastinal disorders [n=2]); [b]Clinically significant AEs for Lenvima in all patients; [c]AE of interest for KEYTRUDA in all patients. Table adapted from Makker V et al. *N Engl J Med* 2022 (supplementary appendix).

AE, adverse event; PPE, palmar–plantar erythrodysesthesia; SmPC, Summary of Product Characteristics; TEAE, treatment-emergent adverse event.

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

Prescribing Information: KEYTRUDA UK ; Lenvima UK

KEYNOTE-775: Treatment-emergent adverse events with ≥10% incidence in either arm (2)

AE, n (%)	KEYTRUDA + Lenvima (n=406)		Chemotherapy (n=388)	
	Any grade	Grade ≥3[a]	Any grade	Grade ≥3[a]
Increased ALT	63 (15.5)	13 (3.2)	14 (3.6)	2 (0.5)
Increased AST	58 (14.3)	13 (3.2)	12 (3.1)	2 (0.5)
Anaemia	58 (14.3)	8 (2.0)	150 (38.7)	43 (11.1)
Myalgia	54 (13.3)	3 (0.7)	13 (3.4)	0
Headache	53 (13.1)	1 (0.2)	14 (3.6)	0
Rash	47 (11.6)	2 (0.5)	6 (1.5)	0
Mucosal inflammation	45 (11.1)	6 (1.5)	35 (9.0)	3 (0.8)
Decreased platelet count	43 (10.6)	7 (1.7)	20 (5.2)	3 (0.8)
Increased blood TSH	40 (9.9)	0	1 (0.3)	0
Constipation	36 (8.9)	0	51 (13.1)	0
Neutropenia	22 (5.4)	4 (1.0)	127 (32.7)	95 (24.5)
Leukopenia	20 (4.9)	0	47 (12.1)	27 (7.0)
Alopecia	17 (4.2)	0	117 (30.2)	2 (0.5)
Decreased neutrophil count	17 (4.2)	7 (1.7)	93 (24.0)	82 (21.2)
Decreased white blood cell count	15 (3.7)	4 (1.0)	58 (14.9)	40 (10.3)

For further information on the safety of KEYTRUDA + Lenvima, please refer to the SmPC: United Kingdom

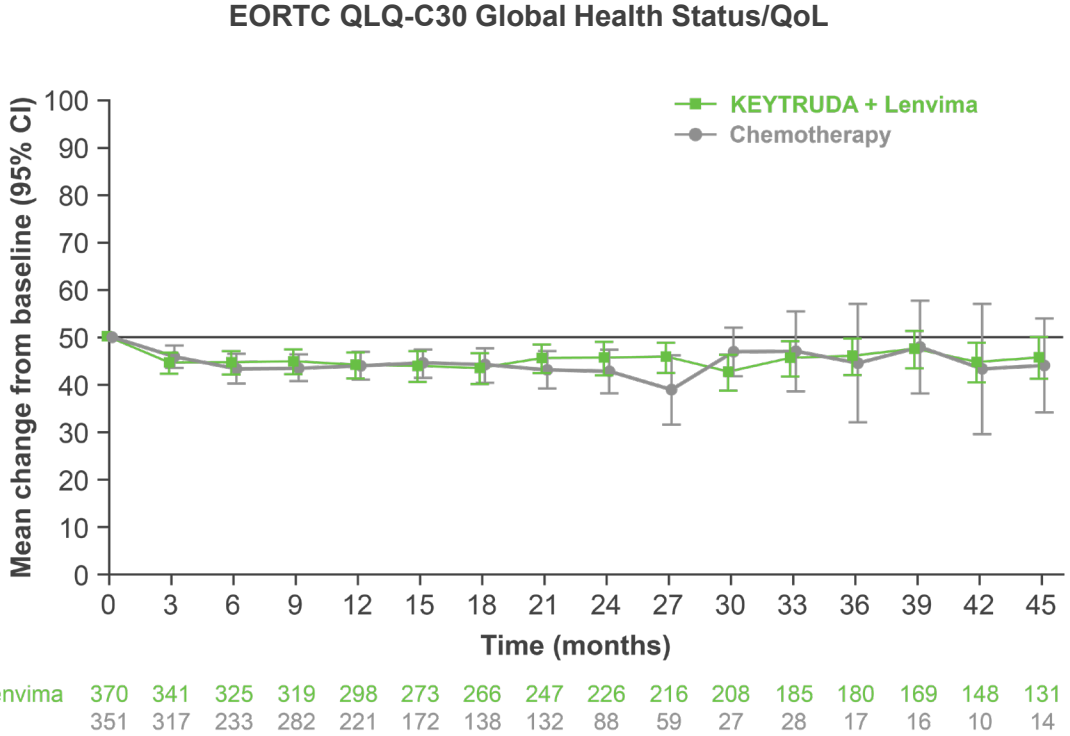
[a]TEAEs led to death in 1.5% of patients in the KEYTRUDA + Lenvima group (cardiac disorder [n=1]; gastrointestinal disorder [n=1]; general disorders and administration site conditions [n=2]; benign, malignant and unspecified neoplasms [n=1]; nervous system disorders [n=1]), and 2.1% of patients in the chemotherapy group (cardiac disorders [n=3]; infections and infestations [n=3]; respiratory, thoracic, mediastinal disorders [n=2]).
Table adapted from Makker V et al. *N Engl J Med* 2022 (supplementary appendix).

AE, adverse event; ALT, alanine aminotransferase; AST, aspartate aminotransferase; SmPC, Summary of Product Characteristics; TEAE, treatment-emergent adverse event; TSH, thyroid-stimulating hormone.

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

Prescribing Information: KEYTRUDA UK ; Lenvima UK

KEYNOTE-775: No substantial between-group differences were observed in the QLQ-C30 global health status QoL scores over time



Analysis cut-off date: 26 October 2020.

Figure adapted from Makker V et al. *N Engl J Med* 2022 (supplementary appendix).

CI, confidence interval; EORTC QLQ-C30, European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire Core 30; QoL, quality of life.

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

Prescribing Information: KEYTRUDA UK ; Lenvima UK