KEYNOTE-522: Neoadjuvant KEYTRUDA® (pembrolizumab) + chemotherapy followed by adjuvant KEYTRUDA monotherapy in patients with triple-negative breast cancer (TNBC)

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Adverse events should be reported. Reporting forms and information can be found at https://yellowcard.mhra.gov.uk/ (please note that the MHRA Yellow Card link will redirect you to an external website, for which MSD does not review or control the content) 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 8154 8000).

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Job code: GB-OBR-00166 Date of preparation: October 2025

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MoA, mechanism of action; TNBC, triple-negative breast cancer.

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MoA, mechanism of action; TNBC, triple-negative breast cancer.

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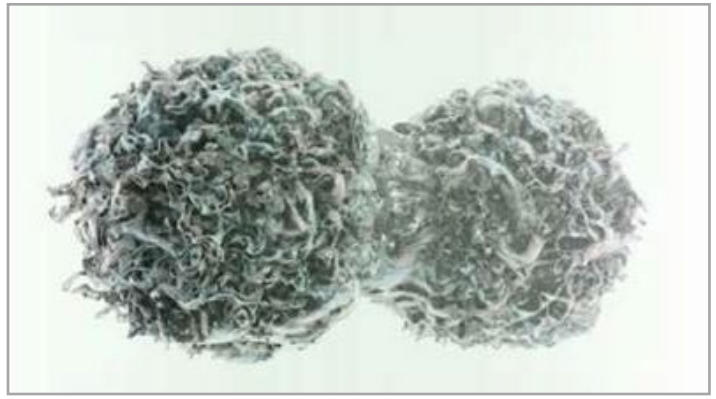
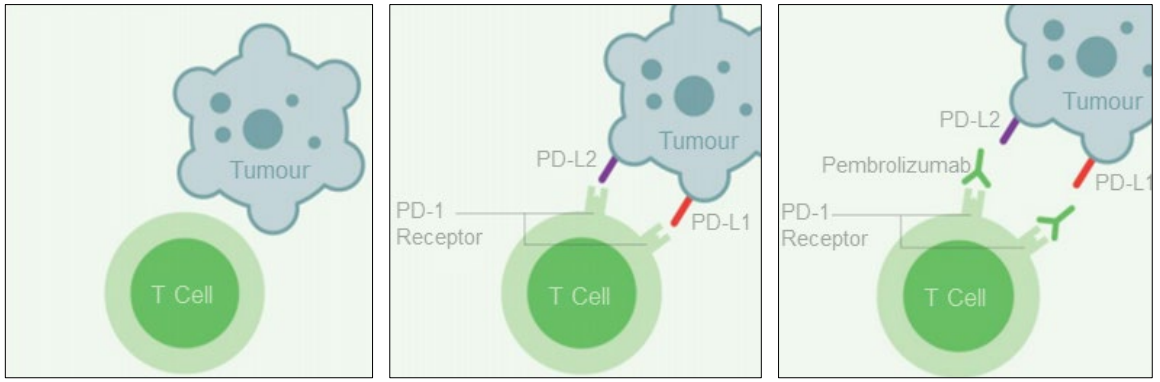
KEYTRUDA and chemotherapy: Two different mechanisms of action

Chemotherapy induces immunogenic cell death



- Chemotherapy results in the immunogenic death of tumour cells, leading to the release of tumour antigens that can be recognised by the immune system[1]
- Chemotherapy has been shown to increase tumour expression of PD-L1[2]

KEYTRUDA activates the anti-tumour immune response



- PD-L1 (and PD-L2) on tumour cells bind to PD-1 on T cells to prevent their activation, leading to immune evasion[1,3]
- KEYTRUDA is a humanised monoclonal antibody that binds to PD-1, blocking its interaction with PD-L1/-L2 and leading to activation of the anti-tumour response[4,5]

When combined with immunotherapies such as KEYTRUDA, chemotherapy may increase tumour immunogenicity and activate an immune response by increasing antigen shedding and presentation, and by stimulating T-cell infiltration[2]

PD-1, programmed death receptor-1; PD-L1, programmed death ligand-1; PD-L2, programmed death ligand-2.

1. Emens LA and Middleton G. *Cancer Immunol Res* 2015;3:436–443; 2. Bailly C et al. *NAR Cancer* 2020;2(1):zcaa002; 3. Yi M et al. *J Hematol Oncol* 2021;14:10;
4. KEYTRUDA (pembrolizumab) Summary of Product Characteristics. Available at: https://www.medicines.org.uk/emc/product/2498/smpc. Accessed August 2025;
5. Pardoll DM. *Nat Rev Cancer* 2012;12:252–264.

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KEYTRUDA + chemotherapy licence in early-stage TNBC

KEYTRUDA, in combination with chemotherapy as neoadjuvant treatment, and then continued as monotherapy as adjuvant treatment after surgery, is indicated in the treatment of adults with locally advanced or early-stage TNBC at high risk of recurrence

TNBC, triple-negative breast cancer.

KEYTRUDA (pembrolizumab) Summary of Product Characteristics. Available at: https://www.medicines.org.uk/emc/product/2498/smpc. Accessed August 2025.

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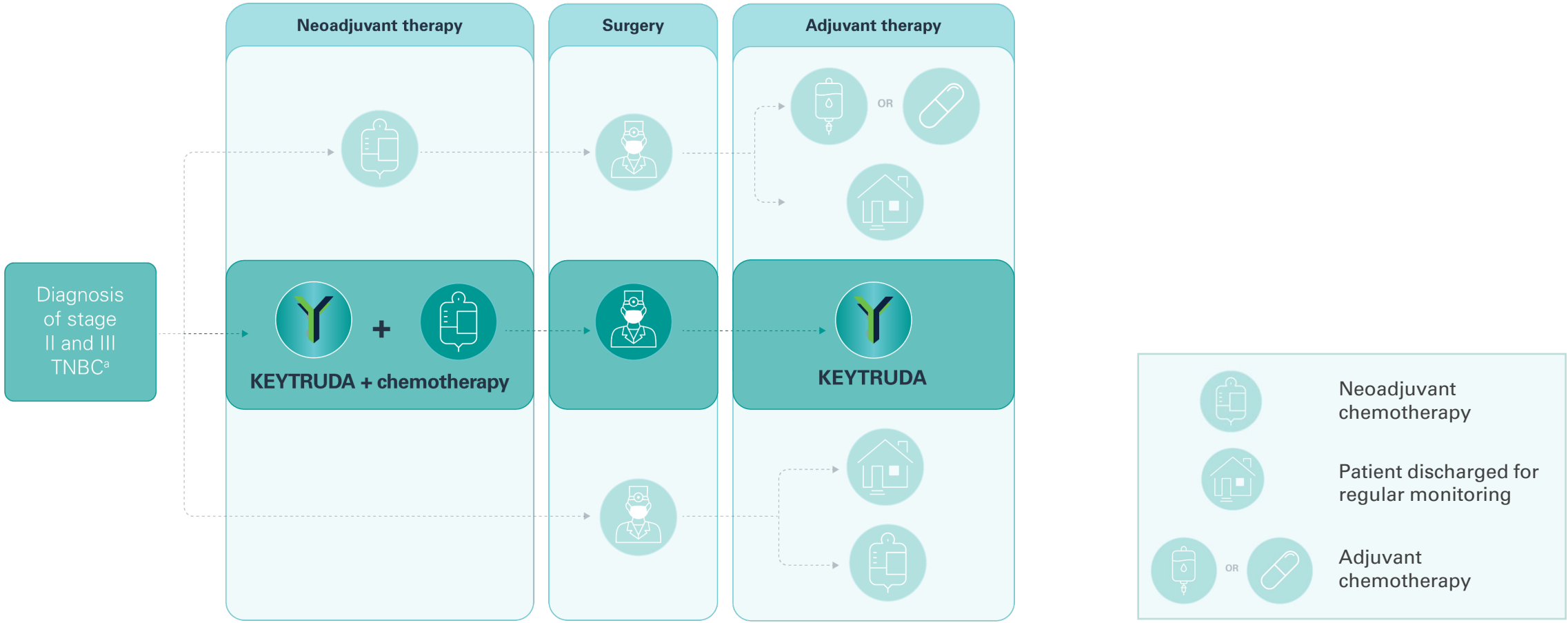
KEYTRUDA in the early-stage TNBC pathway[1–4]



[a]Stage IIA, IIB, IIIA and IIIB early TNBC, and IIIC TNBC, as defined by the primary tumour-regional lymph node staging criteria of the AJCC (7th Edition).[3]

AJCC, American Joint Committee on Cancer; NICE, National Institute for Health and Care Excellence; TNBC, triple-negative breast cancer.

1. NICE. Early and locally advanced breast cancer: diagnosis and management. https://www.nice.org.uk/guidance/ng101/chapter/Recommendations. Accessed August 2025;
2. KEYTRUDA (pembrolizumab) Summary of Product Characteristics. Available at: https://www.medicines.org.uk/emc/product/2498/smpc. Accessed August 2025;
3. AJCC. *AJCC Cancer Staging Manual*. 7th ed. USA: Springer; 2010; 4. NICE. Technology appraisal guidance [TA851] December 2022. Available at: https://www.nice.org.uk/guidance/ta851. Accessed August 2025.

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KEYNOTE-522: Study overview

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Study design

Primary endpoints

Key patient characteristics

Patient baseline characteristics

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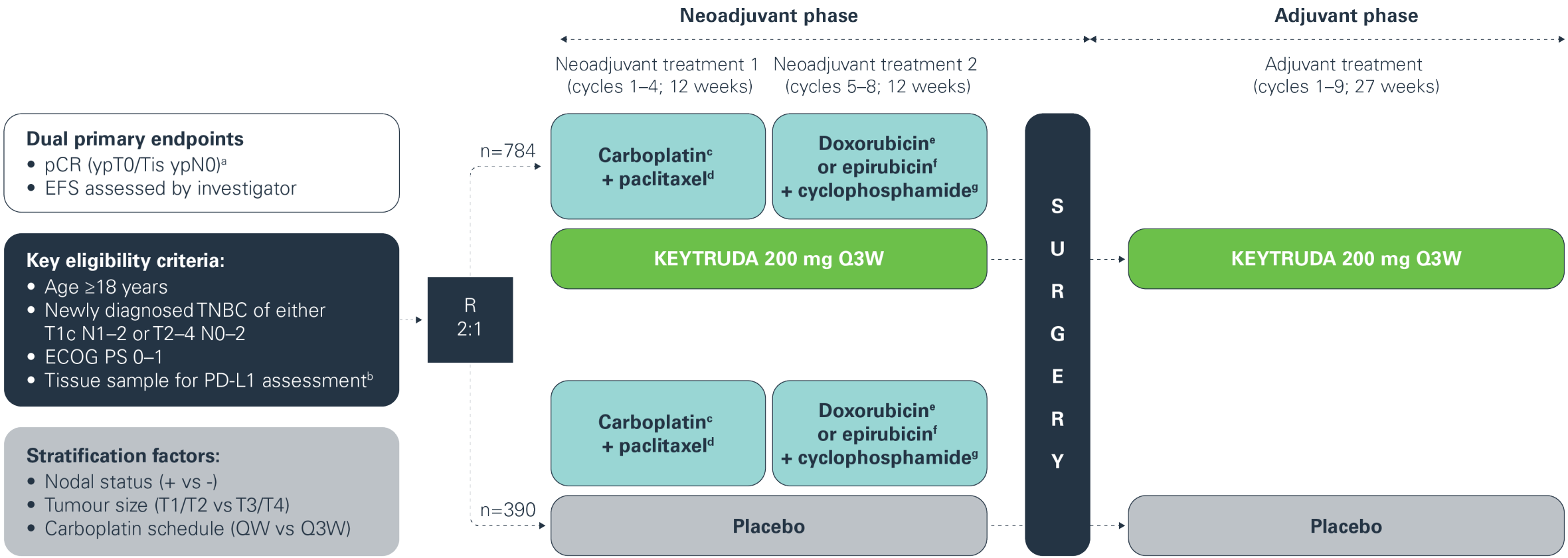
KEYNOTE-522: Study design[1,2]



Adapted from Schmid P et al. 2020 and Schmid P et al. 2022.

AEs were assessed during each phase of the study, as well as the study as a whole.
[a]Blinded assessment performed by local pathologist; [b]Must consist of at least two separate tumour cores from the primary tumour; [c]Carboplatin dose was AUC 5 Q3W or AUC 1.5 QW; [d]Paclitaxel dose was 80 mg/m² QW; [e]Doxorubicin dose was 60 mg/m² Q3W; [f]Epirubicin dose was 90 mg/m² Q3W; [g]Cyclophosphamide dose was 600 mg/m² Q3W.
AE, adverse event; AUC, area under curve; ECOG PS, Eastern Cooperative Oncology Group performance status; EFS, event-free survival; pCR, pathologic complete response; PD-L1, programmed death ligand-1; QW, every week; Q3W, every 3 weeks; R, randomisation; TNBC, triple-negative breast cancer.
1. Schmid P et al. *N Engl J Med* 2020;382:810–821 (plus supplementary appendix); 2. Schmid P et al. *N Engl J Med* 2022;386:556–567 (plus supplementary appendix).

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KEYNOTE-522: Primary endpoints[1,2]

The primary endpoints of the KEYNOTE-522 trial were pCR and EFS, and were defined as follows:

pCR: The absence of invasive cancer in the breast and lymph nodes (ypT0/Tis ypN0). Blinded assessment performed by local pathologist at the time of definitive surgery

EFS: The time from randomisation to the first occurrence of any of the following events:

- Progression of disease that precludes definitive surgery
- Local or distant recurrence
- Second primary malignancy, OR
- Death due to any cause

EFS, event-free survival; pCR, pathologic complete response.

1. Schmid P et al. *N Engl J Med* 2020;382:810–821 (plus supplementary appendix); 2. Schmid P et al. *N Engl J Med* 2022;386:556–567.

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KEYNOTE-522: Key patient characteristics

Key characteristics of the KEYTRUDA + chemotherapy arm of the KEYNOTE-522 trial:

Median patient age of 49 years (range: 22–80 years)

Primary tumour classification of 74% for T1/2 and 26% for T3/4

Nodal involvement was positive for 52% and negative for 48%

75% of patients with Stage II disease and 25% with Stage III disease

Total population: 1174 patients (KEYTRUDA + chemotherapy [n=784] and placebo + chemotherapy [n=390])

Schmid P et al. *N Engl J Med* 2020;382:810–821.

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KEYNOTE-522: Patient baseline characteristics[1]

Characteristic, n (%)	KEYTRUDA + chemotherapy (n=784)	Placebo + chemotherapy (n=390)
Median age (range), years	49 (22–80)	48 (24–79)
≤65 years	701 (89.4)	342 (87.7)
Menopausal status		
Premenopausal	438 (55.9)	221 (56.7)
Postmenopausal	345 (44.0)	169 (43.3)
PD-L1 status[a]		
Positive	656 (83.7)	317 (81.3)
Negative	127 (16.2)	69 (17.7)
ECOG PS		
0	678 (86.5)	341 (87.4)
1	106 (13.5)	49 (12.6)
Lactase dehydrogenase level		
≤ULN	631 (80.5)	309 (79.2)
>ULN	149 (19.0)	80 (20.5)
Administration of carboplatin		
QW	449 (57.3)	223 (57.2)
Q3W	335 (42.7)	167 (42.8)
Primary tumour classification		
T1/T2	580 (74.0)	290 (74.4)
T3/T4	204 (26.0)	100 (25.6)
Nodal involvement		
Positive	405 (51.7)	200 (51.3)
Negative	379 (48.3)	190 (48.7)
Overall disease stage		
Stage II	590 (75.3)	291 (74.6)
Stage III	194 (24.7)	98 (25.1)
HER2 status score		
0–1	595 (75.9)	286 (73.3)
≥2	188 (24.0)	104 (26.7)

Adapted from Schmid P et al. 2020.

[a]PD-L1 assessed at a central laboratory using the PD-L1 IHC 22C3 pharmDx assay and measured using the CPS (number of PD-L1-positive tumour cells, lymphocytes and macrophages divided by the total number of viable tumour cells x100).

CPS, combined positive score; ECOG PS, Eastern Cooperative Oncology Group performance status; HER2, human epidermal growth factor receptor 2; IHC, immunohistochemistry; PD-L1, programmed death ligand-1; QW, every week; Q3W, every 3 weeks; ULN, upper limit of normal range.

1. Schmid P et al. *N Engl J Med* 2020;382:810–821 (plus supplementary appendix);

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KEYNOTE-522: Results – Efficacy

Click the links below to navigate to the section of interest

pCR	EFS		OS	DPFS and DRFS
pCR in the ITT population (primary analysis)	EFS in the ITT population (primary analysis)	EFS by nodal status (60-month follow up)	OS in the ITT population (75-month follow up)	DPFS or DRFS (36- and 60-month follow up)
pCR in the ITT population (final analysis)	EFS in the ITT population (75-month follow up)	EFS by disease stage with and without pCR (60-month follow up)	OS in key subgroups (75-month follow up)	
	EFS in key subgroups (primary analysis)	EFS by nodal status with and without pCR (60-month follow up)	OS by pCR (75-month follow up)	
	EFS in key subgroups (60-month follow up)	EFS in patients with baseline T2N0 disease (60-month follow up)	OS in patients with baseline T2N0 disease (75-month follow up)	
	EFS by pCR (36- and 60-month follow up)	Distant recurrence as first EFS event (60-month follow up)		
	EFS by disease stage (60-month follow up)	Distant recurrence as first EFS event by pCR (60-month follow up)		

DPFS, distant progression-free survival; DRFS, distant recurrence-free survival; EFS, event-free survival; ITT, intention-to-treat; OS, overall survival; pCR, pathologic complete response.

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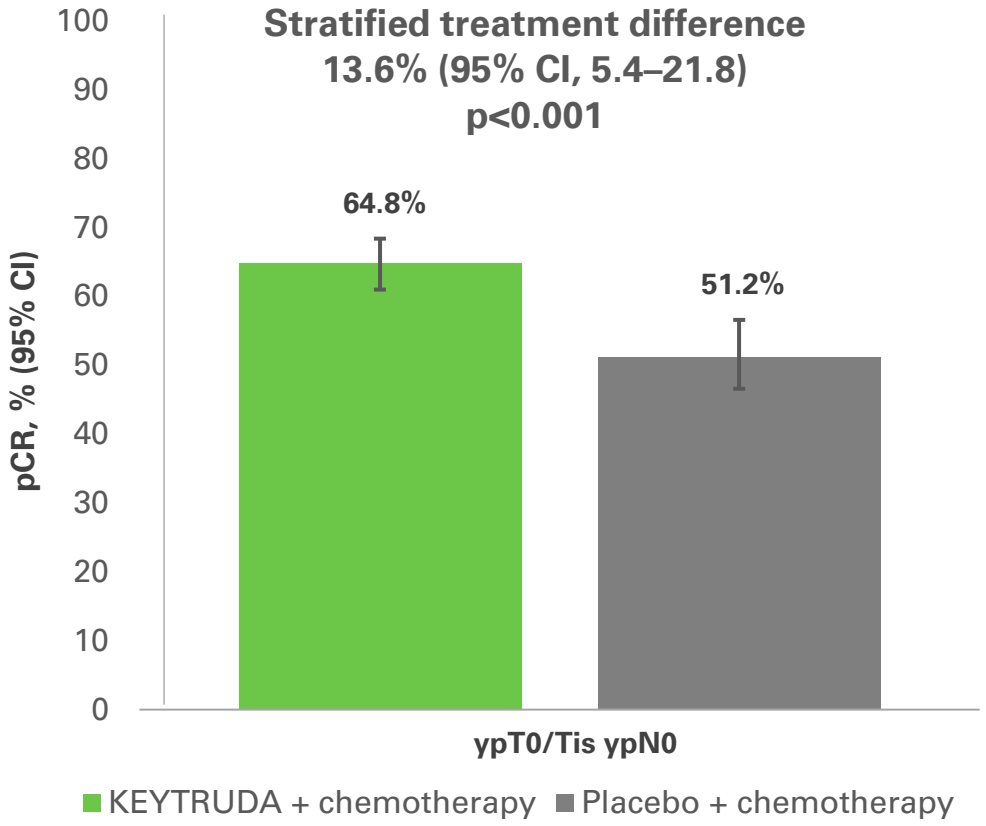
KEYNOTE-522: pCR in the ITT population at primary analysis



- Statistically significant improvement was observed in pCR rates with KEYTRUDA + chemotherapy (neoadjuvant treatment) vs placebo + chemotherapy (neoadjuvant treatment) in the primary analysis of KEYNOTE-522 (p<0.001)
- 64.8% of patients (95% CI, 59.9–69.5) achieved pCR in the KEYTRUDA + chemotherapy (neoadjuvant treatment) group vs 51.2% of patients (95% CI, 44.1–58.3) in the placebo + chemotherapy (neoadjuvant treatment) group

Adapted from Schmid P et al. 2020.

Data cut-off: 24 September 2018. KEYTRUDA + chemotherapy (n=401); placebo + chemotherapy (n=201).
The analysis is based on the Miettinen and Nurminen method stratified according to nodal status (+ vs –), tumour size (T1 [diameter >1–2 cm] to T2 [diameter >2–5 cm] or T3 [diameter >5 cm] to T4 [locally advanced disease]), and frequency of carboplatin administration (QW or Q3W). For the other subgroups, the analysis is based on the unstratified Miettinen and Nurminen method.
CI, confidence interval; ITT, intention-to-treat; pCR, pathologic complete response; Q3W, once every three weeks; QW, once weekly.
Schmid P et al. *N Engl J Med* 2020;382:810–821.

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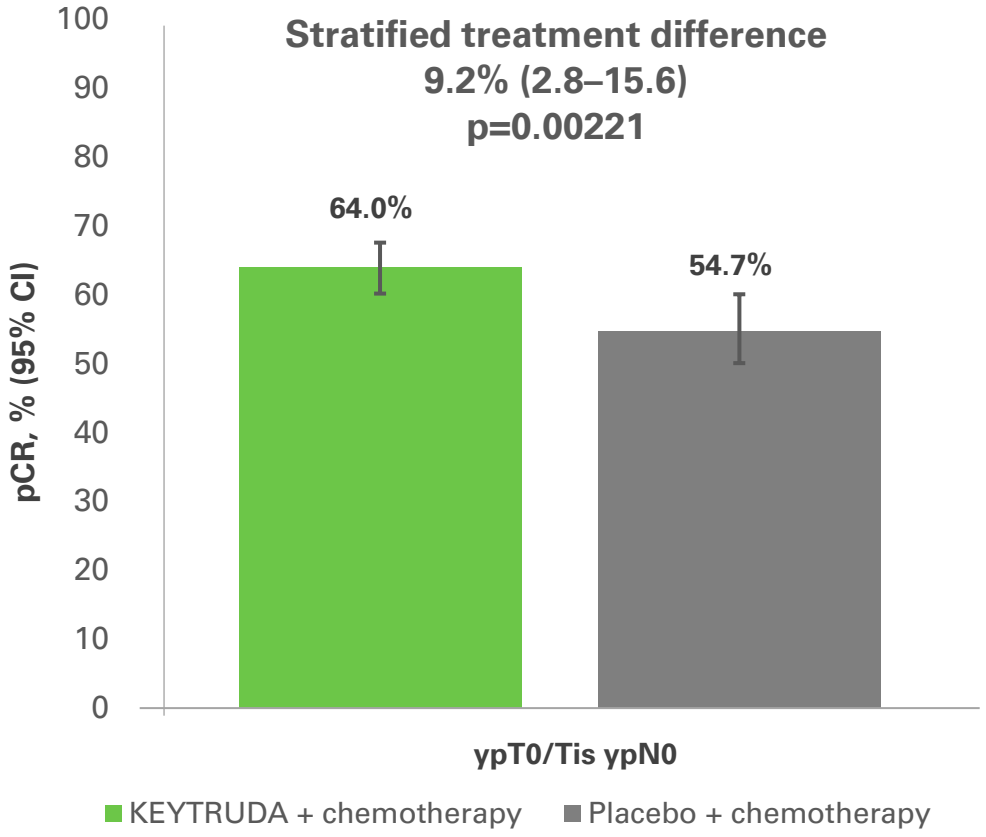
KEYNOTE-522: pCR in the ITT population at final analysis



- Statistically significant improvement in pCR was observed with KEYTRUDA + chemotherapy (neoadjuvant treatment) vs placebo + chemotherapy (neoadjuvant treatment) in the final analysis of KEYNOTE-522 (p=0.00221)
- 64.0% of patients (95% CI, 60.2–67.6) achieved pCR in the KEYTRUDA + chemotherapy (neoadjuvant treatment) group vs 54.7% of patients (95% CI, 49.1–60.1) in the placebo + chemotherapy (neoadjuvant treatment) group

Adapted from KEYTRUDA SmPC.

Data cut-off: 23 March 2021. KEYTRUDA + chemotherapy (n=669); placebo + chemotherapy (n=333).
The analysis is based on the Miettinen and Nurminen method stratified according to nodal status (+ vs –), tumour size (T1 [diameter >1–2 cm] to T2 [diameter >2–5 cm] or T3 [diameter >5 cm] to T4 [locally advanced disease]), and frequency of carboplatin administration (QW or Q3W). For the other subgroups, the analysis is based on the unstratified Miettinen and Nurminen method.
CI, confidence interval; ITT, intention-to-treat; pCR, pathologic complete response; Q3W, once every three weeks; QW, once weekly; SmPC, Summary of Product Characteristics.
KEYTRUDA (pembrolizumab) Summary of Product Characteristics. Available at: https://www.medicines.org.uk/emc/product/2498/smpc. Accessed August 2025.

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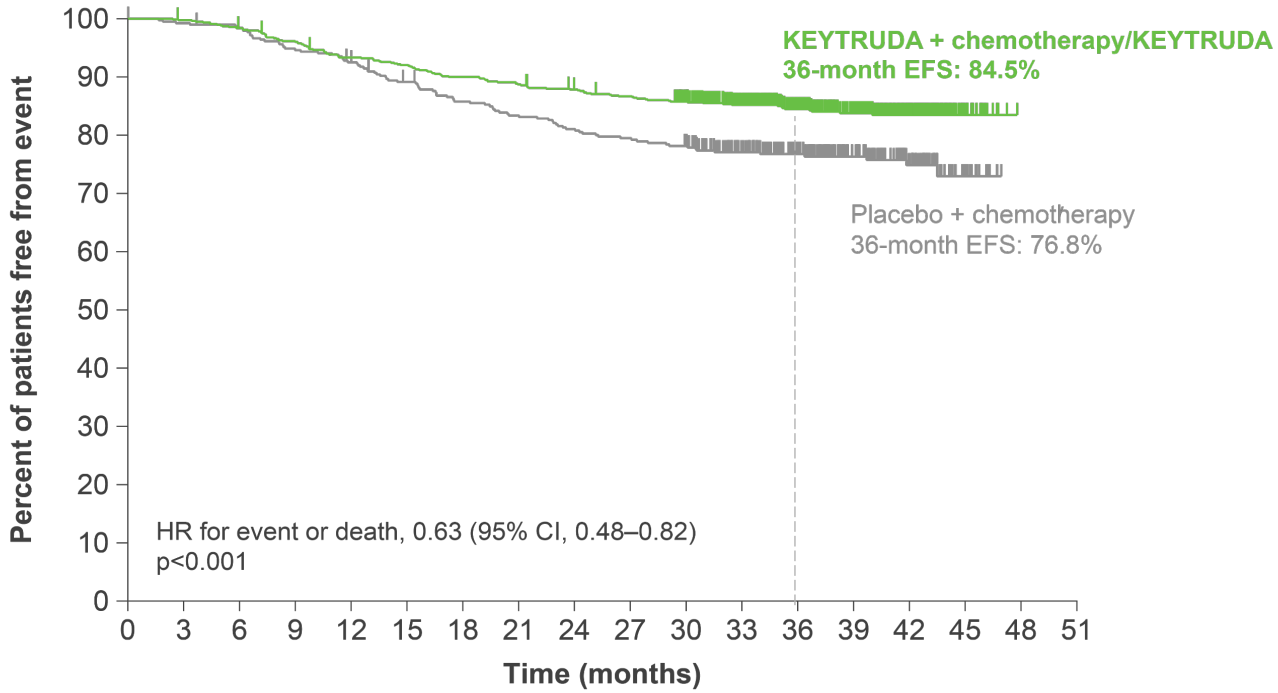
KEYNOTE-522: EFS in the ITT population at primary analysis



KEYTRUDA + chemotherapy/KEYTRUDA	784	781	769	751	728	718	702	692	681	671	652	551	433	303	165	28	0	0
Placebo + chemotherapy/placebo	390	386	382	368	358	342	328	319	310	304	297	250	195	140	83	17	0	0

Adapted from Schmid P et al. 2022.

- KEYTRUDA + chemotherapy in the neoadjuvant setting, followed by KEYTRUDA monotherapy as adjuvant treatment, resulted in a statistically significant improvement in EFS vs neoadjuvant placebo + chemotherapy followed by adjuvant placebo
- The 36-month estimated EFS was:
  - 84.5% in the neoadjuvant KEYTRUDA + chemotherapy followed by adjuvant KEYTRUDA group (95% CI, 81.7–86.9)
  - 76.8% in the neoadjuvant placebo + chemotherapy followed by adjuvant placebo group (95% CI, 72.2–80.7)
- Median EFS was not reached for either group

Click here to view the forest plot for EFS in key subgroups

Data cut-off: 23 March 2021.
Tick marks indicate data censored at the last time the patient was known to be alive and without an event (disease progression that precludes definitive surgery; local or distant recurrence or a second primary tumour; or death from any cause). The HR and CI were analysed with the use of a Cox regression model with treatment as a covariate stratified according to the randomisation stratification factors of nodal status (+ or −), tumour size (T1/T2 or T3/T4) and frequency of carboplatin administration (QW or Q3W).
CI, confidence interval; EFS, event-free survival; HR, hazard ratio; ITT, intention-to-treat; QW, every week; Q3W, every 3 weeks.
Schmid P et al. *N Engl J Med* 2022;386:556–567.

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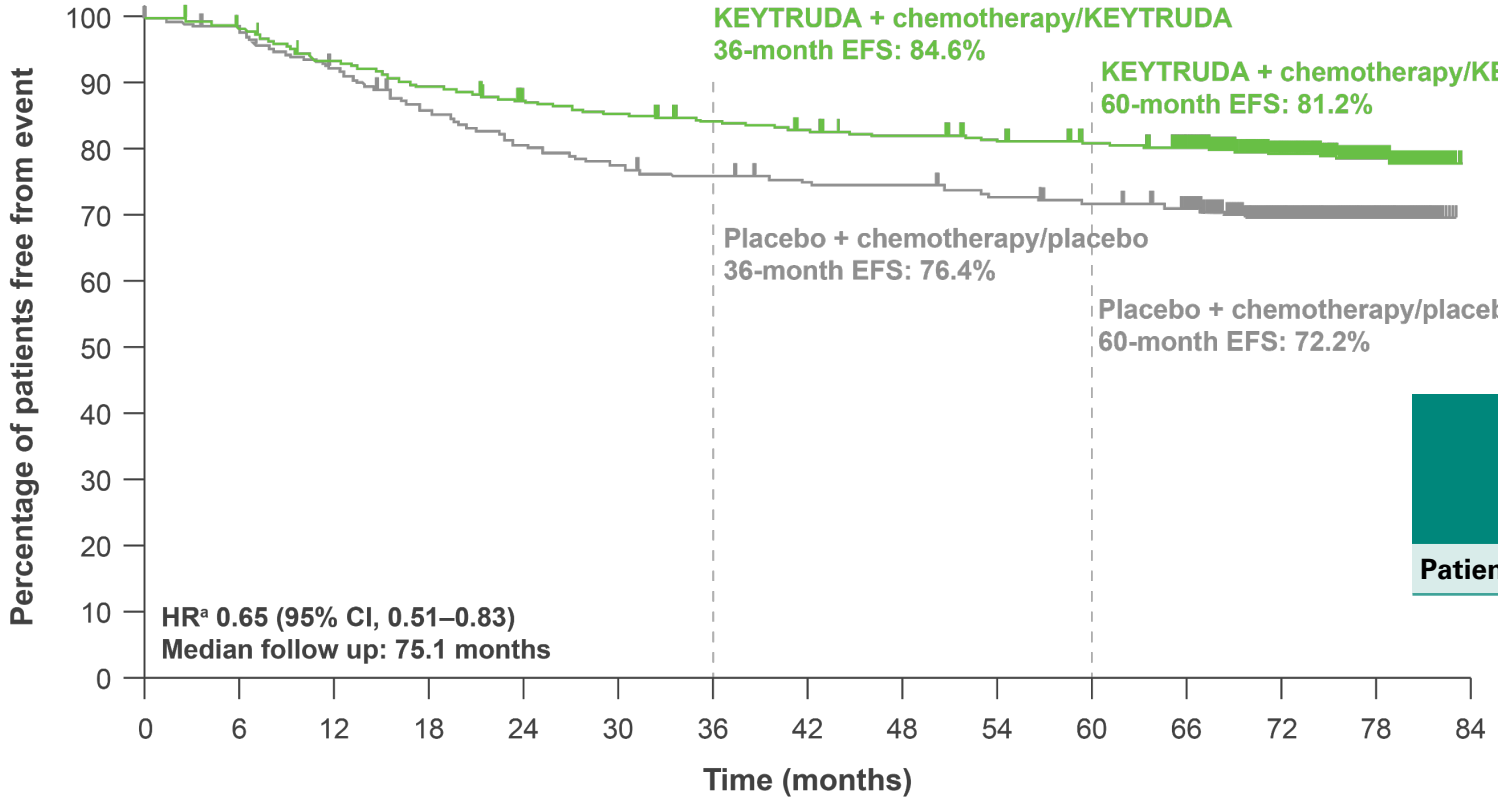
KEYNOTE-522: Exploratory analysis – EFS in the ITT population at 75-month follow up



	KEYTRUDA + chemotherapy/ KEYTRUDA (n=784)	Placebo + chemotherapy/ placebo (n=390)
Patients with event, %	20.3	29.2

No. at risk															
KEYTRUDA + chemotherapy/KEYTRUDA	784	769	728	702	681	665	654	644	633	625	618	602	409	164	0
Placebo + chemotherapy/placebo	390	382	358	330	312	300	293	287	285	278	273	264	178	76	0

This was an exploratory analysis; significance was not tested and no statistical conclusions can be drawn

Adapted from Schmid P et al. Presented at ESMO 2024.

Data cut-off: 22 March 2024.
[a]HR (CI) analysed based on a Cox regression model with treatment as a covariate stratified by the randomisation stratification factors.
CI, confidence interval; HR, hazard ratio; ITT, intention-to-treat.
Schmid P et al. Presented at the European Society of Medical Oncology Congress 2024, 13–17 September, Barcelona, Spain.

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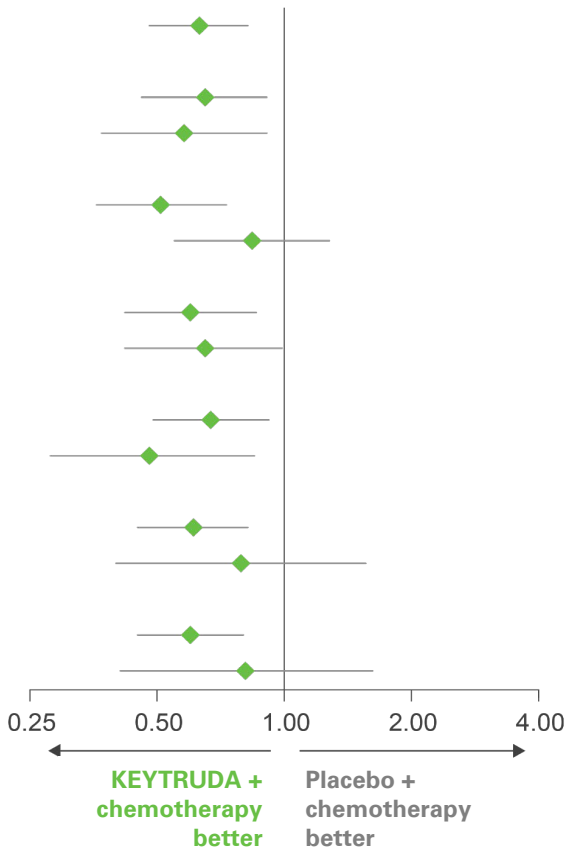
KEYNOTE-522: EFS in key subgroups at primary analysis

Subgroup	KEYTRUDA + chemotherapy	Placebo + chemotherapy	HR for event or death (95% CI)
	no. of patients with event/total no. (%)		
Overall	123/784 (15.7)	93/390 (23.8)	0.63 (0.48–0.82)
Nodal status			
Positive	80/408 (19.6)	57/196 (29.1)	0.65 (0.46–0.91)
Negative	43/376 (11.4)	36/194 (18.6)	0.58 (0.37–0.91)
Tumour size			
T1 to T2	64/581 (11.0)	59/290 (20.3)	0.51 (0.36–0.73)
T3 to T4	59/203 (29.1)	34/100 (34.0)	0.84 (0.55–1.28)
Carboplatin schedule			
QW	71/444 (16.0)	56/220 (25.5)	0.60 (0.42–0.86)
Q3W	50/334 (15.0)	37/167 (22.2)	0.65 (0.42–0.99)
PD-L1 status			
Positive	98/656 (14.9)	68/317 (21.5)	0.67 (0.49–0.92)
Negative	25/128 (19.5)	25/69 (36)	0.48 (0.28–0.85)
Age			
<65 yr	103/700 (14.7)	79/342 (23.1)	0.61 (0.45–0.82)
≥65 yr	20/84 (24)	14/48 (29)	0.79 (0.40–1.56)
ECOG PS			
0	101/678 (14.9)	80/341 (23.5)	0.60 (0.45–0.80)
1	22/106 (20.8)	13/49 (27)	0.81 (0.41–1.62)



KEYNOTE-522 was not powered to detect differences in treatment effect between these subgroups. Results from exploratory analyses should be interpreted with caution due to modest patient numbers and potential imbalances in baseline characteristics

Adapted from Schmid P et al. 2022.

Data cut-off: 23 March 2021.
The HR and CI were analysed with the use of a Cox regression model, with treatment as a covariate and stratified according to the randomisation stratification factors of nodal status (+ or –), tumour size (T1/T2 or T3/T4) and frequency of carboplatin administration (QW or Q3W).
CI, confidence interval; ECOG PS, Eastern Cooperative Oncology Group performance status; EFS, event-free survival; HR, hazard ratio; ITT, intention-to-treat; pCR, pathologic complete response; PD-L1, programmed death ligand-1; QW, every week; Q3W, every 3 weeks; Yr, years.
Schmid P et al. *N Engl J Med* 2022;386:556–567 (plus supplementary appendix).

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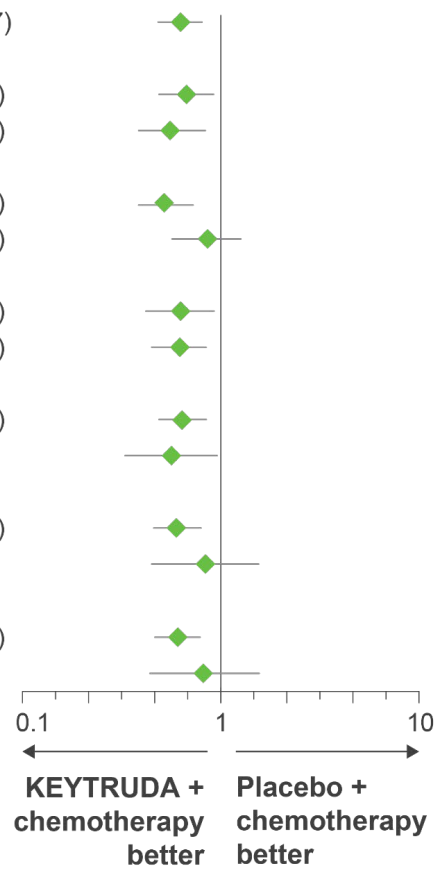
KEYNOTE-522: Exploratory analysis – EFS in key subgroups at 60-month follow up

Subgroup	KEYTRUDA + chemotherapy	Placebo + chemotherapy	HR (95% CI)
	no. of patients with events/total no. (%)		
Overall	145/784 (18.5)	108/390 (27.7)	0.63 (0.49–0.81)
Nodal status			
Positive	94/408 (23.0)	64/196 (32.6)	0.67 (0.49–0.93)
Negative	51/376 (13.6)	44/194 (22.7)	0.56 (0.38–0.84)
Tumour size			
T1 to T2	80/581 (13.8)	71/290 (24.5)	0.52 (0.38–0.72)
T3 to T4	65/203 (32.0)	37/100 (37.0)	0.85 (0.57–1.27)
Carboplatin schedule			
Q3W	58/334 (17.4)	44/167 (26.3)	0.63 (0.42–0.93)
QW	85/444 (19.1)	64/220 (29.1)	0.62 (0.45–0.86)
PD-L1 status			
Positive	115/656 (17.5)	81/317 (25.5)	0.64 (0.48–0.85)
Negative	30/128 (23.4)	25/69 (36.2)	0.57 (0.33–0.98)
Age			
<65 yr	121/700 (17.3)	92/342 (26.9)	0.61 (0.46–0.80)
≥65 yr	24/84 (28.6)	16/48 (33.3)	0.83 (0.44–1.56)
ECOG PS			
0	119/678 (17.5)	93/341 (27.3)	0.60 (0.46–0.79)
1	26/106 (24.5)	15/49 (30.6)	0.83 (0.44–1.57)



KEYNOTE-522 was not powered to detect differences in treatment effect between these subgroups. Results from exploratory analyses should be interpreted with caution due to modest patient numbers and potential imbalances in baseline characteristics

Adapted from Schmid P et al. Presented at ESMO 2023.

Data cut-off: 23 March 2023.
For the overall population and PD-L1 subgroups, analyses were based on a Cox regression model with Efron's method of tie handling, with treatment as a covariate and stratification by nodal status (positive vs negative), tumour size (T1/T2 vs T3/T4) and frequency of carboplatin administration (QW vs Q3W); for other subgroups, analysis was based on an unstratified Cox model.
CI, confidence interval; ECOG PS, Eastern Cooperative Oncology Group performance status; EFS, event-free survival; HR, hazard ratio; pCR, pathologic complete response; PD-L1, programmed death ligand-1; QW, every week; Q3W, every 3 weeks; yr, years.
Schmid P et al. Presented at the European Society of Medical Oncology Congress 2023, 20–24 September, Madrid, Spain.

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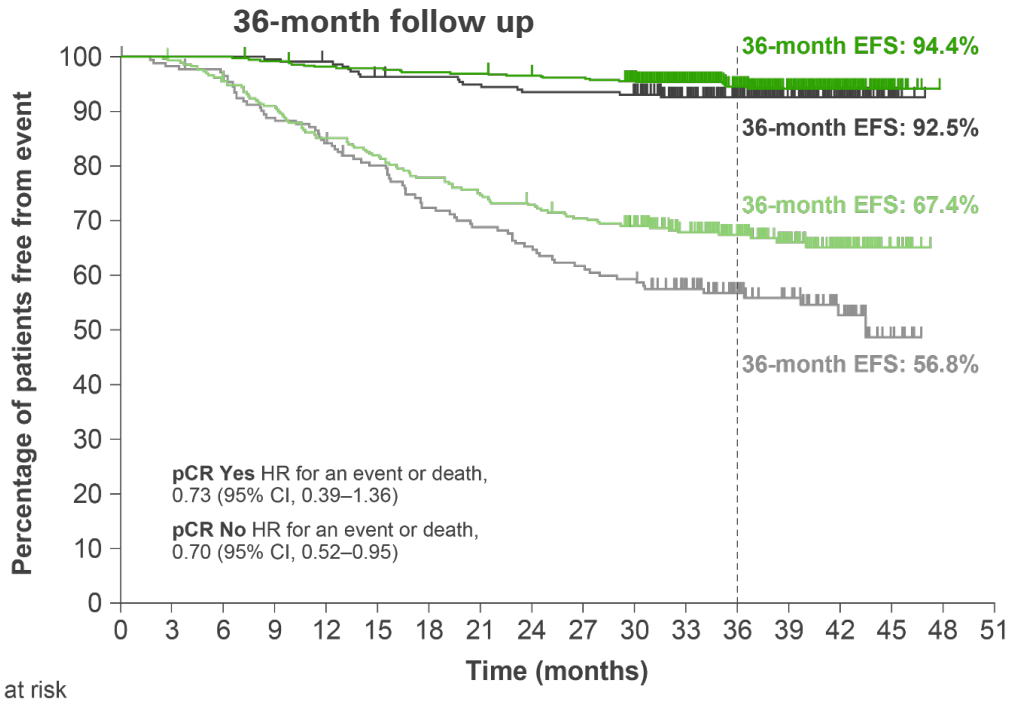
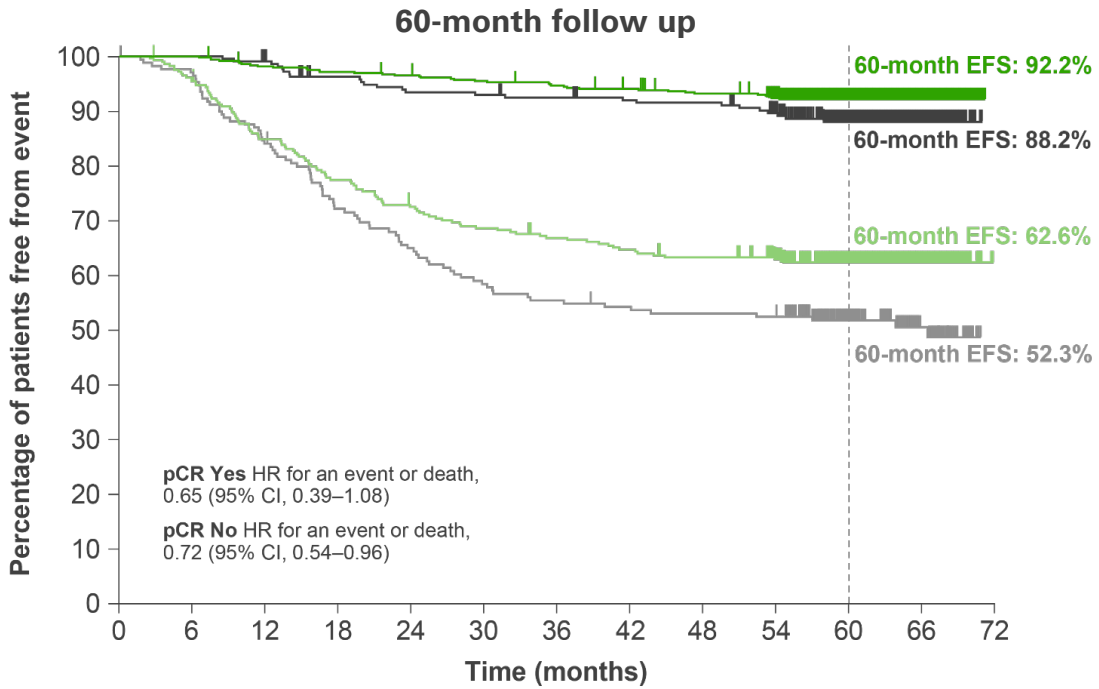
KEYNOTE-522: Exploratory analysis – EFS by pCR





No. at risk																		
KEYTRUDA + chemotherapy/ KEYTRUDA responder	494	494	494	489	483	482	478	477	472	470	460	387	307	220	122	18	0	0
Placebo + chemotherapy/ placebo responder	217	217	217	216	214	207	206	203	200	200	197	165	130	87	56	9	0	0
KEYTRUDA + chemotherapy/ KEYTRUDA non-responder	290	287	275	262	245	236	224	215	209	201	192	164	126	83	43	10	0	0
Placebo + chemotherapy/ placebo non-responder	173	169	165	152	144	135	122	116	110	104	100	85	65	53	27	8	0	0

495	495	484	479	473	468	463	458	451	439	295	120	0
217	217	214	206	200	199	197	195	194	185	130	53	0
289	274	244	223	208	197	191	185	180	173	116	42	0
173	165	144	123	111	100	95	91	90	89	59	26	0

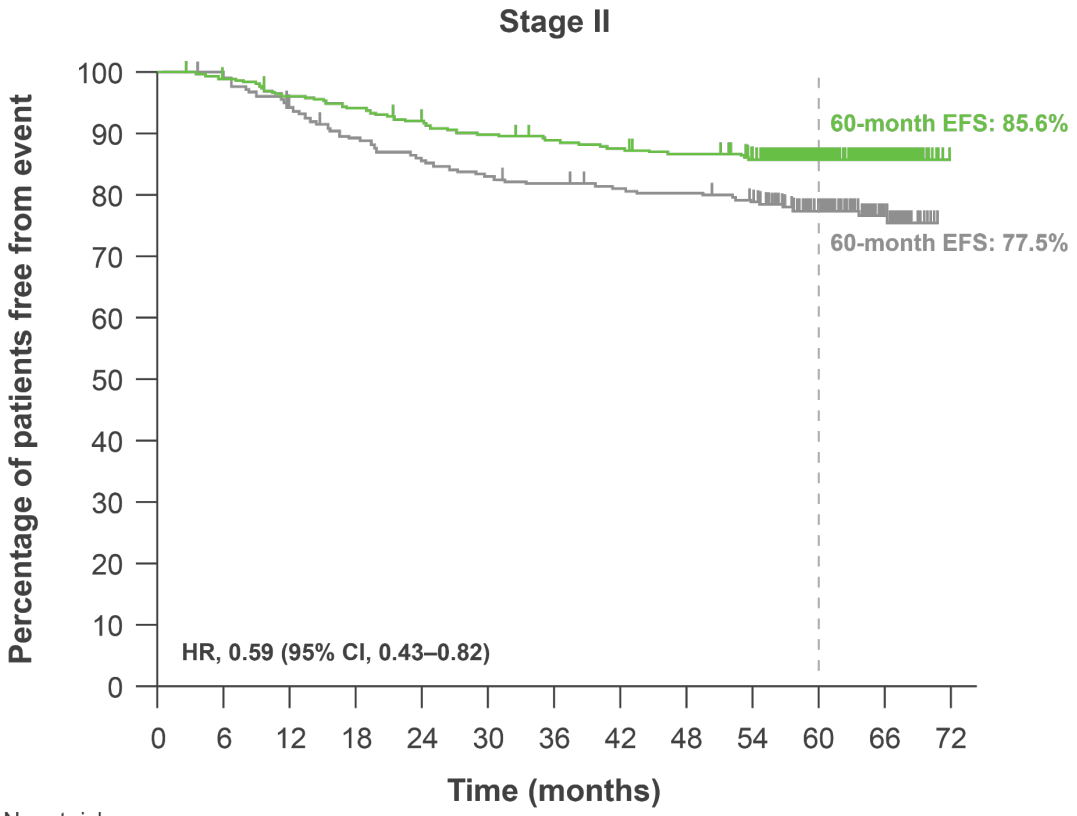
Adapted from Schmid P et al. Presented at ESMO 2023.

This was an exploratory analysis; significance was not tested and no statistical conclusions can be drawn

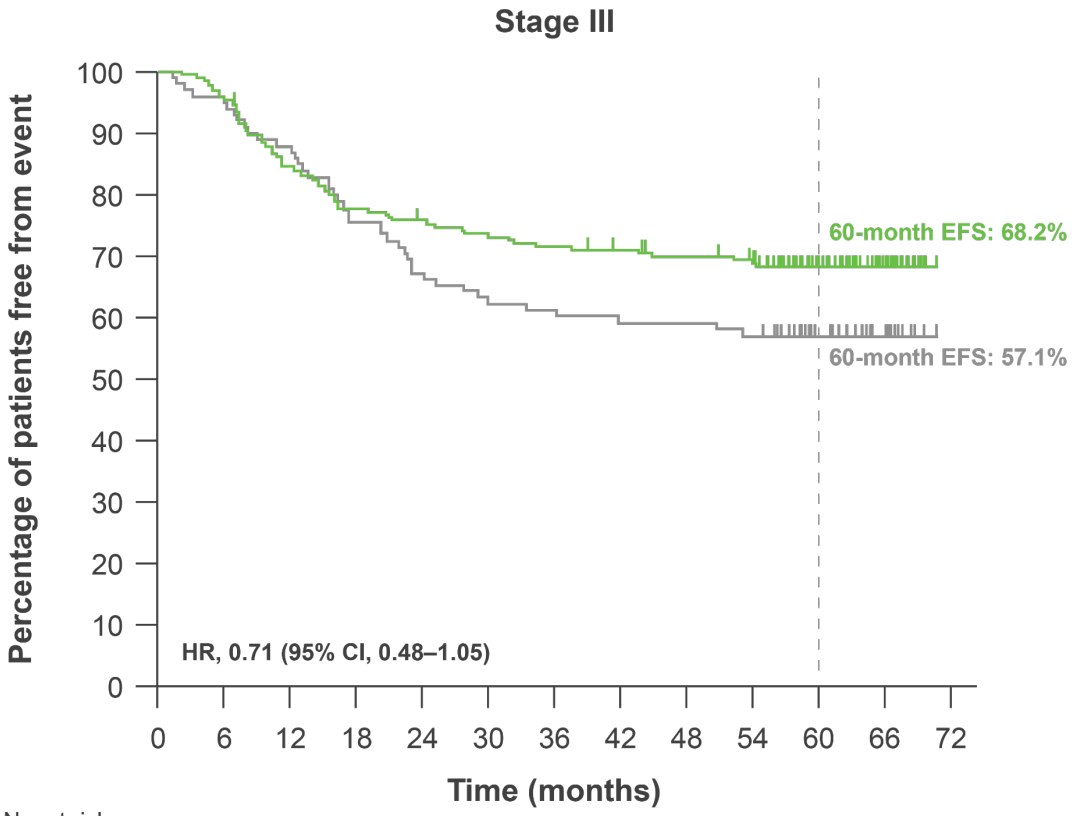
Data cut-off: 23 March 2021 and 23 March 2023.
CI, confidence interval; EFS, event-free survival; HR, hazard ratio; pCR, pathologic complete response.
Schmid P et al. Presented at the European Society of Medical Oncology Congress 2023, 20–24 September, Madrid, Spain.

UK Prescribing Information

KEYNOTE-522: Exploratory analysis – EFS by disease stage at 60-month follow up



No. at risk													
KEYTRUDA + chemotherapy/ KEYTRUDA	590	583	565	552	536	524	517	509	501	486	331	125	0
Placebo + chemotherapy/ placebo	291	287	271	255	245	237	232	228	226	218	153	60	0



No. at risk													
KEYTRUDA + chemotherapy/ KEYTRUDA	194	186	163	150	145	141	137	134	130	126	80	37	0
Placebo + chemotherapy/ placebo	98	94	86	74	66	62	60	58	58	56	36	19	0

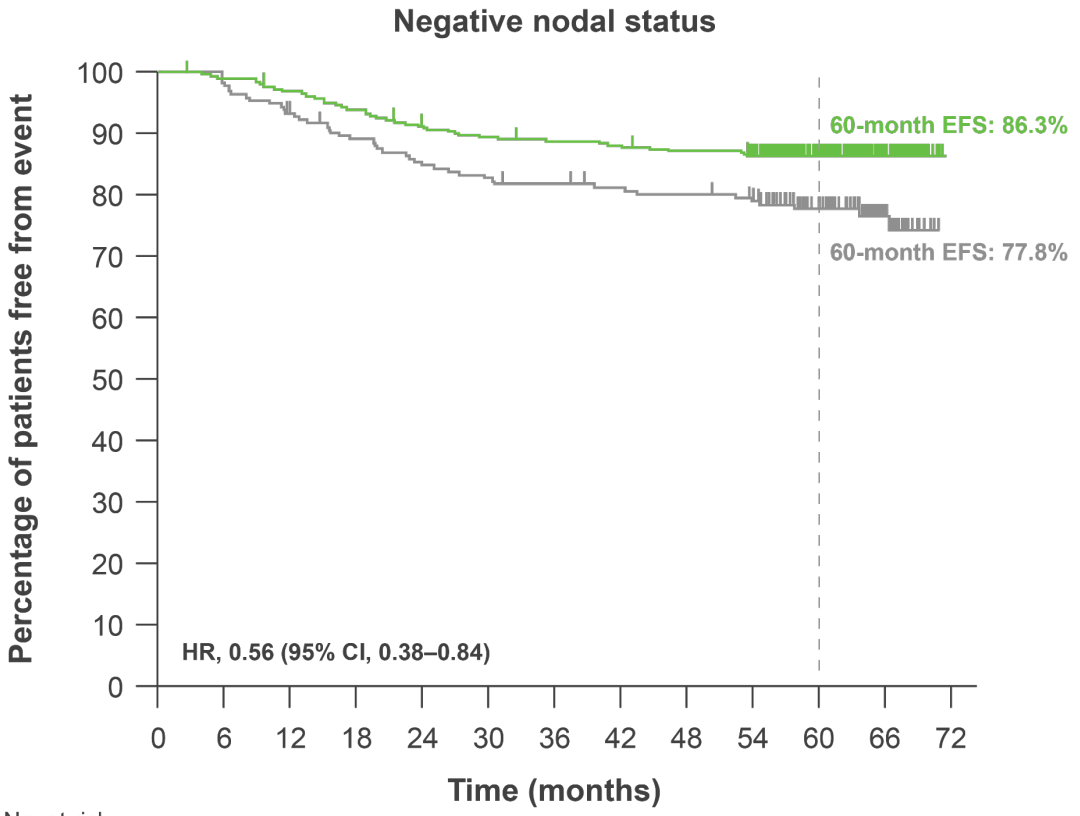
Adapted from Schmid P et al. Presented at SABCS 2023.

This was an exploratory analysis; significance was not tested and no statistical conclusions can be drawn

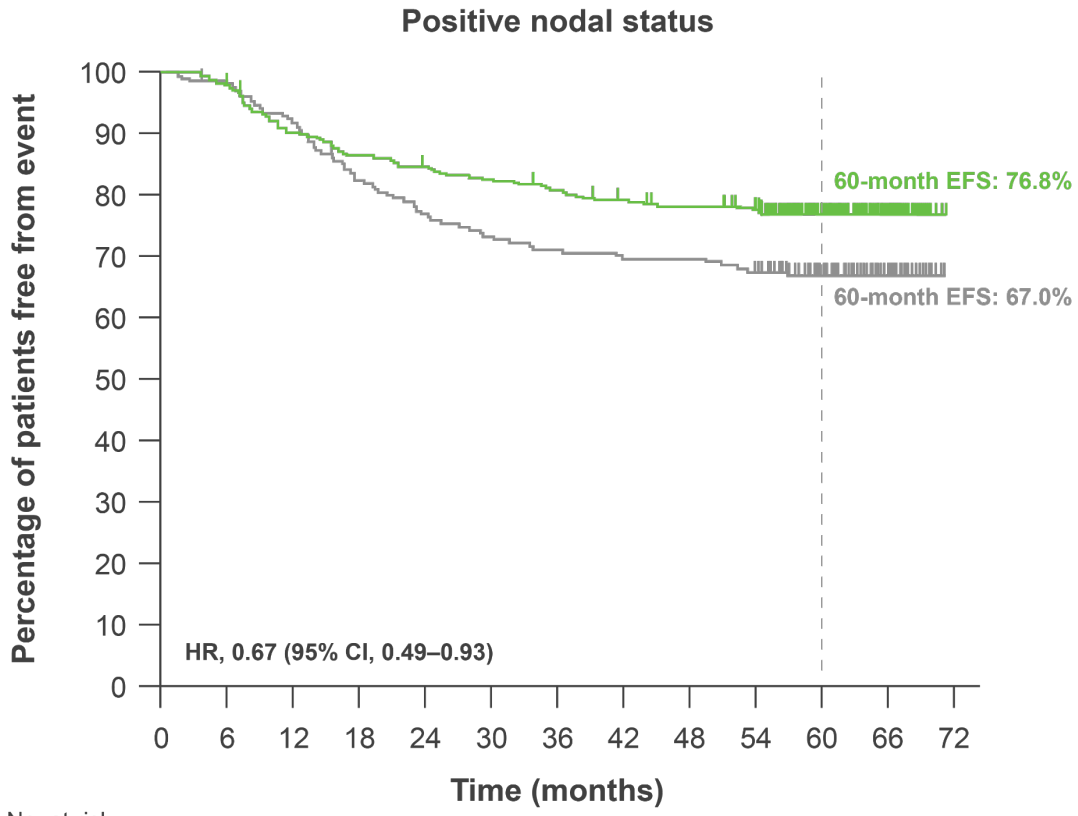
Data cut-off: 23 March 2023.
CI, confidence interval; EFS, event-free survival; HR, hazard ratio.
Schmid P et al. Presented at the San Antonio Breast Cancer Symposium Congress 2023, 5–9 December, San Antonio, USA.

UK Prescribing Information

KEYNOTE-522: Exploratory analysis – EFS by nodal status at 60-month follow up



No. at risk													
KEYTRUDA + chemotherapy/ KEYTRUDA	376	371	362	351	338	331	328	325	320	309	210	80	0
Placebo + chemotherapy/ placebo	194	190	179	169	162	157	154	151	149	144	98	38	0



No. at risk													
KEYTRUDA + chemotherapy/ KEYTRUDA	408	398	366	351	343	334	326	318	311	303	201	82	0
Placebo + chemotherapy/ placebo	196	192	179	160	149	142	138	135	135	130	91	41	0

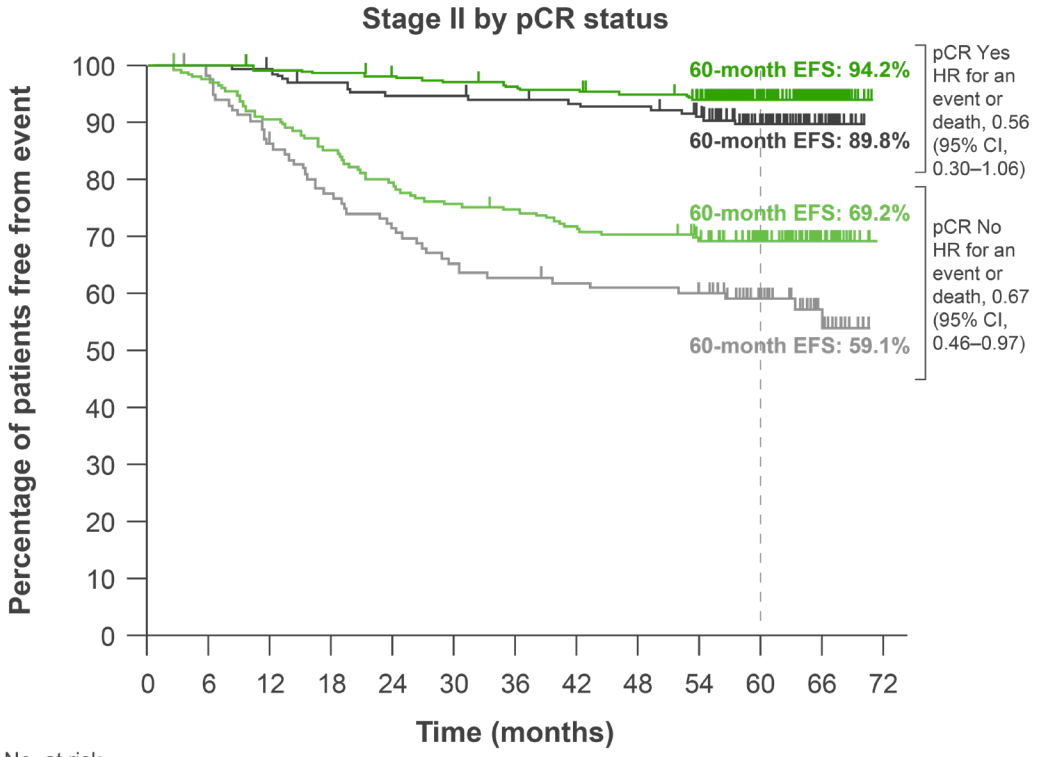
Adapted from Schmid P et al. Presented at SABCS 2023.

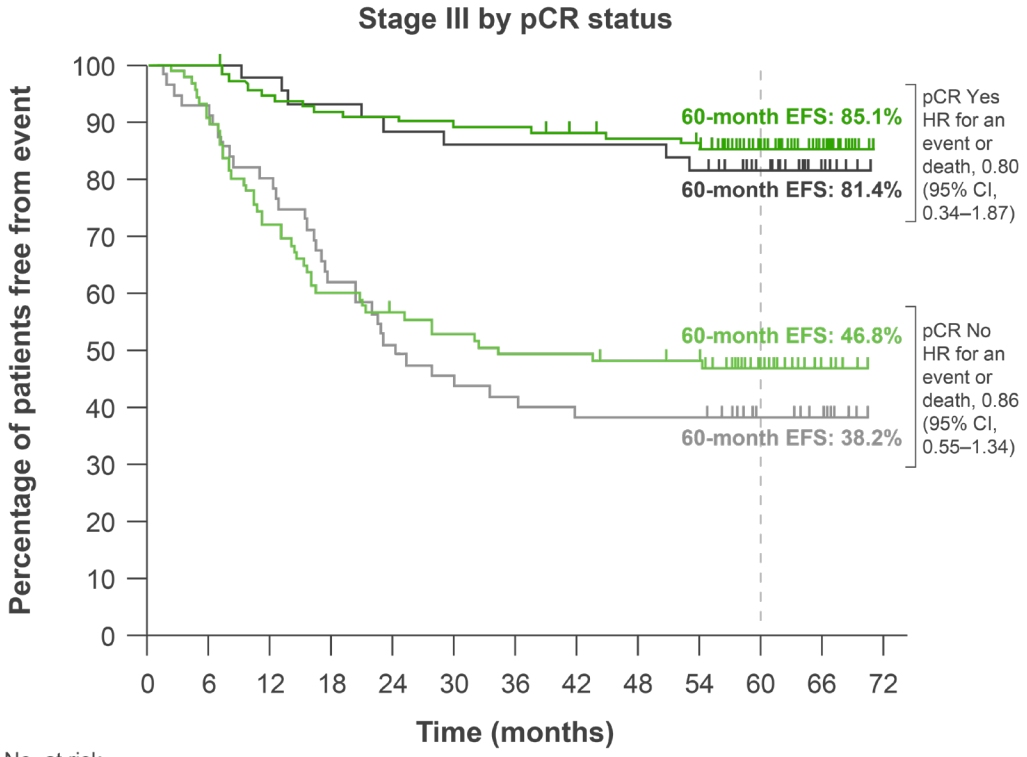
This was an exploratory analysis; significance was not tested and no statistical conclusions can be drawn

Data cut-off: 23 March 2023.
CI, confidence interval; EFS, event-free survival; HR, hazard ratio.
Schmid P et al. Presented at the San Antonio Breast Cancer Symposium Congress 2023, 5–9 December, San Antonio, USA.

UK Prescribing Information

KEYNOTE-522: Exploratory analysis – EFS by disease stage in patients with and without pCR at 60-month follow up





No. at risk

KEYTRUDA + chemotherapy/ KEYTRUDA responder	386	386	382	380	375	371	367	365	360	351	236	90	0
Placebo + chemotherapy/ placebo responder	173	173	171	166	162	162	160	158	157	150	106	42	0
KEYTRUDA + chemotherapy/ KEYTRUDA non-responder	204	197	183	172	161	153	150	144	141	135	95	35	0
Placebo + chemotherapy/ placebo non-responder	118	114	100	89	83	75	72	70	69	68	47	18	0

No. at risk

KEYTRUDA + chemotherapy/ KEYTRUDA responder	109	109	102	99	98	97	96	93	91	88	59	30	0
Placebo + chemotherapy/ placebo responder	43	43	42	40	38	37	37	37	37	35	24	11	0
KEYTRUDA + chemotherapy/ KEYTRUDA non-responder	85	77	61	51	47	44	41	41	39	38	21	7	0
Placebo + chemotherapy/ placebo non-responder	55	51	44	34	28	25	23	21	21	21	12	8	0

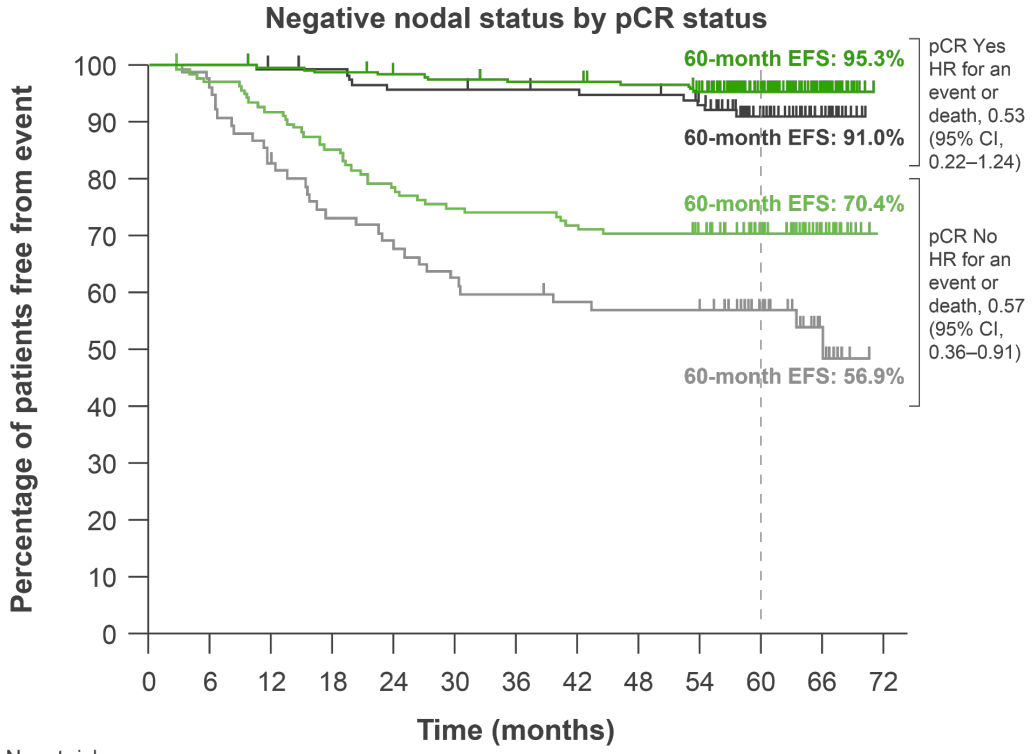
Adapted from Schmid P et al. Presented at SABCS 2023.

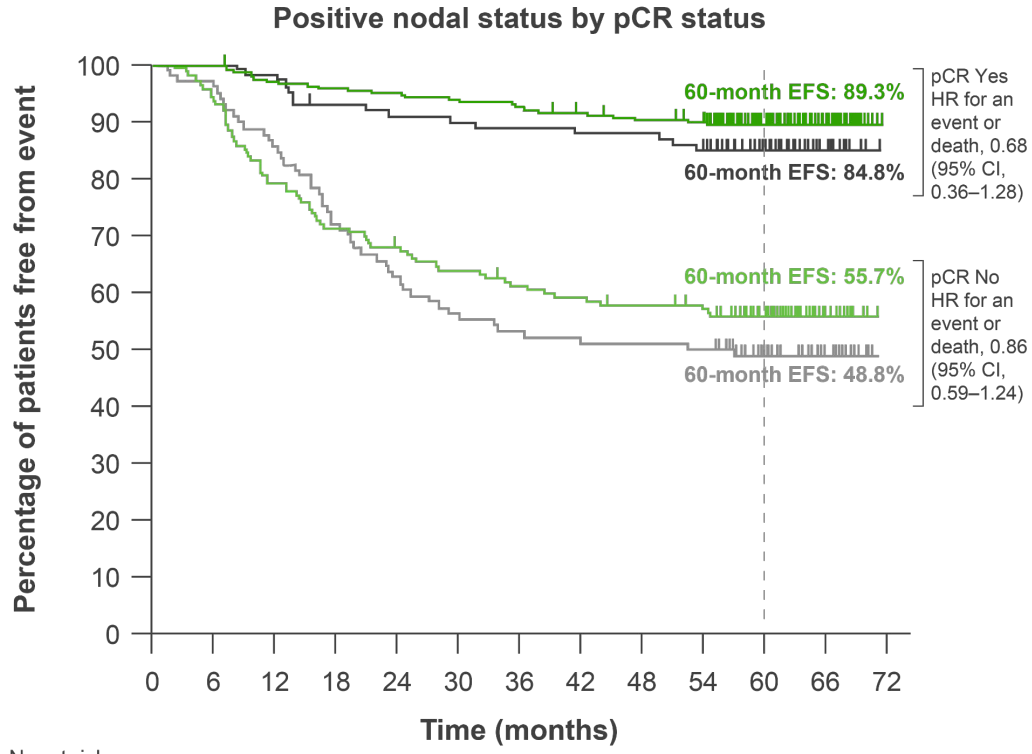
This was an exploratory analysis; significance was not tested and no statistical conclusions can be drawn

Data cut-off: 23 March 2023.
CI, confidence interval; EFS, event-free survival; HR, hazard ratio; pCR, pathologic complete response.
Schmid P et al. Presented at the San Antonio Breast Cancer Symposium Congress 2023, 5–9 December, San Antonio, USA.

UK Prescribing Information

KEYNOTE-522: Exploratory analysis – EFS by nodal status in patients with and without pCR at 60-month follow up





No. at risk

KEYTRUDA + chemotherapy/ KEYTRUDA responder	240	240	238	236	232	230	228	228	225	218	149	55	0
Placebo + chemotherapy/ placebo responder	118	118	117	115	111	111	110	109	108	103	70	28	0
KEYTRUDA + chemotherapy/ KEYTRUDA non-responder	136	131	124	115	106	101	100	97	95	91	61	25	0
Placebo + chemotherapy/ placebo non-responder	76	72	62	54	51	46	44	42	41	41	28	10	0

No. at risk

KEYTRUDA + chemotherapy/ KEYTRUDA responder	255	255	246	243	241	238	235	230	226	221	146	65	0
Placebo + chemotherapy/ placebo responder	99	99	97	91	89	88	87	86	86	82	60	25	0
KEYTRUDA + chemotherapy/ KEYTRUDA non-responder	153	143	120	108	102	96	91	88	85	82	55	17	0
Placebo + chemotherapy/ placebo non-responder	97	93	82	69	60	54	51	49	49	48	31	16	0

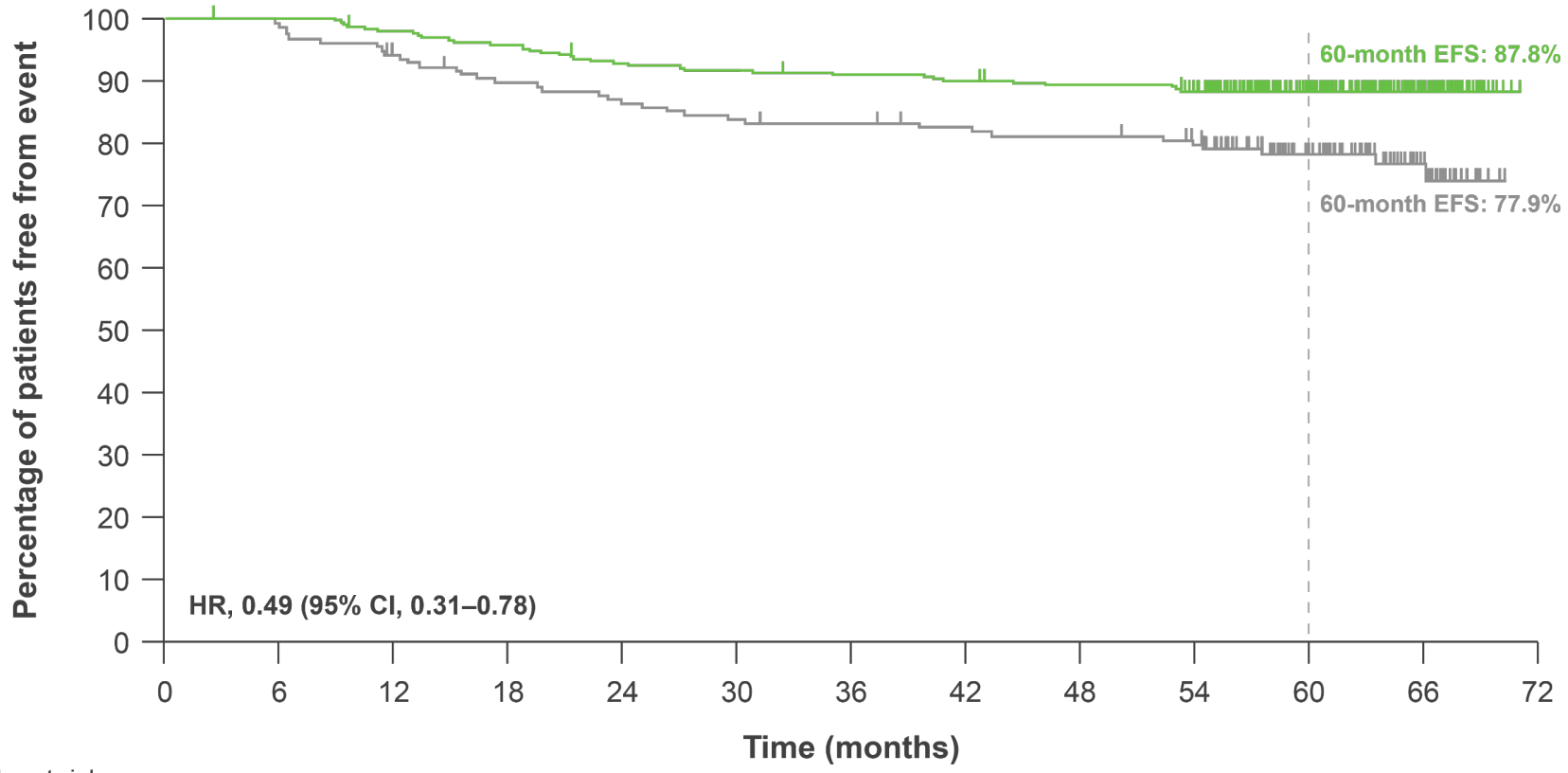
Adapted from Schmid P et al. Presented at SABCS 2023.

This was an exploratory analysis; significance was not tested and no statistical conclusions can be drawn

Data cut-off: 23 March 2023.
CI, confidence interval; EFS, event-free survival; HR, hazard ratio; pCR, pathologic complete response.
Schmid P et al. Presented at the San Antonio Breast Cancer Symposium Congress 2023, 5–9 December, San Antonio, USA.

UK Prescribing Information

KEYNOTE-522: Exploratory analysis – EFS in patients with baseline T2N0 disease at 60-month follow up



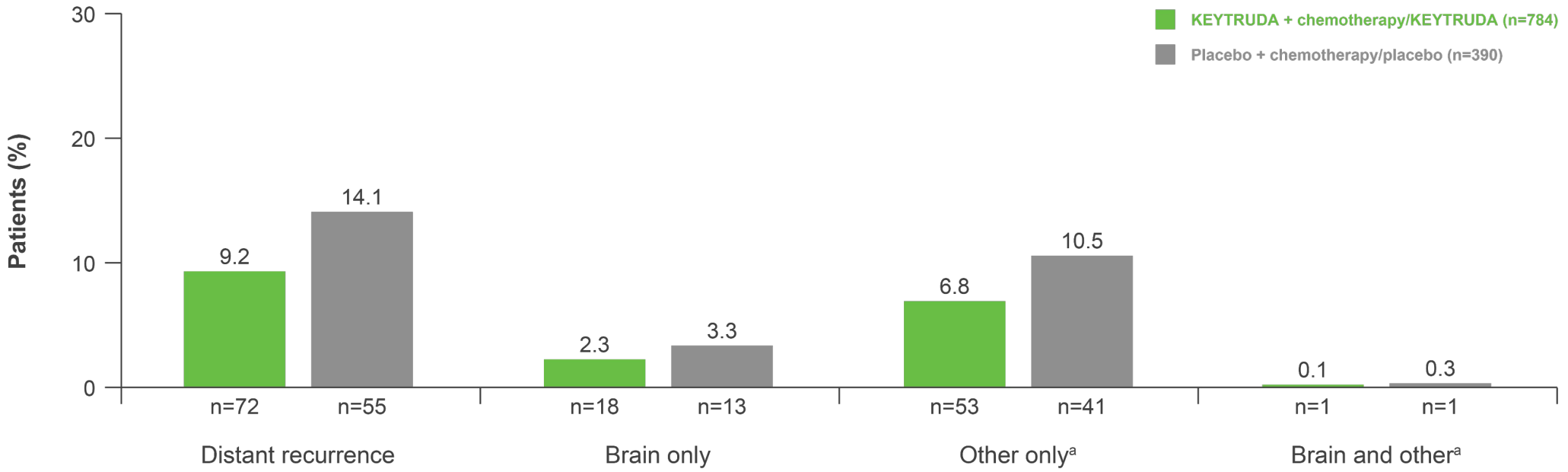
Adapted from Schmid P et al. Presented at SABCS 2023.

This was an exploratory analysis; significance was not tested and no statistical conclusions can be drawn

Data cut-off: 23 March 2023.
CI, confidence interval; EFS, event-free survival; HR, hazard ratio.
Schmid P et al. Presented at the San Antonio Breast Cancer Symposium Congress 2023, 5–9 December, San Antonio, USA.

UK Prescribing Information

KEYNOTE-522: Exploratory analysis – Distant recurrence as first EFS event at 60-month follow up



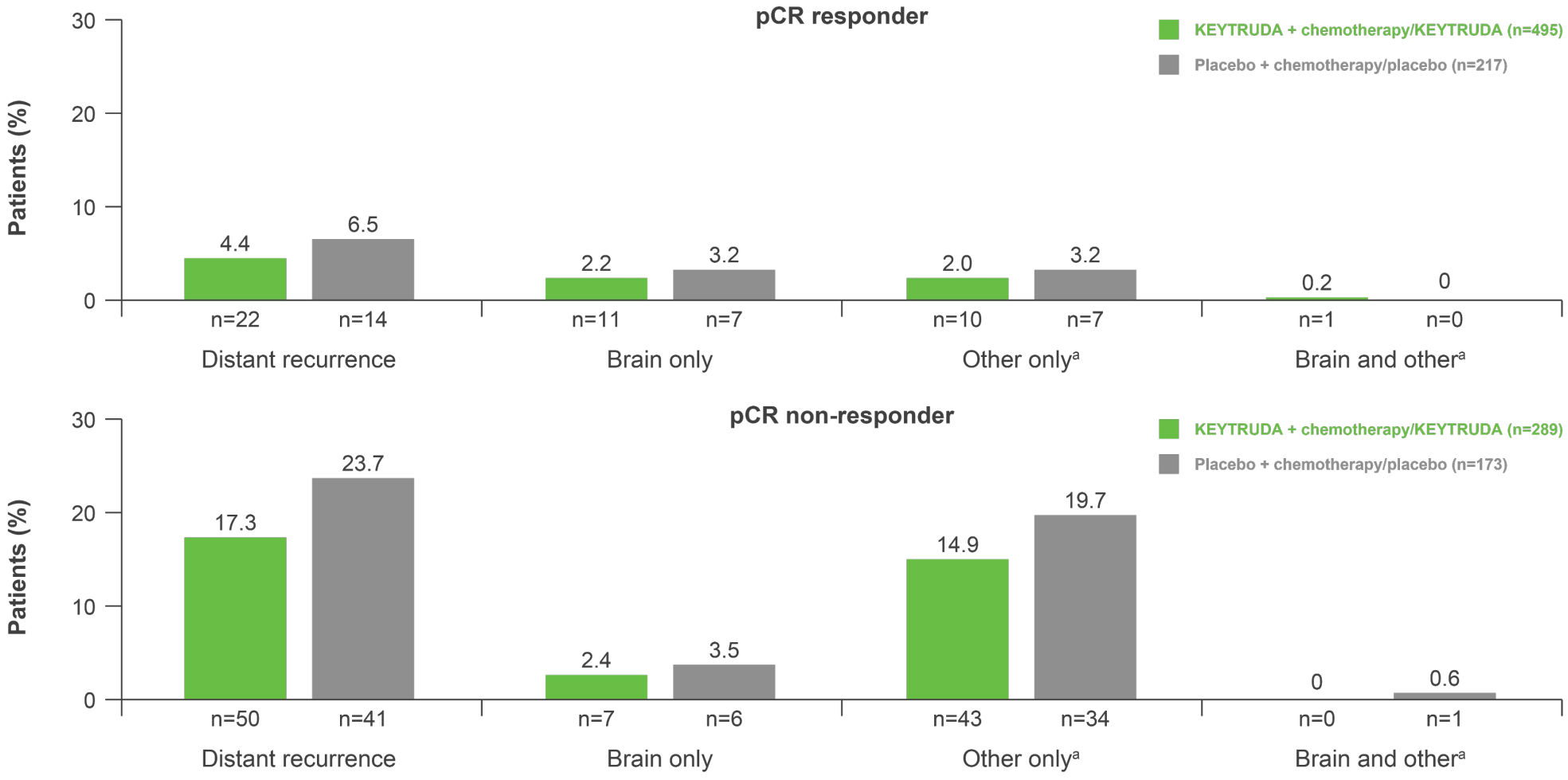
Adapted from Schmid P et al. Presented at SABCS 2023.

This was an exploratory analysis; significance was not tested and no statistical conclusions can be drawn

Data cut-off: 23 March 2023.
[a]Other refers to non-brain distant recurrence sites, which were classified per clinical identification.
CI, confidence interval; EFS, event-free survival; HR, hazard ratio.
Schmid P et al. Presented at the San Antonio Breast Cancer Symposium Congress 2023, 5–9 December, San Antonio, USA.

UK Prescribing Information

KEYNOTE-522: Exploratory analysis – Distant recurrence as first EFS event by pCR (ypT0/Tis ypN0) at 60-month follow up



Adapted from Schmid P et al. Presented at SABCS 2023.

This was an exploratory analysis; significance was not tested and no statistical conclusions can be drawn

Data cut-off: 23 March 2023.

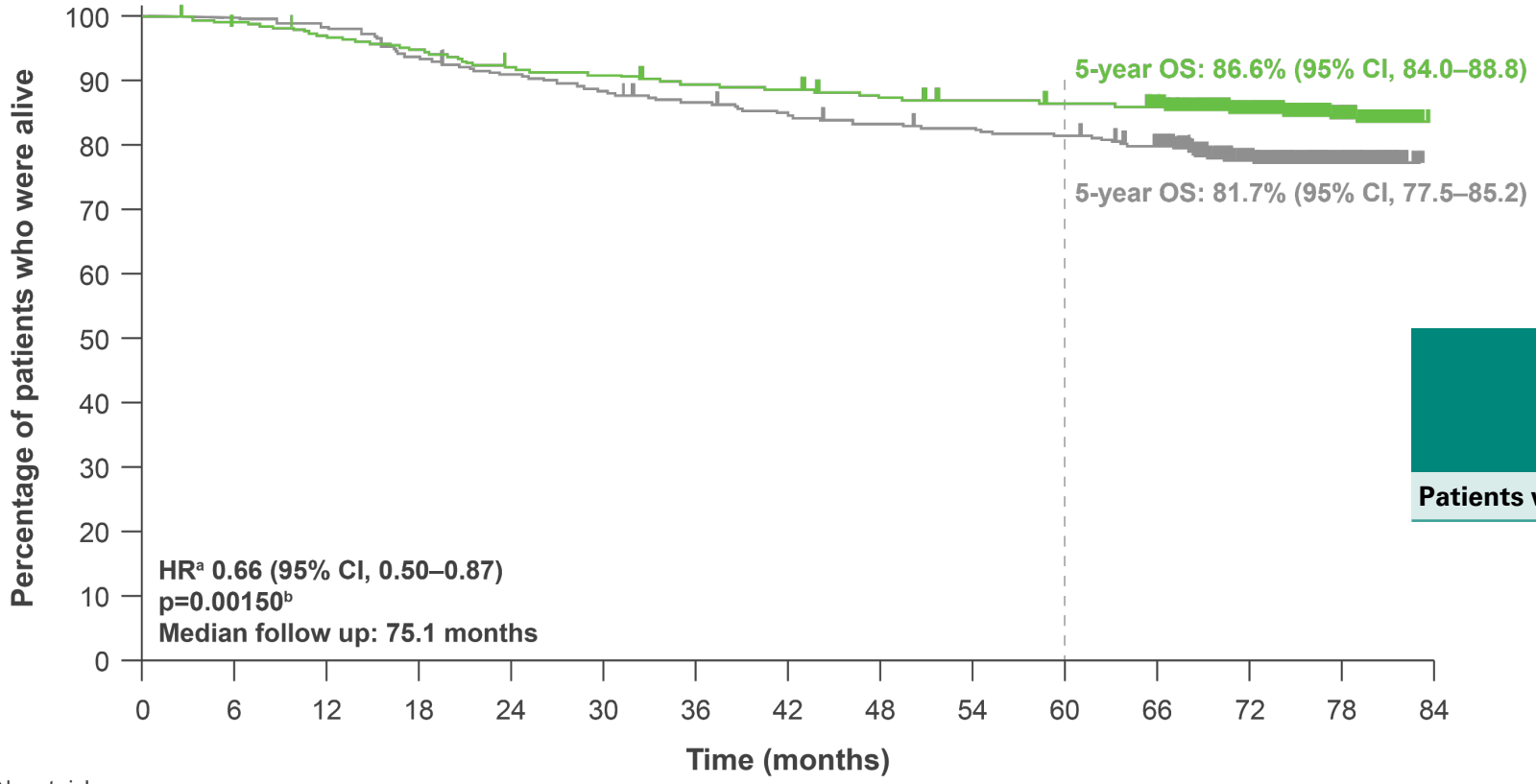
[a]Other refers to non-brain distant recurrence sites, which were classified per clinical identification.

CI, confidence interval; EFS, event-free survival; HR, hazard ratio; pCR, pathologic complete response.

Schmid P et al. Presented at the San Antonio Breast Cancer Symposium Congress 2023, 5–9 December, San Antonio, USA.

UK Prescribing Information

KEYNOTE-522: Key secondary endpoint – OS in the ITT population at 75-month follow up



	KEYTRUDA + chemotherapy/ KEYTRUDA (n=784)	Placebo + chemotherapy/ placebo (n=390)
Patients with event, %	14.7	21.8

No. at risk

KEYTRUDA + chemotherapy/KEYTRUDA	784	777	760	742	720	712	698	693	683	677	670	656	448	176	0
Placebo + chemotherapy/placebo	390	389	385	366	354	345	336	328	321	318	313	300	199	82	0

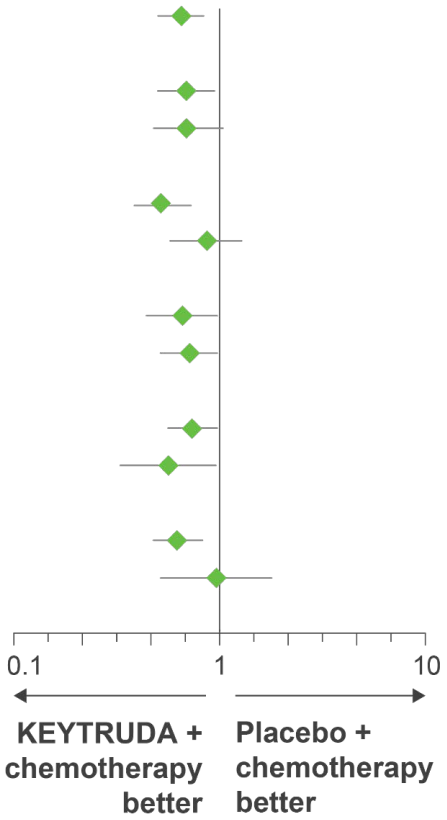
Adapted from Schmid P et al. Presented at ESMO 2024.

Data cut-off: 22 March 2024.
[a]The unstratified piecewise HR was 0.87 (95% CI, 0.57–1.32) before the 2-year follow up and 0.51 (95% CI, 0.35–0.75) afterwards. The weighted average HR with weights of number of events before and after 2-year follow up was 0.66; [b]With 200 events (67.3% information fraction), the observed p-value crossed the prespecified nominal boundary of 0.00503 (one-sided) at this interim analysis.
CI, confidence interval; HR, hazard ratio; ITT, intention-to-treat; OS, overall survival.
Schmid P et al. Presented at the European Society of Medical Oncology Congress 2024, 13–17 September, Barcelona, Spain.

UK Prescribing Information

KEYNOTE-522: Exploratory analysis – OS in key patient subgroups at 75-month follow up

Subgroup	KEYTRUDA + chemotherapy	Placebo + chemotherapy	HR (95% CI)
	no. of patients with events/total no. (%)		
Overall	115/784 (14.7)	85/390 (21.8)	0.66 (0.50–0.87)
Nodal status			
Positive	78/408 (19.1)	56/196 (28.6)	0.65 (0.46–0.91)
Negative	37/376 (9.8)	29/194 (14.9)	0.65 (0.40–1.05)
Tumour size			
T1 to T2	54/580 (9.3)	51/290 (17.6)	0.51 (0.35–0.75)
T3 to T4	61/204 (29.9)	34/100 (34.0)	0.88 (0.58–1.34)
Carboplatin schedule			
Q3W	46/334 (13.8)	36/167 (21.6)	0.63 (0.41–0.97)
QW	68/444 (15.3)	49/220 (22.3)	0.67 (0.46–0.96)
PD-L1 status			
CPS ≥1	92/656 (14.0)	62/317 (19.6)	0.70 (0.51–0.97)
CPS <1	23/128 (18.0)	23/69 (33.3)	0.51 (0.28–0.91)
Age			
<65 yr	93/700 (13.3)	72/342 (21.1)	0.62 (0.45–0.84)
≥65 yr[a]	22/84 (26.2)	13/48 (27.1)	0.96 (0.48–1.91)



Adapted from Schmid P et al. Presented at ESMO 2024.

This was an exploratory analysis; significance was not tested and no statistical conclusions can be drawn

Data cut-off: 22 March 2024.

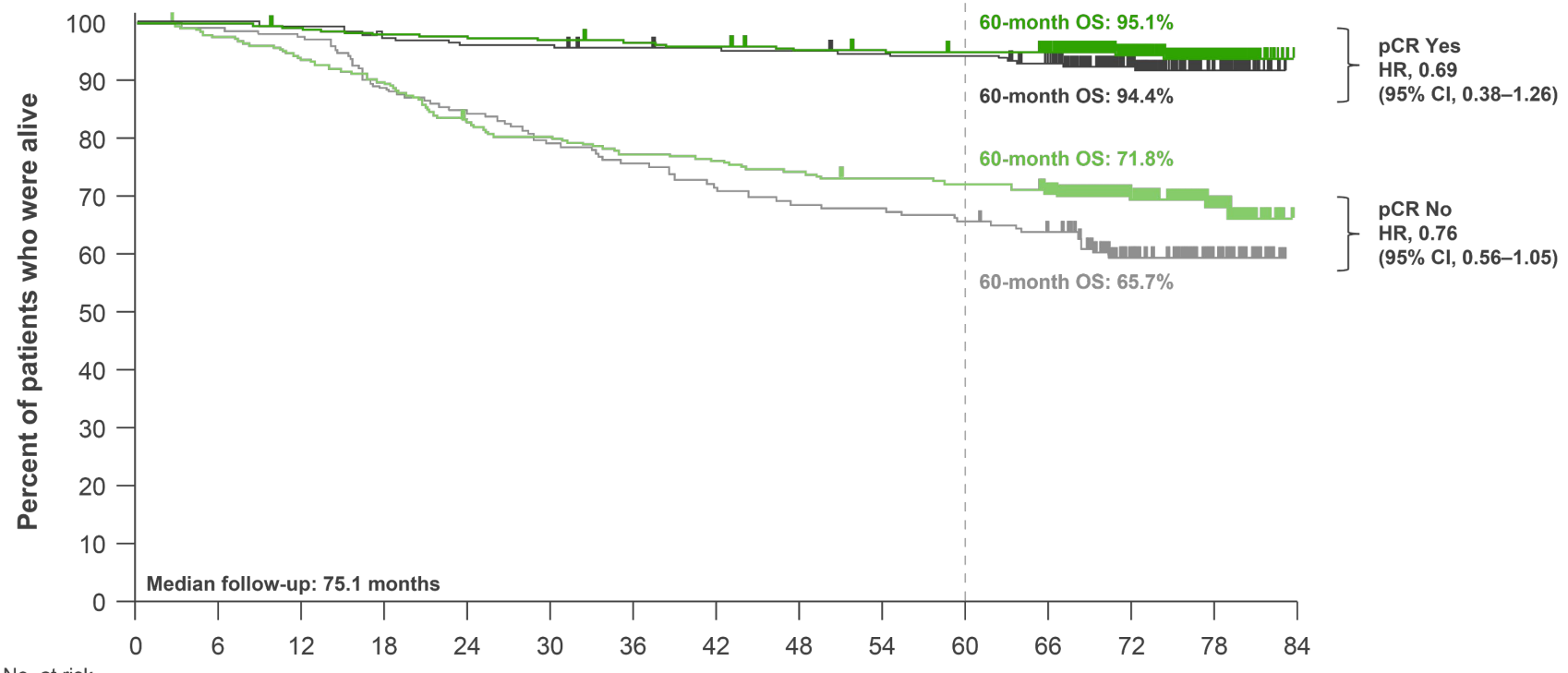
[a]Based on the small sample size and few events, results should be interpreted with caution. For overall population and PD-L1 subgroups, analyses were based on Cox regression model with Efron's method of tie handling, with treatment as a covariate and stratified by nodal status (positive vs negative), tumour size (T1/T2 vs T3/T4), and frequency of carboplatin (Q3W vs QW); for other subgroups, analysis was based on an unstratified Cox model.

CI, confidence interval; CPS, combined positive score; HR, hazard ratio; OS, overall survival; PD-L1, programmed death ligand-1; Q3W, once every three weeks; QW, once weekly; yr, years.

Schmid P et al. Presented at the European Society of Medical Oncology Congress 2024, 13–17 September, Barcelona, Spain.

UK Prescribing Information

KEYNOTE-522: Exploratory analysis – OS by pCR (pathological stage ypT0/Tis ypN0) at 75-month follow up



No. at risk

KEYTRUDA + chemotherapy/ KEYTRUDA responder	495	495	490	484	482	481	476	474	469	468	465	460	318	130	0
Placebo + chemotherapy/ placebo responder	217	217	216	212	209	209	206	205	204	202	201	193	133	54	0
KEYTRUDA + chemotherapy/ KEYTRUDA non-responder	289	282	270	258	238	231	222	219	214	209	205	196	130	46	0
Placebo + chemotherapy/ placebo non-responder	173	172	169	154	145	136	130	123	117	116	112	107	66	28	0

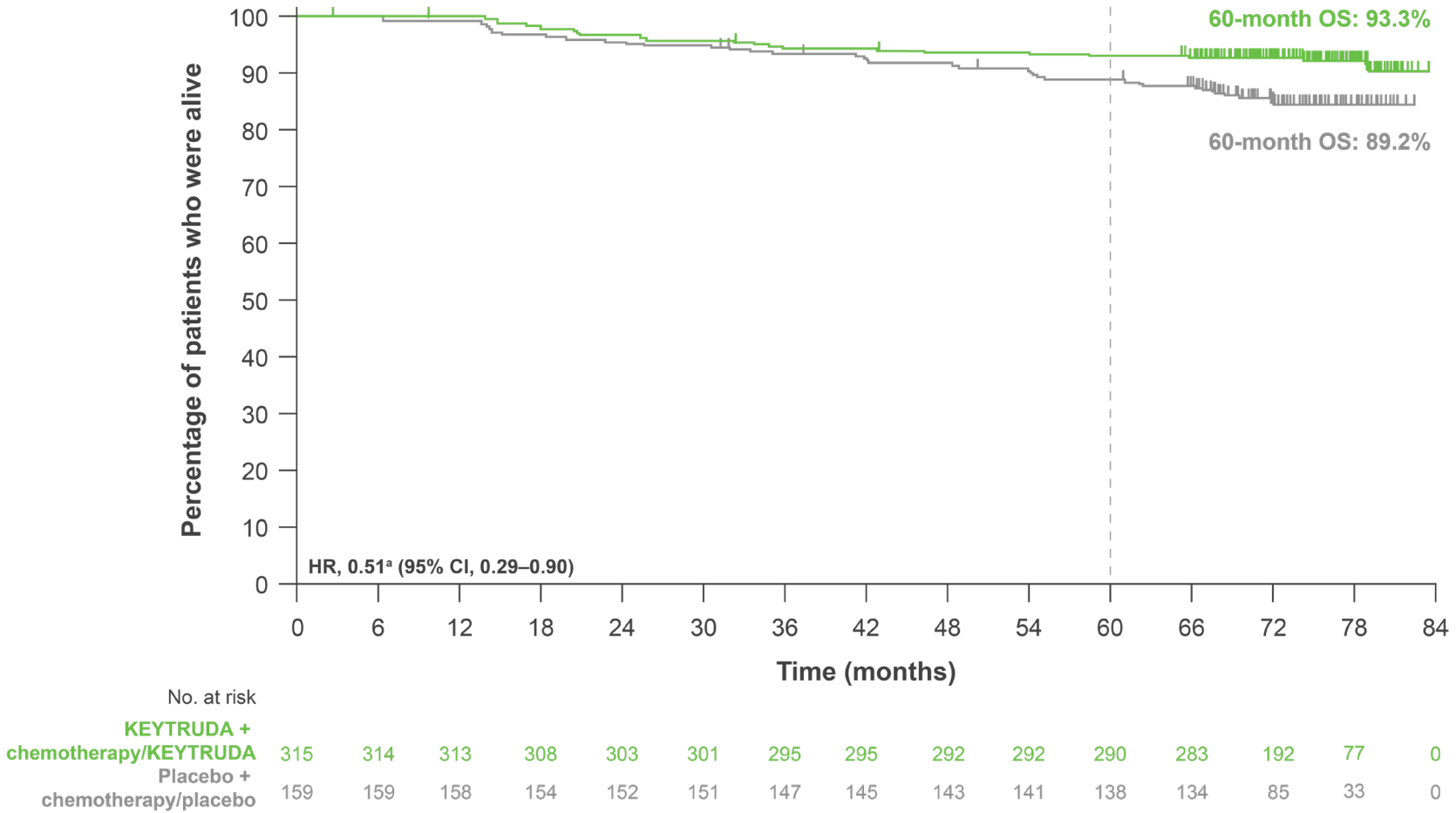
Adapted from Schmid P et al.
Presented at ESMO 2024.

This was an exploratory analysis; significance was not tested and no statistical conclusions can be drawn

Data cut-off: 22 March 2024.
This is a non-randomised subgroup analysis based on the post-treatment outcome of pCR. HRs should therefore be interpreted with caution.
CI, confidence interval; HR, hazard ratio; OS, overall survival; pCR, pathologic complete response.
Schmid P et al. Presented at the European Society of Medical Oncology Congress 2024, 13–17 September, Barcelona, Spain.

UK Prescribing Information

KEYNOTE-522: Exploratory analysis – OS in patients with baseline T2N0 disease at 75-month follow up



	KEYTRUDA + chemotherapy/ KEYTRUDA (n=315)	Placebo + chemotherapy/ placebo (n=159)
Patients with event, %	7.6	14.5

Adapted from Dent R et al.
Presented at SABCS 2024.

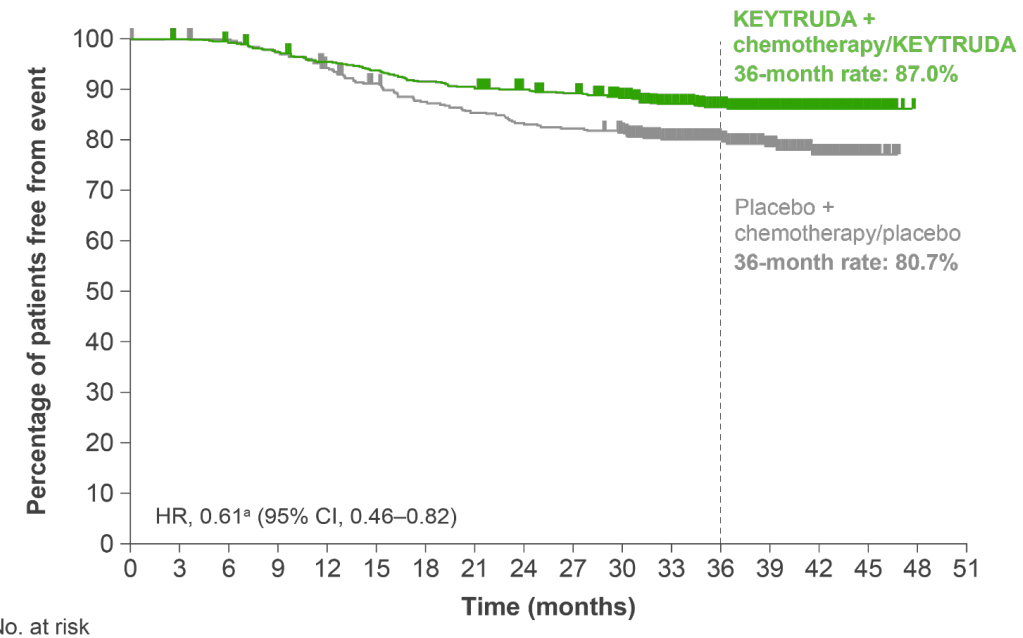
This was an exploratory analysis; significance was not tested, and no statistical conclusions can be drawn

Data cut-off: 22 March 2024.
[a]HR (CI) analysed based on an unstratified Cox regression model with treatment as a covariate.
CI, confidence interval; HR, hazard ratio; OS, overall survival.
Dent R et al. Presented at the San Antonio Breast Cancer Symposium 2024, 10–13 December, San Antonio, USA.

UK Prescribing Information

KEYNOTE-522: Exploratory analysis – DPFS or DRFS at 36- and 60-month follow up

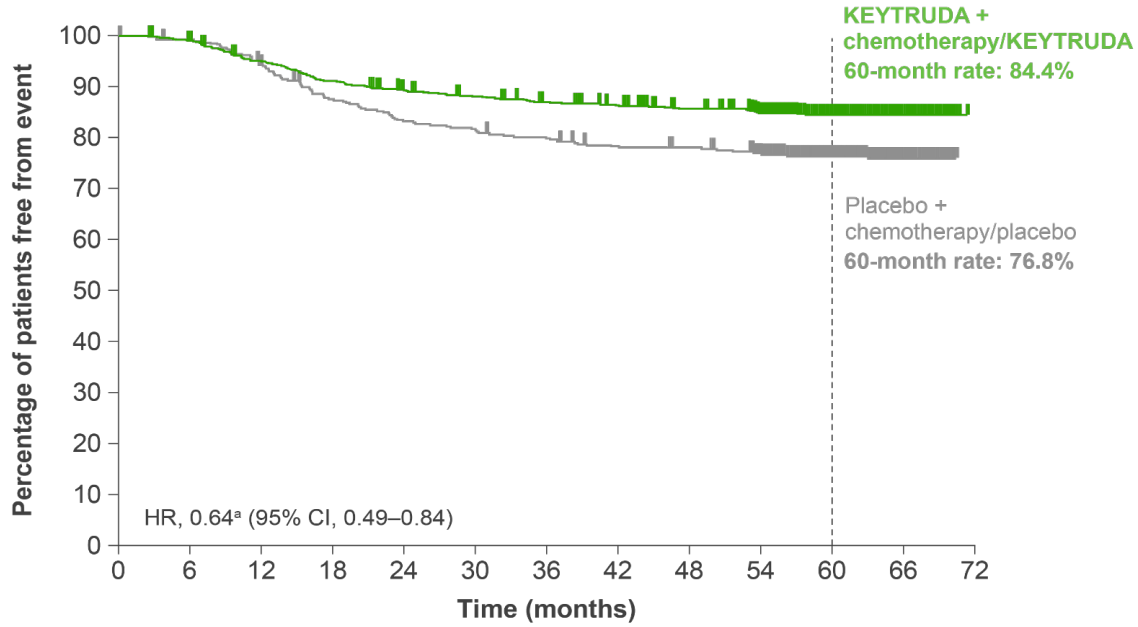
36-month follow up



No. at risk

KEYTRUDA + chemotherapy/KEYTRUDA	784	782	773	758	741	728	711	702	692	685	663	561	439	308	167	29	0	0
Placebo + chemotherapy/placebo	390	389	387	379	367	352	337	330	321	317	312	259	202	143	84	17	0	0

60-month follow up



784	774	742	711	692	681	667	659	645	626	416	164	0
390	387	367	338	322	316	308	298	295	287	195	82	0

Adapted from Schmid P et al. Presented at ESMO 2023.

This was an exploratory analysis; significance was not tested and no statistical conclusions can be drawn

Data cut-off: 23 March 2021 and 23 March 2023.
[a]HR (CI) analysed based on a Cox regression model with treatment as a covariate stratified by randomisation stratification factors.
CI, confidence interval; DPFS, distant progression-free survival; DRFS, distant recurrence-free survival; HR, hazard ratio.
Schmid P et al. Presented at the European Society of Medical Oncology Congress 2023, 20–24 September, Madrid, Spain.

UK Prescribing Information

KEYNOTE-522: Results – Safety

Click the links below to navigate to the section of interest

Safety assessments

Neoadjuvant phase

- Summary of any-grade AEs in the neoadjuvant phase (primary analysis)
- AEs of interest in the neoadjuvant phase (primary analysis)

Adjuvant phase

- TRAEs in the adjuvant phase (36-month follow up)
- Immune-mediated AEs and infusion reactions in the adjuvant phase (36-month follow up)

Combined phase

- Summary of safety results in the combined phase (36-month follow up)
- Summary of any grade TRAEs in the combined phase (75-month follow up)
- Summary of immune-mediated AEs in the combined phase (75-month follow up)

AE, adverse event; TRAE, treatment-related adverse event.

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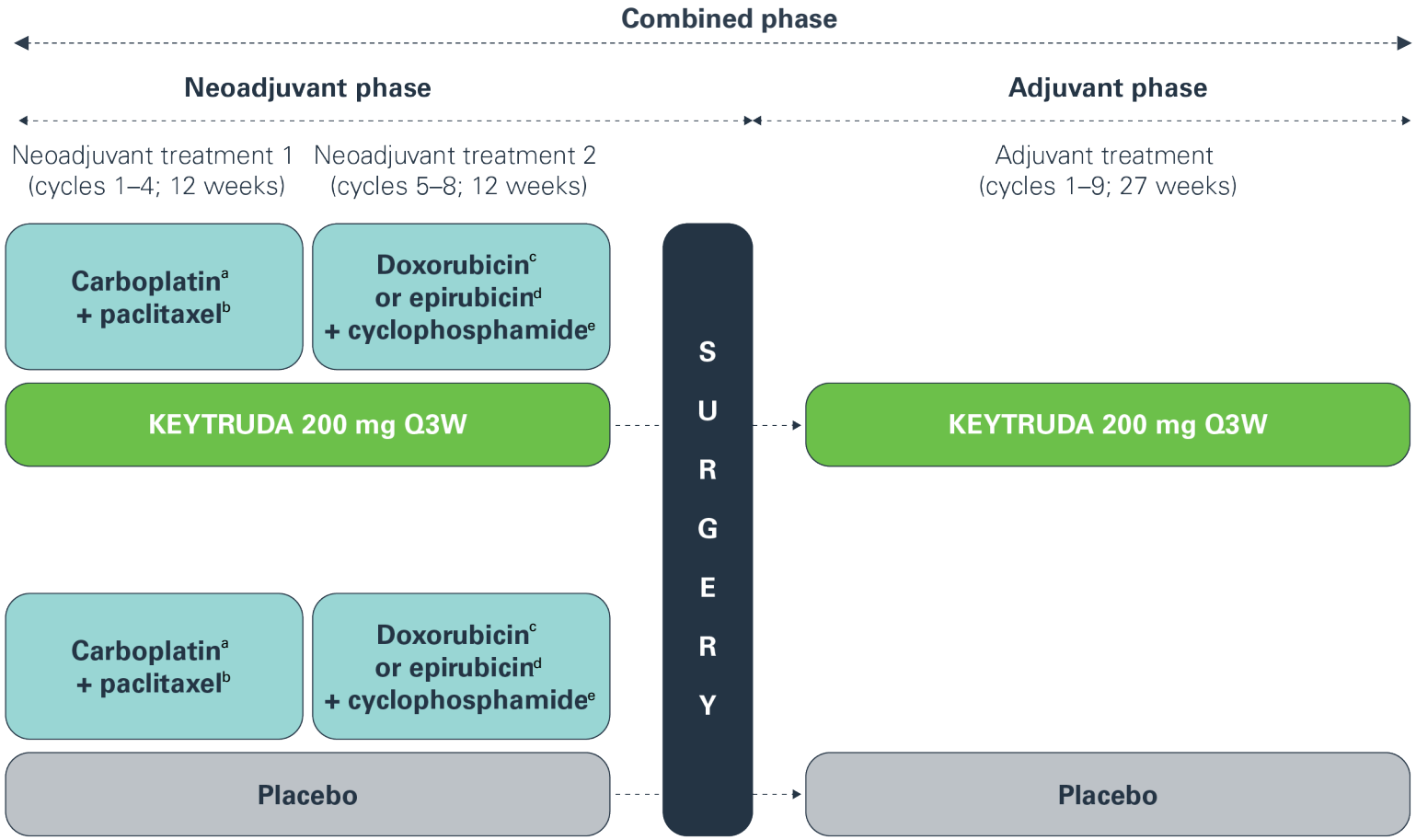
KEYNOTE-522: Safety assessments[1,2]



AEs were assessed during each phase of the study, as well as the study as a whole

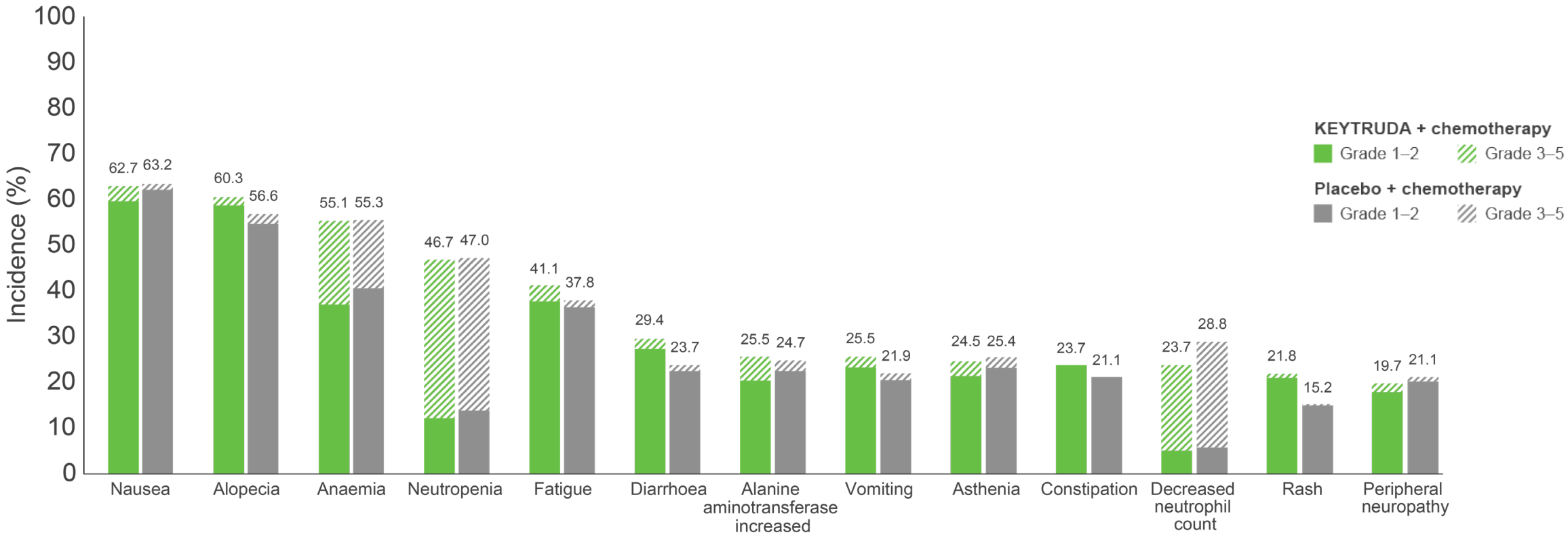
Adapted from Schmid P et al. 2020 and Schmid P et al. 2022.

[a]Carboplatin dose was AUC 5 Q3W or AUC 1.5 QW; [b]Paclitaxel dose was 80 mg/m² QW; [c]Doxorubicin dose was 60 mg/m² Q3W; [d]Epirubicin dose was 90 mg/m² Q3W; [e]Cyclophosphamide dose was 600 mg/m² Q3W.
AE, adverse event; AUC, area under curve; ECOG PS, Eastern Cooperative Oncology Group performance status; EFS, event-free survival; pCR, pathologic complete response; PD-L1, programmed death ligand-1; QW, every week; Q3W, every 3 weeks; R, randomisation; TNBC, triple-negative breast cancer.

1. Schmid P et al. *N Engl J Med* 2020;382:810–821 (plus supplementary appendix); 2. Schmid P et al. *N Engl J Med* 2022;386:556–567 (plus supplementary appendix).

UK Prescribing Information

KEYNOTE-522: Summary of any-grade AEs occurring in ≥20% of patients in the neoadjuvant phase at primary analysis



Adapted from Schmid P et al. 2020.

The tabular data for this plot is shown in the appendix. Click here to view.

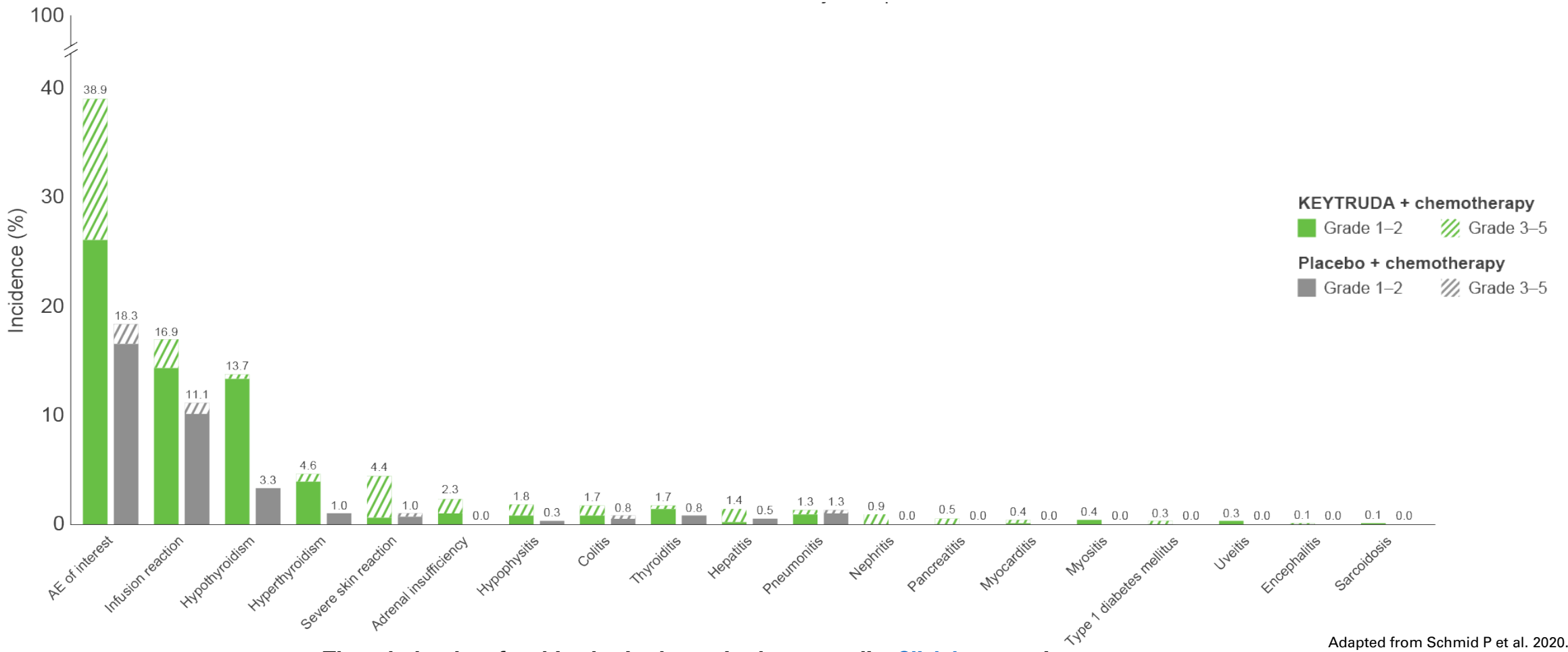
Listed are AEs that occurred during the treatment period or within 30 days after the treatment period (or, for serious AEs, within 90 days) in patients who were randomised and received at least one trial drug or surgery. The severity of the AEs was graded according to the Common Terminology Criteria for Adverse Events, v4.0, of the National Cancer Institute. Patients may have had more than one event.

AE, adverse event.

Schmid P et al. *N Engl J Med* 2020;382:810–821.

UK Prescribing Information

KEYNOTE-522: AEs of interest in the neoadjuvant phase at primary analysis[a]



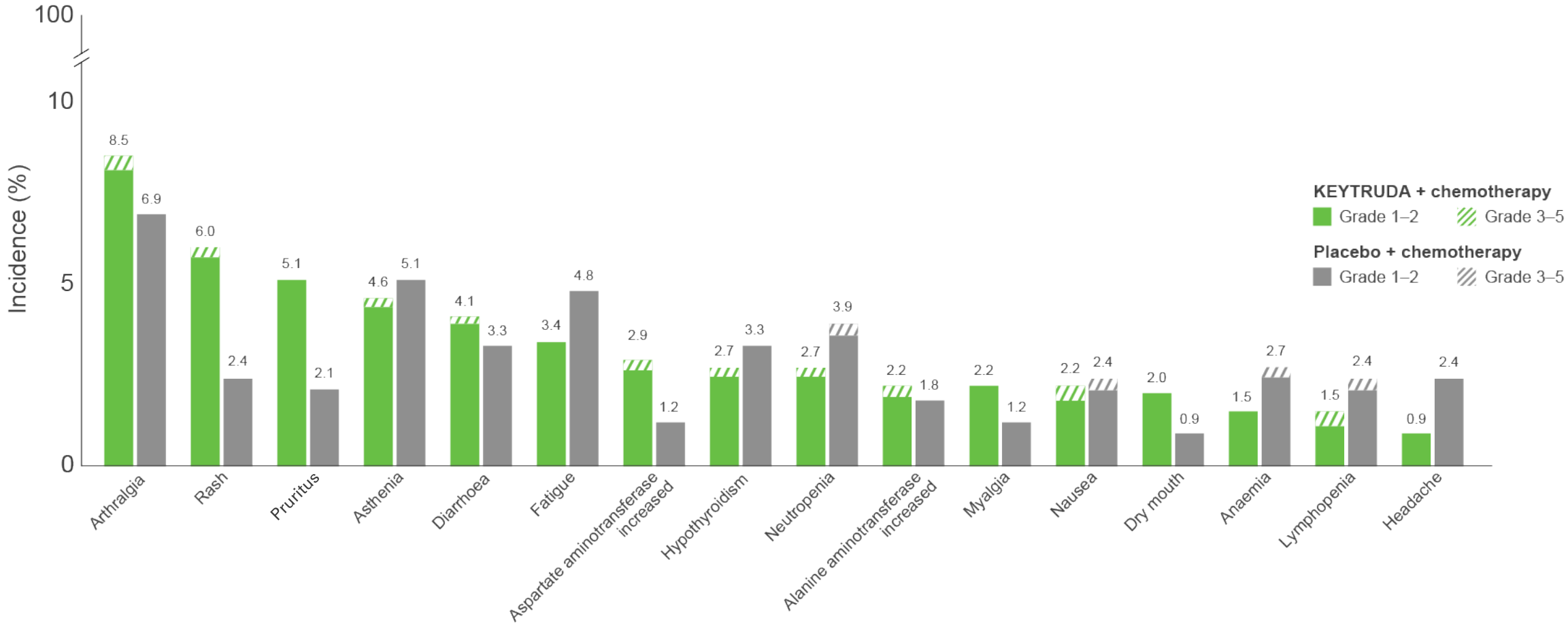
Adapted from Schmid P et al. 2020.

The tabular data for this plot is shown in the appendix. Click here to view.

Listed are AEs that occurred during the treatment period or within 30 days after the treatment period (or, for serious AEs, within 90 days) in patients who were randomised and received at least one trial drug or surgery. The severity of the AEs was graded according to the Common Terminology Criteria for Adverse Events, v4.0, of the National Cancer Institute. Patients may have had more than one event.
[a]AEs of interest were determined according to a list of terms specified by the sponsor, regardless of attribution to any trial treatment by the investigators.
AE, adverse event.
Schmid P et al. *N Engl J Med* 2020;382:810–821 (plus supplementary appendix).

UK Prescribing Information

KEYNOTE-522: TRAEs occurring in ≥2% of patients in the adjuvant phase at 36-month follow up



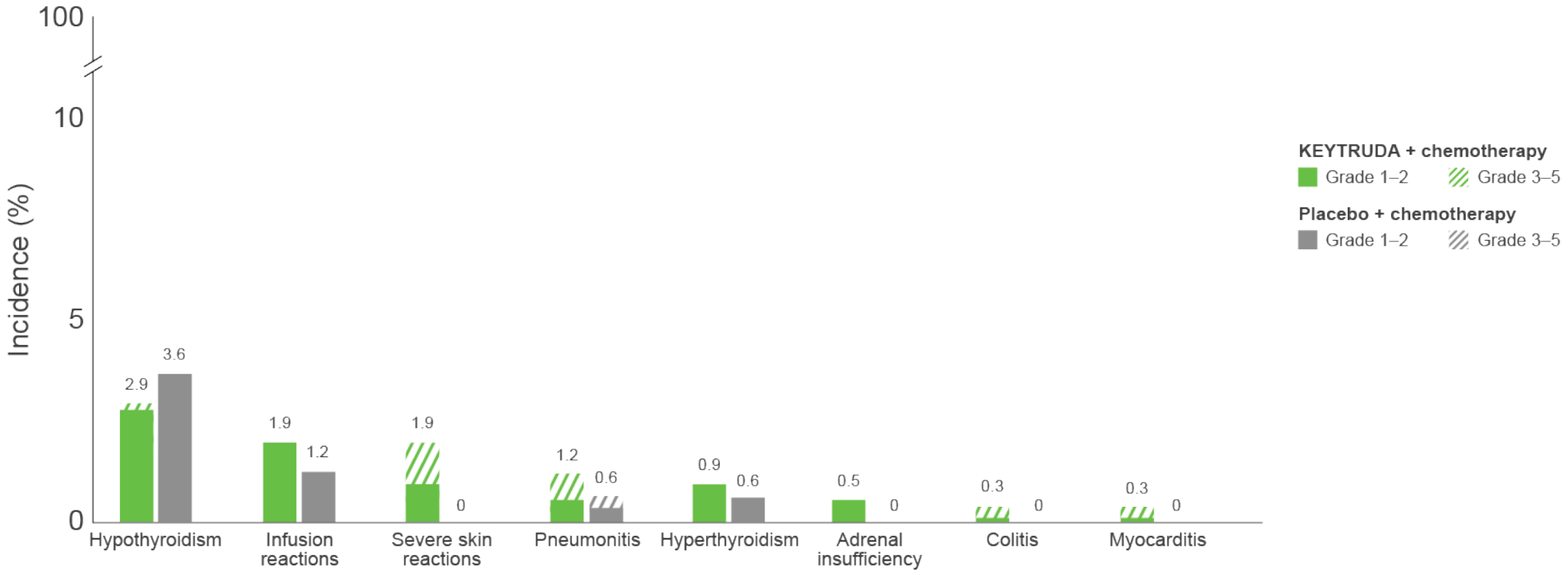
Adapted from Schmid P et al. Presented at ESMO 2021.

The tabular data for this plot is shown in the appendix. Click here to view.

Listed are AEs that occurred during the treatment period or within 30 days after the treatment period (or, for serious AEs, within 90 days) in patients who were randomised and received at least one trial drug or surgery. The severity of the AEs was graded according to the Common Terminology Criteria for Adverse Events, v4.0, of the National Cancer Institute. Patients may have had more than one event.
AE, adverse event; TRAE, treatment-related adverse event.
Schmid P et al. Presented at the European Society for Medical Oncology (ESMO) Virtual Plenary 2021, 16–21 September.

UK Prescribing Information

KEYNOTE-522: Immune-mediated AEs and infusion reactions in the adjuvant phase at 36-month follow up



The tabular data for this plot is shown in the appendix. Click here to view.

Adapted from Schmid P et al. Presented at ESMO 2021.

Listed are AEs that occurred during the treatment period or within 30 days after the treatment period (or, for serious AEs, within 90 days) in patients who were randomised and received at least one trial drug or surgery. The severity of the AEs was graded according to the Common Terminology Criteria for Adverse Events, v4.0, of the National Cancer Institute. Patients may have had more than one event. Immune-mediated AEs were determined according to the sponsor, regardless of attribution to any trial treatment. Grade 5 immune-mediated AEs were pulmonary embolism and autoimmune encephalitis (n=1 each) in the KEYTRUDA + chemotherapy group.

AE, adverse event.

Schmid P et al. Presented at the European Society for Medical Oncology (ESMO) Virtual Plenary 2021, 16–21 September.

UK Prescribing Information

KEYNOTE-522: Summary of safety results in the combined (neoadjuvant and adjuvant) phase at 36-month follow up

Immune-mediated AEs and infusion reactions

	KEYTRUDA + chemotherapy/ KEYTRUDA (n=783)	Placebo + chemotherapy/ placebo (n=389)
Any	341 (43.6)	85 (21.9)
Grade 1–2	224 (28.6)	77 (19.8)
Grade 3–4	115 (14.7)	8 (2.1)[a]
Grade 5	2 (0.3)[b]	0
Led to dose reduction[c]		
Chemotherapy[d]	1 (0.1)[e]	0
Led to treatment interruption		
KEYTRUDA/placebo	43 (5.5)	9 (2.3)
Chemotherapy[d]	88 (11.2)	25 (6.4)
Led to discontinuation of any drug		
KEYTRUDA/placebo	61 (7.8)	4 (1.0)
Chemotherapy[d]	45 (5.7)	7 (1.8)

Time to onset and management of the most common (≥20 patients) immune-mediated AEs and infusion reactions

	KEYTRUDA + chemotherapy/ KEYTRUDA (n=783)	Placebo + chemotherapy/ placebo (n=389)
Infusion reactions, n (%)	141 (18.0)	45 (11.6)
Median time to onset (range), days	16 (1–458)	22 (1–325)
Treated with corticosteroids, n	85	28
Hypothyroidism, n (%)	118 (15.1)	22 (5.7)
Median time to onset (range), days	105 (7–510)	255 (7–527)
Treated with thyroid replacement, n	106	13
Severe skin reactions, n (%)	45 (5.7)	4 (1.0)
Median time to onset (range), days	64 (4–479)	50.5 (32–186)
Treated with corticosteroids, n	28	0
Hyperthyroidism, n (%)	41 (5.2)	7 (1.8)
Median time to onset (range), days	107 (20–470)	184 (1–284)
Adrenal insufficiency, n (%)	20 (2.6)	0
Median time to onset (range), days	175.5 (100–383)	-
Treated with hormone replacement, n	20	-

Adapted from Cortés J et al. Presented at SABCS 2023.

[a]There were no Grade 4 immune-mediated AEs or infusion reactions; [b]n=1 with pneumonitis (neoadjuvant phase), n=1 with autoimmune encephalitis (adjuvant phase); [c]Dose reduction was not allowed for KEYTRUDA or placebo; [d]Chemotherapy was administered during the neoadjuvant phase only; [e]Due to a severe skin reaction.

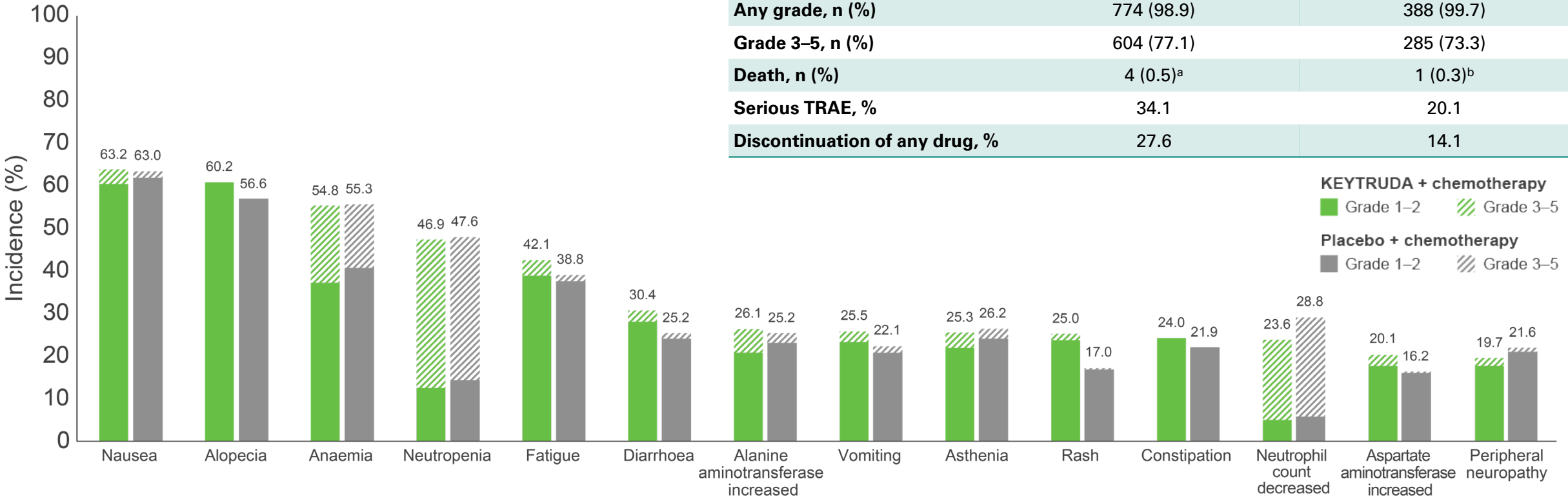
AE, adverse event.

Cortés J et al. Presented at the San Antonio Breast Cancer Symposium Congress 2023, 5–9 December, San Antonio, USA.

UK Prescribing Information

KEYNOTE-522: Summary of any-grade TRAEs occurring in ≥20% of patients in the combined neoadjuvant and adjuvant phases at 75-month follow up[1,2]

All TRAEs	KEYTRUDA + chemotherapy/ KEYTRUDA (n=783)	Placebo + chemotherapy/ placebo (n=389)
Any grade, n (%)	774 (98.9)	388 (99.7)
Grade 3–5, n (%)	604 (77.1)	285 (73.3)
Death, n (%)	4 (0.5)[a]	1 (0.3)[b]
Serious TRAE, %	34.1	20.1
Discontinuation of any drug, %	27.6	14.1



The tabular data for this plot is shown in the appendix. Click here to view.

Adapted from Schmid P et al. Presented at ESMO 2024.[1]

Data cut-off: 22 March 2024. AEs were assessed during each phase of the study, as well as the study as a whole. Listed are AEs that occurred during the treatment period or within 30 days after the treatment period (or, for serious AEs, within 90 days) in patients who were randomised and received at least one trial drug or surgery. The severity of the AEs was graded according to the Common Terminology Criteria for Adverse Events v4.0 of the National Cancer Institute. Patients may have had more than one event.

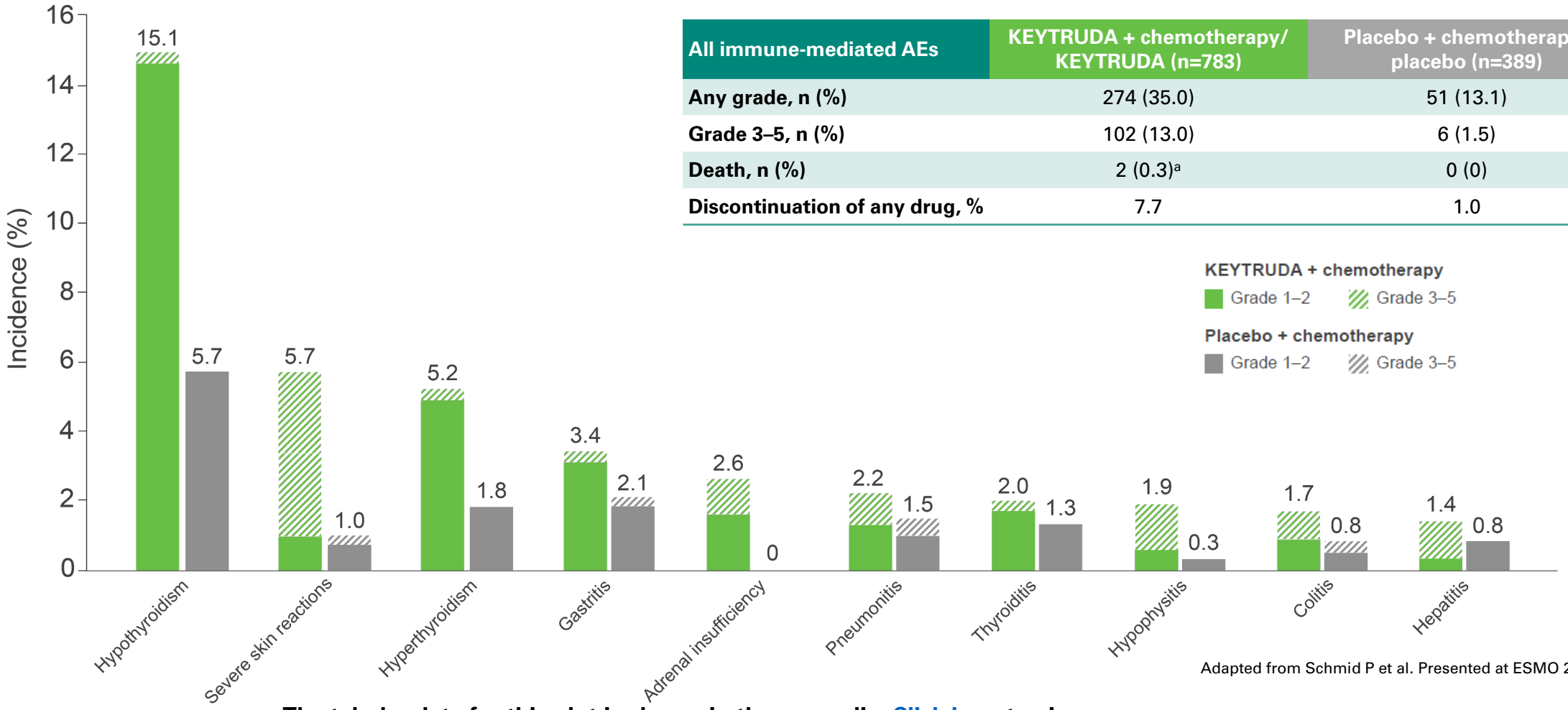
[a]**Grade 5 AEs in the KEYTRUDA + chemotherapy arm were sepsis and multiple organ dysfunction syndrome (n=1) and pneumonitis, pulmonary embolism and autoimmune encephalitis (n=1 in each group);** [b]**Grade 5 AEs in the placebo + chemotherapy arm were septic shock (n=1).** AE, adverse event; TRAE, treatment-related adverse event.

1. Schmid P et al. Presented at the European Society of Medical Oncology Congress 2024, 13–17 September, Barcelona, Spain;
2. Schmid P et al. *N Engl J Med* 2024; doi:10.1056/NEJMoa2409932 [Epub ahead of print].

UK Prescribing Information

KEYNOTE-522: Summary of immune-mediated AEs occurring in ≥10 patients in the combined neoadjuvant and adjuvant phases at 75-month follow up[1,2]

All immune-mediated AEs	KEYTRUDA + chemotherapy/ KEYTRUDA (n=783)	Placebo + chemotherapy/ placebo (n=389)
Any grade, n (%)	274 (35.0)	51 (13.1)
Grade 3–5, n (%)	102 (13.0)	6 (1.5)
Death, n (%)	2 (0.3)[a]	0 (0)
Discontinuation of any drug, %	7.7	1.0



Adapted from Schmid P et al. Presented at ESMO 2024.[1]

The tabular data for this plot is shown in the appendix. Click here to view.

Data cut-off: 22 March 2024. Data presented for AEs experienced by ≥10 patients.
[a]One patient from pneumonitis and one patient from autoimmune encephalitis. Considered regardless of attribution to treatment or immune-relatedness by the investigator. Related terms included in addition to preferred terms listed. AE, adverse event.

1. Schmid P et al. Presented at the European Society of Medical Oncology Congress 2024, 13–17 September, Barcelona, Spain;
2. Schmid P et al. *N Engl J Med* 2024; doi:10.1056/NEJMoa2409932 [Epub ahead of print].

UK Prescribing Information

Implementing KEYTRUDA + chemotherapy for early-stage TNBC

Click the links below to navigate to the section of interest

KEYTRUDA dosing in KEYNOTE-522

KEYTRUDA offers flexibility of dosing

TNBC, triple-negative breast cancer.

UK Prescribing Information

KEYTRUDA dosing in KEYNOTE-522

First neoadjuvant phase[1]

200 mg KEYTRUDA
+ paclitaxel[a] and carboplatin[b]

Q3W
up to 12 weeks

Second neoadjuvant phase[1]

200 mg KEYTRUDA + doxorubicin[c]
or epirubicin[d] and
cyclophosphamide[e]

Q3W
up to 12 weeks

Adjuvant cycle[2]

200 mg KEYTRUDA monotherapy
(radiation therapy concurrently or
2 weeks prior to adjuvant KEYTRUDA)

Q3W
up to 27 weeks

Patients should be treated with KEYTRUDA until disease progression or unacceptable toxicity[3]

Atypical responses (i.e. an initial transient increase in tumour size or new small lesions within the first few months, followed by tumour shrinkage) have been observed[3]

It is recommended to continue treatment in clinically stable patients with initial evidence of disease progression until disease progression is confirmed[3]

No dose reductions of KEYTRUDA are recommended. KEYTRUDA should be withheld or discontinued to manage AEs as described within the SmPC[3]

When administering KEYTRUDA in combination with IV chemotherapy, KEYTRUDA should be administered first[3]

Consult the full KEYTRUDA SmPC for guidance on dosing

[a]80 mg/m² QW; [b]AUC of 5 mg/mm/min Q3W or 1.5 mg/mm/min QW; [c]60 mg/m² Q3W; [d]90 mg/m² Q3W; [e]600 mg/m² Q3W.
AE, adverse event; AUC, area under the curve; IV, intravenous; Q3W, every 3 weeks; QW, once weekly; SmPC, Summary of Product Characteristics.
1. Schmid P et al. *N Engl J Med* 2020;382:810–821; 2. Schmid P et al. *N Engl J Med* 2022;386:556–567;
3. KEYTRUDA (pembrolizumab) Summary of Product Characteristics. Available at: https://www.medicines.org.uk/emc/product/2498/smpc. Accessed August 2025.

UK Prescribing Information

KEYTRUDA offers flexibility of dosing

KEYTRUDA dosing:

Administered as an IV infusion

Over 30 minutes

200 mg Q3W or 400 mg Q6W

Patients should be treated with KEYTRUDA until disease progression or unacceptable toxicity.

Atypical responses (i.e. an initial transient increase in tumour size or new small lesions within the first few months, followed by tumour shrinkage) have been observed.

It is recommended to continue treatment in clinically stable patients with suspected disease progression until disease progression is confirmed.

No dose reductions of KEYTRUDA are recommended. KEYTRUDA should be withheld or discontinued to manage AEs as described within the SmPC.

When administering KEYTRUDA in combination with IV chemotherapy, KEYTRUDA should be administered first.

Consult the full KEYTRUDA SmPC for guidance on dosing.

The KEYTRUDA 200 mg Q3W regimen has been assessed in Phase 2 and Phase 3 registration studies across a multitude of indications.
An exposure–response evaluation (using modelling and simulation) led to the approval of the 400 mg Q6W dosing for monotherapy and combination therapy.

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

KEYTRUDA (pembrolizumab) Summary of Product Characteristics. Available at: https://www.medicines.org.uk/emc/product/2498/smpc. Accessed August 2025.

UK Prescribing Information

KEYNOTE-522: Summary

Click the links below to navigate to the section of interest

Summary: Efficacy

Summary: Safety

UK Prescribing Information

Summary: Efficacy (1)

KEYTRUDA, in combination with chemotherapy as neoadjuvant treatment, and then continued as monotherapy as adjuvant treatment after surgery, is indicated in the treatment of adults with locally advanced or early-stage TNBC at high risk of recurrence[1]

- There was a statistically significant improvement in pCR rates with KEYTRUDA + chemotherapy (neoadjuvant treatment) vs placebo + chemotherapy (neoadjuvant treatment) in the primary analysis (64.8% vs 51.2%, respectively; p<0.001) and in the prespecified final analysis of KEYNOTE-522 (64.0% vs 54.7%, respectively; p=0.00221)[1]
- KEYTRUDA + chemotherapy in the neoadjuvant setting, followed by KEYTRUDA monotherapy as adjuvant treatment, resulted in a statistically significant improvement in EFS compared with placebo + chemotherapy followed by placebo at the 36-month analysis (HR: 0.63; 95% CI: 0.48–0.82 [p<0.001])[a,b,2] and numerically higher EFS at 75-month follow up (HR: 0.65; 95% CI: 0.51–0.83)[a,3]
    - At 36- and 75-month follow up, the percentage of patients who experienced an event were 15.7% and 20.3% in the KEYTRUDA + chemotherapy group and 23.8% and 29.2% in the placebo + chemotherapy group, respectively[2,3]
- An exploratory analysis of EFS in key subgroups, including disease stage, nodal status and T2N0 status, suggested a benefit for patients treated with KEYTRUDA + chemotherapy vs placebo + chemotherapy[2,4,5]

[a]HR (CI) analysed based on a Cox regression model with treatment as a covariate stratified by the randomisation stratification factors; [b]Prespecified p-value boundary of 0.00517 was crossed.

CI, confidence interval; EFS, event-free survival; HR, hazard ratio; pCR, pathologic complete response; TNBC, triple-negative breast cancer.

1. KEYTRUDA (pembrolizumab) Summary of Product Characteristics. Available at: https://www.medicines.org.uk/emc/product/2498/smpc. Accessed August 2025; 2. Schmid P et al. *N Engl J Med* 2022;386:556–567; 3. Schmid P et al. Presented at the European Society of Medical Oncology Congress 2024, 13–17 September, Barcelona, Spain; 4. Schmid P et al. Presented at the San Antonio Breast Cancer Symposium (SABCS) Congress 2023, 5–9 December, San Antonio, USA; 5. Schmid P et al. Presented at the European Society of Medical Oncology Congress 2023, 20–24 September, Madrid, Spain.

UK Prescribing Information

Summary: Efficacy (2)

KEYTRUDA, in combination with chemotherapy as neoadjuvant treatment, and then continued as monotherapy as adjuvant treatment after surgery, is indicated in the treatment of adults with locally advanced or early-stage TNBC at high risk of recurrence[1]

- An exploratory analysis of EFS by pCR (ypT0/Tis ypN0) suggested a benefit for KEYTRUDA + chemotherapy vs placebo + chemotherapy regardless of pCR outcome at 36 months of follow up, with the difference maintained at 60 months of follow up[2]
- KEYTRUDA + chemotherapy in the neoadjuvant setting, followed by KEYTRUDA monotherapy as adjuvant treatment, resulted in a statistically significant and clinically meaningful improvement in OS (key secondary endpoint) at 75-month follow up (HR: 0.66; 95% CI: 0.50–0.87 [p=0.00150])[a] compared with neoadjuvant placebo + chemotherapy followed by placebo in patients with previously untreated, high-risk, early-stage TNBC[3]
  - OS was numerically higher for patients treated with KEYTRUDA + chemotherapy vs placebo + chemotherapy in an exploratory analysis of key subgroups, including nodal status, tumour size T1/T2 vs T3/T4 and patients with baseline T2N0 disease[3,4]

[a]With 200 events (67.3% information fraction), the observed p-value crossed the prespecified nominal boundary of 0.00503 (one-sided) at this interim analysis.

CI, confidence interval; EFS, event-free survival; HR, hazard ratio; OS, overall survival; pCR, pathologic complete response; TNBC, triple-negative breast cancer.

1. KEYTRUDA (pembrolizumab) Summary of Product Characteristics. Available at: https://www.medicines.org.uk/emc/product/2498/smpc. Accessed August 2025;
2. Schmid P et al. Presented at the European Society of Medical Oncology Congress 2023, 20–24 September, Madrid, Spain; 3. Schmid P et al. Presented at the European Society of Medical Oncology Congress 2024, 13–17 September, Barcelona, Spain; 4. Dent R et al. Presented at the San Antonio Breast Cancer Symposium 2024, 10–13 December, San Antonio, USA.

UK Prescribing Information

Summary: Safety

KEYTRUDA, in combination with chemotherapy as neoadjuvant treatment, and then continued as monotherapy as adjuvant treatment after surgery, is indicated in the treatment of adults with locally advanced or early-stage TNBC at high risk of recurrence[1]

- The safety data for KEYTRUDA + chemotherapy as neoadjuvant treatment, followed by KEYTRUDA monotherapy as adjuvant treatment, are consistent with the known AE profiles of each regimen, being generally manageable in both phases[2–4]
- No indication-specific immune-mediated AEs were identified at the 36-month analysis[4]
  - Most immune-mediated AEs and infusion reactions were Grade 1–2 in severity, manageable with corticosteroids, treatment interruption and/or hormone replacement, and did not result in treatment discontinuation[4]
- The safety profile remained consistent with the previous analyses and the established safety profiles of KEYTRUDA + chemotherapy.[5] No new safety concerns were identified with longer follow up (75 months)

AE, adverse event; TNBC, triple-negative breast cancer.

1. KEYTRUDA (pembrolizumab) Summary of Product Characteristics. Available at: https://www.medicines.org.uk/emc/product/2498/smpc. Accessed August 2025; 2. Schmid P et al. *N Engl J Med* 2022;386:556–567; 3. Schmid P et al. *N Engl J Med* 2020;382:810–821; 4. Cortés J et al. Presented at the San Antonio Breast Cancer Symposium Congress 2023, 5–9 December, San Antonio, USA;
5. Schmid P et al. Presented at the European Society of Medical Oncology Congress 2024, 13–17 September, Barcelona, Spain.

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Appendix

Click the links below to navigate to the section of interest

Efficacy

- EFS by RCB category
- First EFS events by RCB category
- pCR by PD-L1 expression level

Safety

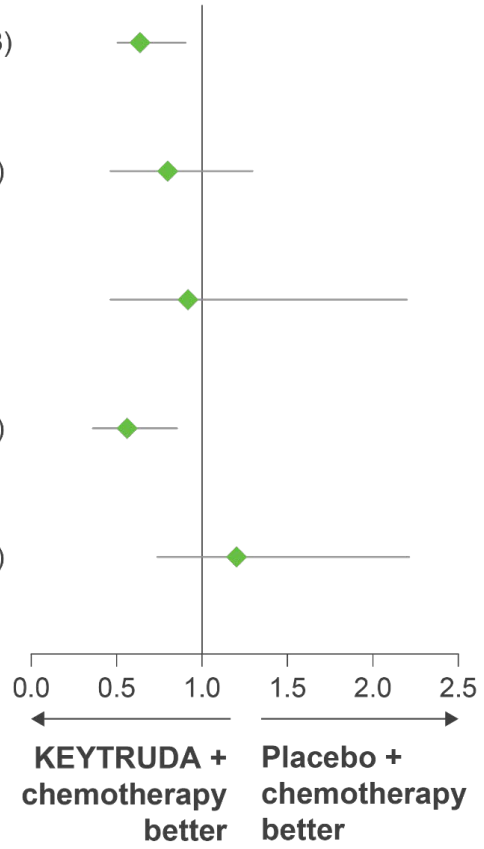
- Summary of any-grade AEs in the neoadjuvant phase (primary analysis)
- AEs of interest in the neoadjuvant phase (1/2) (primary analysis)
- AEs of interest in the neoadjuvant phase (2/2) (primary analysis)
- TRAEs in the adjuvant phase (36-month follow up)
- Immune-mediated AEs and infusion reactions in the adjuvant phase (36-month follow up)
- Any-grade AEs in the combined phase (75-month follow up)
- Immune-mediated AEs in the combined phase (75-month follow up)

AE, adverse event; EFS, event-free survival; pCR, pathologic complete response; PD-L1, programmed death ligand-1; RCB, residual cancer burden; TRAE, treatment-related adverse event.

UK Prescribing Information

KEYNOTE-522: Exploratory analysis – EFS by RCB category

Subgroup	KEYTRUDA + chemotherapy *no. of patients with events/total no. (%)*	Placebo + chemotherapy	HR (95% CI)
Overall	123/784 (15.7)	93/390 (23.8)	0.63 (0.48–0.82)
RCB-0	26/497 (5.2)	16/219 (7.3)	0.70 (0.38–1.31)
RCB-1	12/69 (17.4)	9/45 (20.0)	0.92 (0.39–2.20)
RCB-2	37/145 (25.5)	35/79 (44.3)	0.52 (0.32–0.82)
RCB-3	29/40 (72.5)	18/26 (69.2)	1.24 (0.69–2.23)



Adapted from Pusztai L et al. Presented at ASCO 2022.

This was an exploratory analysis; significance was not tested and no statistical conclusions can be drawn

Data cut-off: 23 March 2021.
EFS in the overall population is based on a stratified Cox model; EFS by RCB is based on an unstratified Cox model.
CI, confidence interval; EFS, event-free survival; HR, hazard ratio; RCB, residual cancer burden.
Pusztai L et al. Presented at the American Society of Clinical Oncology (ASCO) Annual Meeting 2022, 3–7 June, Chicago, USA.

UK Prescribing Information

KEYNOTE-522: Exploratory analysis – First EFS events by RCB category

Event, %	RCB-0		RCB-1		RCB-2		RCB-3	
	KEYTRUDA + chemo (n=497)	Placebo + chemo (n=219)	KEYTRUDA + chemo (n=69)	Placebo + chemo (n=45)	KEYTRUDA + chemo (n=145)	Placebo + chemo (n=79)	KEYTRUDA + chemo (n=40)	Placebo + chemo (n=26)
Any EFS event	5.2	7.3	17.4	20.0	25.5	44.3	72.5	69.2
Secondary primary malignancy	0.2	0	1.4	2.2	1.4	3.8	2.5	0
PD precluded definitive surgery	0	0	1.4	2.2	1.4	5.1	10.0	7.7
Local recurrence	0.6	1.4	4.3	6.7	6.9	8.9	25.0	7.7
Distant recurrence	3.2	5.5	8.7	8.9	15.2	22.8	35.0	53.8
Death	1.2	0.5	1.4	0	0.7	3.8	0	0

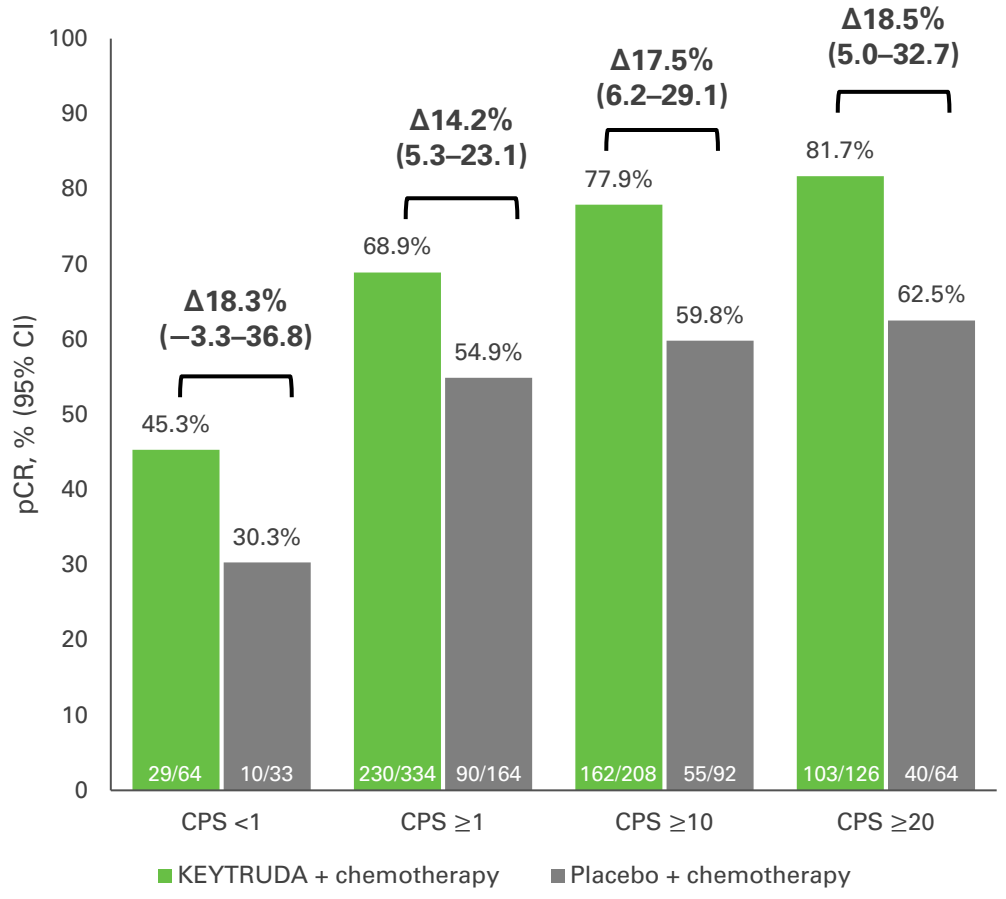
Adapted from Pusztai L et al. Presented at ASCO 2022.

Data cut-off: 23 March 2021.
The treatment regimen in each arm included chemotherapy. Among all patients (N=1174), 54 (4.6%) patients had missing RCB categorical data: 33 (4.2%) in the KEYTRUDA + chemotherapy group and 21 (5.4%) in the placebo + chemotherapy group.
EFS, event-free survival; PD, progressive disease; RCB, residual cancer burden.
Pusztai L et al. Presented at the American Society of Clinical Oncology (ASCO) Annual Meeting 2022, 3–7 June, Chicago, USA.

UK Prescribing Information

KEYNOTE-522: Exploratory analysis – pCR by PD-L1 expression level

Similar pCR[a] benefits were observed in PD-L1–positive and PD-L1–negative patients treated with KEYTRUDA + chemotherapy



Adapted from Schmid P et al. Presented at SABCS 2019.

This was an exploratory analysis; significance was not tested and no statistical conclusions can be drawn

Data cut-off: 24 September 2018.

[a]Estimated treatment difference based on Miettinen and Nurminen method stratified by nodal status (+ vs −), tumour size (T1/T2 vs T3/T4) and frequency of carboplatin administration (Q3W vs QW).

CI, confidence interval; CPS, combined positive score; pCR, pathologic complete response; PD-L1, programmed death ligand-1; Q3W, once every three weeks; QW, once weekly.

Schmid P et al. Presented at the San Antonio Breast Cancer Symposium 2019, 11–14 December, San Antonio, USA.

UK Prescribing Information

KEYNOTE-522: Summary of any-grade AEs occurring in ≥20% of patients in the neoadjuvant phase at primary analysis

AE, n (%)	KEYTRUDA + chemotherapy (n=781)		Placebo + chemotherapy (n=389)	
	Any grade	Grade ≥3	Any grade	Grade ≥3
Any AE	777 (99.2)	633 (81.0)	389 (100.0)	295 (75.8)
Treatment-related AE[a]	773 (99.0)	600 (76.8)	388 (99.7)	281 (72.2)
Nausea	490 (62.7)	26 (3.3)	246 (63.2)	5 (1.3)
Alopecia	471 (60.3)	14 (1.8)	220 (56.6)	8 (2.1)
Anaemia	430 (55.1)	142 (18.2)	215 (55.3)	58 (14.9)
Neutropenia	365 (46.7)	270 (34.6)	183 (47.0)	129 (33.2)
Fatigue	321 (41.1)	27 (3.5)	147 (37.8)	6 (1.5)
Diarrhoea	230 (29.4)	17 (2.2)	92 (23.7)	5 (1.3)
Alanine aminotransferase increased	199 (25.5)	41 (5.2)	96 (24.7)	9 (2.3)
Vomiting	199 (25.5)	18 (2.3)	85 (21.9)	6 (1.5)
Asthenia	191 (24.5)	25 (3.2)	99 (25.4)	9 (2.3)
Constipation	185 (23.7)	0	82 (21.1)	0
Decreased neutrophil count	185 (23.7)	146 (18.7)	112 (28.8)	90 (23.1)
Rash	170 (21.8)	7 (0.9)	59 (15.2)	1 (0.3)
Peripheral neuropathy	154 (19.7)	15 (1.9)	82 (21.1)	4 (1.0)

Adapted from Schmid P et al. 2020.

Listed are AEs that occurred during the treatment period or within 30 days after the treatment period (or, for serious AEs, within 90 days) in patients who were randomised and received at least one trial drug or surgery. The severity of the AEs was graded according to the Common Terminology Criteria for Adverse Events, v4.0, of the National Cancer Institute. Patients may have had more than one event.

AE, adverse event.

Schmid P et al. *N Engl J Med* 2020;382:810–821.

UK Prescribing Information

KEYNOTE-522: AEs of interest in the neoadjuvant phase at primary analysis (1/2)

AE, n (%)	KEYTRUDA + chemotherapy (n=781)		Placebo + chemotherapy (n=389)	
	Any grade	Grade ≥3	Any grade	Grade ≥3
Any AE	777 (99.5)	633 (81.0)	389 (100.0)	295 (75.8)
Treatment-related AE[a]	773 (99.0)	600 (76.8)	388 (99.7)	281 (72.2)
AE of interest[b]	304 (38.9)	101 (12.9)	71 (18.3)	7 (1.8)
Infusion reaction	132 (16.9)	20 (2.6)	43 (11.1)	4 (1.0)
Hypothyroidism	107 (13.7)	3 (0.4)	13 (3.3)	0
Hyperthyroidism	36 (4.6)	2 (0.3)	4 (1.0)	0
Severe skin reaction	34 (4.4)	30 (3.8)	4 (1.0)	1 (0.3)
Adrenal insufficiency	18 (2.3)	10 (1.3)	0	0
Hypophysitis	14 (1.8)	8 (1.0)	1 (0.3)	0
Colitis	13 (1.7)	7 (0.9)	3 (0.8)	1 (0.3)
Thyroiditis	13 (1.7)	2 (0.3)	3 (0.8)	0
Hepatitis	11 (1.4)	9 (1.2)	2 (0.5)	0

Adapted from Schmid P et al. 2020.

Listed are AEs that occurred during the treatment period or within 30 days after the treatment period (or, for serious AEs, within 90 days) in patients who underwent randomisation and received at least one trial drug or surgery. The severity of the AEs was graded according to the Common Terminology Criteria for Adverse Events, v4.0, of the National Cancer Institute. Patients may have had more than one event.
[a]Treatment-related AEs were events occurring in ≥20% of patients or considered medically relevant by the investigator; [b]AEs of interest were determined according to a list of terms specified by the sponsor, regardless of attribution to any trial treatment by the investigators.
AE, adverse event.
Schmid P et al. *N Engl J Med* 2020;382:810–821.

UK Prescribing Information

KEYNOTE-522: AEs of interest in the neoadjuvant phase at primary analysis (2/2)

AE, n (%)	KEYTRUDA + chemotherapy (n=781)		Placebo + chemotherapy (n=389)	
	Any grade	Grade ≥3	Any grade	Grade ≥3
Any AE	777 (99.5)	633 (81.0)	389 (100.0)	295 (75.8)
Treatment-related AE[a]	773 (99.0)	600 (76.8)	388 (99.7)	281 (72.2)
AE of interest[b]	304 (38.9)	101 (12.9)	71 (18.3)	7 (1.8)
Pneumonitis	10 (1.3)	3 (0.4)	5 (1.3)	1 (0.3)
Nephritis	7 (0.9)	7 (0.9)	0	0
Pancreatitis	4 (0.5)	4 (0.5)	0	0
Myocarditis	3 (0.4)	2 (0.3)	0	0
Myositis	3 (0.4)	0	0	0
Type 1 diabetes mellitus	2 (0.3)	2 (0.3)	0	0
Uveitis	2 (0.3)	0	0	0
Encephalitis	1 (0.1)	1 (0.1)	0	0
Sarcoidosis	1 (0.1)	0	0	0

Adapted from Schmid P et al. 2020.

Listed are AEs that occurred during the treatment period or within 30 days after the treatment period (or, for serious AEs, within 90 days) in patients who were randomised and received at least one trial drug or surgery. The severity of the AEs was graded according to the Common Terminology Criteria for Adverse Events, v4.0, of the National Cancer Institute. Patients may have had more than one event.
[a]Treatment-related AEs were events occurring in ≥20% of patients or considered medically relevant by the investigator; [b]AEs of interest were determined according to a list of terms specified by the sponsor, regardless of attribution to any trial treatment by the investigators.
AE, adverse event.
Schmid P et al. *N Engl J Med* 2020;382:810–821.

UK Prescribing Information

KEYNOTE-522: TRAEs occurring in ≥2% of patients in the adjuvant phase at 36-month follow up

AE, n (%)[a]	KEYTRUDA + chemotherapy (n=588)	Placebo + chemotherapy (n=331)
Any grade	316	286
Arthralgia	50 (8.5)	41 (6.9)
Rash	35 (6.0)	14 (2.4)
Pruritus	30 (5.1)	12 (2.1)
Asthenia	27 (4.6)	30 (5.1)
Diarrhoea	24 (4.1)	19 (3.3)
Fatigue	20 (3.4)	28 (4.8)
Aspartate aminotransferase increased	17 (2.9)	7 (1.2)
Hypothyroidism	16 (2.7)	19 (3.3)
Neutropenia	16 (2.7)	23 (3.9)
Alanine aminotransferase increased	13 (2.2)	11 (1.8)
Myalgia	13 (2.2)	7 (1.2)
Nausea	13 (2.2)	14 (2.4)
Dry mouth	12 (2.0)	5 (0.9)
Anaemia	9 (1.5)	16 (2.7)
Lymphopenia	9 (1.5)	14 (2.4)
Headache	5 (0.9)	14 (2.4)

Adapted from Schmid P et al. Presented at ESMO 2021.

Listed are AEs that occurred during the treatment period or within 30 days after the treatment period (or, for serious AEs, within 90 days) in patients who were randomised and received at least one trial drug or surgery. The severity of the AEs was graded according to the Common Terminology Criteria for Adverse Events, v4.0, of the National Cancer Institute. Patients may have had more than one event.
[a]n numbers for each AE have been calculated from provided percentages.
AE, adverse event; TRAE, treatment-related adverse event.
Schmid P et al. Presented at the European Society for Medical Oncology (ESMO) Virtual Plenary 2021, 16–21 September.

UK Prescribing Information

KEYNOTE-522: Immune-mediated AEs and infusion reactions in the adjuvant phase at 36-month follow up[a]

AE, n (%)[b]	KEYTRUDA + chemotherapy (n=588)	Placebo + chemotherapy (n=331)
Any grade	60 (10.2)	35 (6.0)
Hypothyroidism	17 (2.9)	21 (3.6)
Infusion reactions	11 (1.9)	7 (1.2)
Severe skin reactions	11 (1.9)	0
Pneumonitis	7 (1.2)	4 (0.6)
Hyperthyroidism	5 (0.9)	4 (0.6)
Adrenal insufficiency	3 (0.5)	0
Colitis	2 (0.3)	0
Myocarditis	2 (0.3)	0

Adapted from Schmid P et al. Presented at ESMO 2021.

Listed are AEs that occurred during the treatment period or within 30 days after the treatment period (or, for serious AEs, within 90 days) in patients who were randomised and received at least one trial drug or surgery. The severity of the AEs was graded according to the Common Terminology Criteria for Adverse Events, v4.0, of the National Cancer Institute. Patients may have had more than one event.
[a]Immune-mediated AEs were considered regardless of attribution to treatment or immune-relatedness by the investigator; [b]n numbers for each AE have been calculated from provided percentages.
AE, adverse event.
Schmid P et al. Presented at the European Society for Medical Oncology (ESMO) Virtual Plenary 2021, 16–21 September.

UK Prescribing Information

KEYNOTE-522: Any-grade AEs in the combined neoadjuvant and adjuvant phases occurring in ≥20% of patients at 75-month follow up

AE, n (%)	KEYTRUDA + chemotherapy (n=783)		Placebo + chemotherapy (n=389)	
	Any grade	Grade ≥3	Any grade	Grade ≥3
Any AE	777 (99.2)	645 (82.4)	389 (100.0)	306 (78.7)
TRAE[a]	774 (98.9)	604 (77.1)	388 (99.7)	285 (73.3)
Nausea	495 (63.2)	27 (3.4)	245 (63.0)	6 (1.5)
Alopecia	471 (60.2)	0	220 (56.6)	0
Anaemia	429 (54.8)	141 (18.0)	215 (55.3)	58 (14.9)
Neutropenia	367 (46.9)	270 (34.5)	185 (47.6)	130 (33.4)
Fatigue	330 (42.1)	28 (3.6)	151 (38.8)	7 (1.8)
Diarrhoea	238 (30.4)	20 (2.6)	98 (25.2)	5 (1.3)
Alanine aminotransferase increased	204 (26.1)	43 (5.5)	98 (25.2)	9 (2.3)
Vomiting	200 (25.5)	19 (2.4)	86 (22.1)	6 (1.5)
Asthenia	198 (25.3)	28 (3.6)	102 (26.2)	9 (2.3)
Rash	196 (25.0)	12 (1.5)	66 (17.0)	1 (0.3)
Constipation	188 (24.0)	0	85 (21.9)	0
Neutrophil count decreased	185 (23.6)	146 (18.6)	112 (28.8)	90 (23.1)
Aspartate aminotransferase increased	157 (20.1)	20 (2.6)	63 (16.2)	1 (0.3)
Peripheral neuropathy	154 (19.7)	15 (1.9)	84 (21.6)	4 (1.0)

Adapted from Schmid P et al. Presented at ESMO 2024.

Listed are AEs that occurred during the treatment period or within 30 days after the treatment period (or, for serious AEs, within 90 days) in patients who were randomised and received at least one trial drug, underwent surgery, or both. The severity of the AEs was graded according to the Common Terminology Criteria for Adverse Events, v4.0, of the National Cancer Institute. Patients may have had more than one event.

[a]Grade 5 TRAEs were sepsis and multiple organ dysfunction syndrome (n=1) and pneumonitis, pulmonary embolism and autoimmune encephalitis (n=1 in each group) in the KEYTRUDA + chemotherapy arm and septic shock (n=1) in the placebo + chemotherapy arm.

AE, adverse event.

Schmid P et al. *N Engl J Med* 2024; doi:10.1056/NEJMoa2409932 [Epub ahead of print].

UK Prescribing Information

KEYNOTE-522: Immune-mediated AEs occurring in patients in the combined neoadjuvant and adjuvant phases at 75-month follow up

AE, n (%)	KEYTRUDA + chemotherapy (n=783)		Placebo + chemotherapy (n=389)	
	Any grade	Grade ≥3	Any grade	Grade ≥3
Any AE	777 (99.2)	645 (82.4)	389 (100.0)	306 (78.7)
TRAE[a]	774 (98.9)	604 (77.1)	388 (99.7)	285 (73.3)
Immune-mediated AE[b]	274 (35.0)	102 (13.0)	51 (13.1)	6 (1.5)
Hypothyroidism	118 (15.1)	4 (0.5)	22 (5.7)	0
Severe skin reaction	45 (5.7)	37 (4.7)	4 (1.0)	1 (0.3)
Hyperthyroidism	41 (5.2)	2 (0.3)	7 (1.8)	0
Gastritis	27 (3.4)	2 (0.3)	8 (2.1)	1 (0.3)
Adrenal insufficiency	20 (2.6)	8 (1.0)	0	0
Pneumonitis	17 (2.2)	7 (0.9)	6 (1.5)	2 (0.5)
Thyroiditis	16 (2.0)	2 (0.3)	5 (1.3)	0
Hypophysitis	15 (1.9)	10 (1.3)	1 (0.3)	0

Adapted from Schmid P et al. 2024.

Listed are AEs that occurred during, or 30 days after the treatment period (or, for serious AEs, within 90 days) in patients who were randomised and received ≥1 trial drug, underwent surgery, or both. The severity of the AEs was graded according to the Common Terminology Criteria for Adverse Events, v4.0, of the National Cancer Institute. Immune-mediated adverse events that occurred in ≥15 patients in either treatment group are reported. Patients may have had more than one event.
[a]Grade 5 TRAEs were sepsis and multiple organ dysfunction syndrome (n=1) and pneumonitis, pulmonary embolism and autoimmune encephalitis (n=1 in each group) in the KEYTRUDA + chemotherapy arm and septic shock (n=1) in the placebo + chemotherapy arm; [b]Immune-mediated AEs were determined according to a list of terms determined by the sponsor, regardless of attribution to any trial treatment by the investigators. Grade 5 immune-mediated AEs were pulmonary embolism and autoimmune encephalitis (n=1 each) in the KEYTRUDA + chemotherapy group.
AE, adverse event.
Schmid P et al. *N Engl J Med* 2024; doi:10.1056/NEJMoa2409932 [Epub ahead of print].

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