Drug assessment at a glance: A26-17[1]

Abemaciclib (breast cancer; adjuvant treatment)

21 August 2026

[1] This is a courtesy translation of the summary provided as a service by IQWiG. For further information on the subject matter and the result of the assessment, please refer to the dossier assessment for Project A26-17. The G-BA decides on the added benefit.

Research question 1 of the benefit assessment

Population	Premenopausal women with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, node-positive early breast cancer at high risk of recurrence; adjuvant treatment
Intervention	abemaciclib + endocrine therapy
Comparator	▪ tamoxifen (accompanied by ovarian function suppression, as appropriate) or ▪ olaparib as monotherapy or in combination with endocrine therapy (only for patients with germline BRCA1/2 mutations) or ▪ an aromatase inhibitor (anastrozole, letrozole or exemestane) in combination with ovarian function suppression (exemestane only in combination with triptorelin) or ▪ ribociclib in combination with an aromatase inhibitor
Outcomes	At least one patient-relevant outcome

Overview of positive and negative effects – research question 1

	Size of the effects	Informative value of the effects
Mortality	↔	–
Morbidity	↑↑ (failure to cure)	★
Symptoms	↔ (FACIT-Fatigue) ↔ (health status)	– –
Health-related quality of life	↔	–
Side effects	↓↓↓	★
	Ø No (suitable) data ↔ No advantage or disadvantage ↑ / ↓ Small advantage/disadvantage ↑↑ / ↓↓ Moderate advantage/disadvantage ↑↑↑ / ↓↓↓ Large advantage/disadvantage	– Not applicable ★ Low ★★ Moderate ★★★ High

Overall: No advantage or disadvantage

Evidence base and noteworthy aspects – research question 1

- Evidence base: the ongoing open-label RCT MONARCH-E for women with node-positive, HR-positive, HER2-negative, early-stage breast cancer who have undergone definitive surgery, without distant metastases and at high risk of recurrence (relevant subpopulation of premenopausal women: abemaciclib in combination with endocrine therapy [N = 864] versus endocrine therapy [N = 851]).
- The risk of bias across outcomes in this study is high due to the consistently high proportion of censored data throughout the study for potentially informative reasons, which was presumably largely attributable to study discontinuations.
- Patients in the comparator arm were at a systematic disadvantage, as only around half of those with distant recurrence received guideline-compliant treatment with a CDK-4/6 inhibitor as subsequent therapy.
- The results for the overall survival outcome could not be interpreted for the reasons stated above.
- The outcome-specific risk of bias for the outcome failure of curative treatment is high due to the unblinded study design with radiological and clinical data interpreted locally at the trial centre – particularly as the 10-year after-care period recommended in the S3 guideline has not yet been reached.

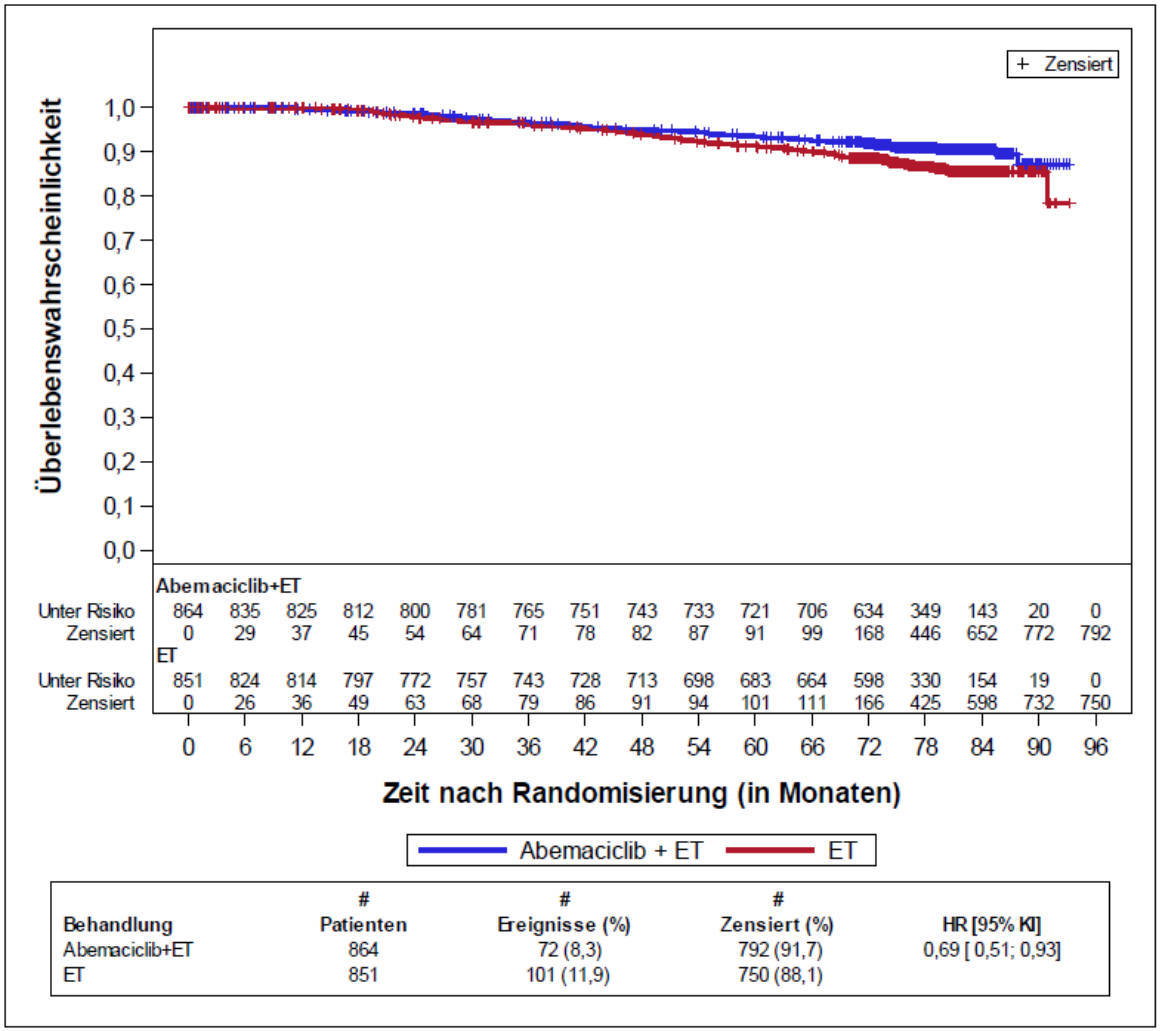
Key study findings – research question 1

Study Outcome category Outcome Timepoint	abemaciclib + endocrine therapy N	 Patients with event n (%)	endocrine therapy N	 Patients with event n (%)	abemaciclib + endocrine therapy vs. endocrine therapy RR [95% CI]; p-value
MONARCH-E					
Mortality					
Supplementary information					
Overall survival	*864*	*72 (8.3)* *Median time to event* *NA*	*851*	*101 (11.9)* *Median time to event* *NA*	*HR: 0.69 [0.51; 0.93]; 0.014*
Morbidity					
Failure of curative treatment					
Recurrence rate	864	154 (17.8)	851	228 (26.8)	0.67 [0.56; 0.80]; < 0.001
Local breast cancer recurrence	864	9 (1.0)	851	18 (2.1)	–
Regional invasive breast cancer recurrence	864	7 (0.8)	851	9 (1.1)	–
Distant recurrence	864	124 (14.4)	851	182 (21.4)	–
Contralateral invasive breast cancer	864	6 (0.7)	851	11 (1.3)	–
Second primary cancer (non-breast cancer)	864	8 (0.9)	851	9 (1.1)	–
Death	864	2 (0.2)	851	6 (0.7)	–
Disease-free survival	864	154 (17.8) Median time to event NA	851	228 (26.8) Median time to event NA	HR: 0.61 [0.50; 0.75]; < 0.001

Study Outcome category	abemaciclib + endocrine therapy		endocrine therapy		abemaciclib + endocrine therapy vs. endocrine therapy
Outcome Timepoint	N	Patients with event n (%)	N	Patients with event n (%)	RR [95% CI]; p-value
Side effects					
SAEs	863	118 (13.7)	852	77 (9.0)	1.51 [1.15; 1.98]; 0.003
Severe AEs	863	420 (48.7)	852	144 (16.9)	2.88 [2.44; 3.39]; < 0.001
Discontinuation due to AEs	863	101 (11.7)	852	7 (0.8)	14.24 [6.66; 30.46]; < 0.001

Study Outcome category Outcome	abemaciclib + endocrine therapy			endocrine therapy			abemaciclib + endocrine therapy vs. endocrine therapy
	N	Values at baseline mean (SD)	Change mean (SE)	N	Values at baseline mean (SD)	Change mean (SE)	MD [95% CI]; p-value; SMD [95% CI]
MONARCH-E							
Morbidity							
Symptoms (FACIT-Fatigue)	754	40.7 (9.1)	−0.7 (0.2)	738	40.3 (9.1)	0.5 (0.2)	−1.23 [−1.86; −0.60]; < 0.001; −0.20 [−0.30; −0.10]
Health status (EQ-5D VAS)	757	77.9 (15.2)	2.0 (0.4)	739	78.4 (15.8)	2.5 (0.4)	−0.47 [−1.52; 0.57]; 0.375; −0.05 [−0.15; 0.06]
Health-related quality of life							
FACT-B	770	107.8 (17.7)	−1.5 (0.5)	751	106.4 (18.2)	0.8 (0.5)	−2.34 [−3.60; −1.08]; < 0.001; −0.19 [−0.29; −0.09]

Kaplan-Meier curves on overall survival – research question 1



Behandlung	# Patienten	# Ereignisse (%)	# Zensiert (%)	HR [95% KI]
Abemaciclib+ET	864	72 (8,3)	792 (91,7)	0,69 [0,51; 0,93]
ET	851	101 (11,9)	750 (88,1)	

Behandlung: Treatment; Ereignisse: Events; Patienten: Patients; Überlebenswahrscheinlichkeit: Probability of survival; Unter Risiko: At risk; Zeit nach Randomisierung (in Monaten): Time since randomization (in months); Zensiert: Censored

Research question 2 of the benefit assessment

Population	Postmenopausal women with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, node-positive early breast cancer at high risk of recurrence; adjuvant treatment
Intervention	abemaciclib + endocrine therapy
Comparator	▪ an aromatase inhibitor (anastrozole or letrozole) alone; tamoxifen if aromatase inhibitors are unsuitable or ▪ an aromatase inhibitor (anastrozole or exemestane) in sequence after tamoxifen or ▪ olaparib as monotherapy or in combination with endocrine therapy (only for patients with germline BRCA1/2 mutations) or ▪ ribociclib in combination with an aromatase inhibitor
Outcomes	At least one patient-relevant outcome

Overview of positive and negative effects – research question 2

	Size of the effects	Informative value of the effects
Mortality	↔	–
Morbidity	↑↑ (failure to cure)	★
Symptoms	↔ (FACIT-Fatigue) ↔ (health status)	– –
Health-related quality of life	↔	–
Side effects	↓↓↓	★
	ø No (suitable) data ↔ No advantage or disadvantage ↑ / ↓ Small advantage/disadvantage ↑↑ / ↓↓ Moderate advantage/disadvantage ↑↑↑ / ↓↓↓ Large advantage/disadvantage	– Not applicable ★ Low ★★ Moderate ★★★ High

Overall: No advantage or disadvantage

Evidence base and noteworthy aspects – research question 2

- Evidence base: the ongoing open-label RCT MONARCH-E for women with node-positive, HR-positive, HER2-negative, early-stage breast cancer who have undergone definitive surgery, without distant metastases and at high risk of recurrence (relevant subpopulation of postmenopausal women: abemaciclib in combination with endocrine therapy [N = 1364] versus endocrine therapy [N = 1384]).
- The risk of bias across outcomes in this study is high due to the consistently high proportion of censored data throughout the study for potentially informative reasons, which was presumably largely attributable to study discontinuations.
- Patients in the comparator arm were at a systematic disadvantage, as only around half of those with distant recurrence received guideline-compliant treatment with a CDK-4/6 inhibitor as subsequent therapy.
- The results for the overall survival outcome could not be interpreted for the reasons stated above.
- The outcome-specific risk of bias for the outcome failure of curative treatment is high due to the unblinded study design with radiological and clinical data interpreted locally at the trial centre – particularly as the 10-year after-care period recommended in the S3 guideline has not yet been reached.

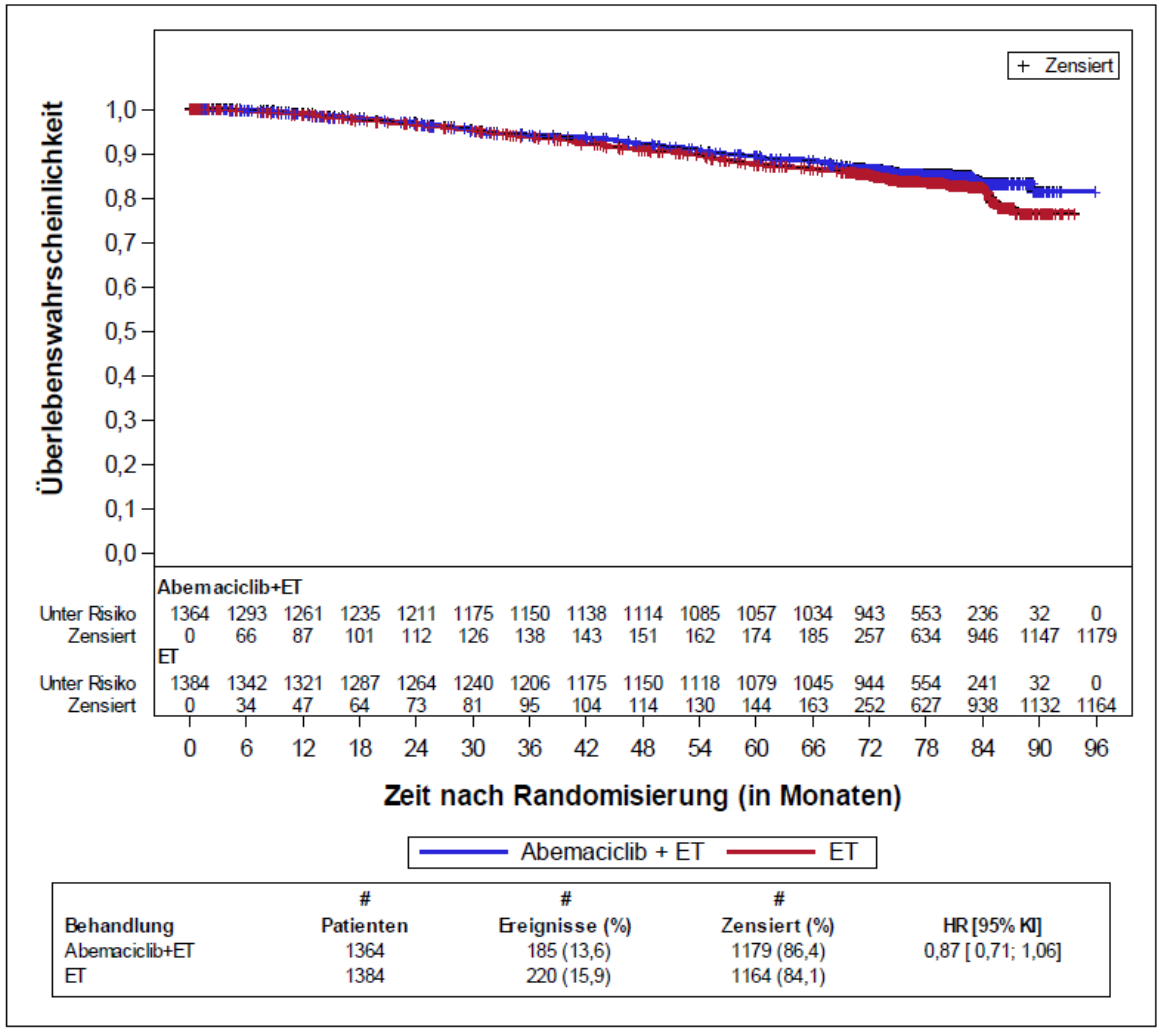
Key study findings – research question 2

Study Outcome category Outcome	abemaciclib + endocrine therapy N	abemaciclib + endocrine therapy Patients with event n (%)	endocrine therapy N	endocrine therapy Patients with event n (%)	abemaciclib + endocrine therapy vs. endocrine therapy RR [95% CI]; p-value
MONARCH-E					
Mortality					
Supplementary information					
Overall survival	*1364*	*185 (13.6)* *Median time to event* *NA*	*1384*	*220 (15.9)* *Median time to event* *NA*	*HR: 0.87 [0.71; 1.06]; 0.155*
Morbidity					
Failure of curative treatment					
Recurrence rate	1364	303 (22.2)	1384	398 (28.8)	0.77 [0.68; 0.88]; < 0.001
Local breast cancer recurrence	1364	23 (1.7)	1384	35 (2.5)	–
Regional invasive breast cancer recurrence	1364	22 (1.6)	1384	23 (1.7)	–
Distant recurrence	1364	185 (13.6)	1384	276 (19.9)	–
Contralateral invasive breast cancer	1364	6 (< 1)	1384	9 (< 1)	–
Second primary cancer (non-breast cancer)	1364	32 (2.3)	1384	35 (2.5)	–
Death	1364	43 (3.2)	1384	26 (1.9)	–
Disease-free survival	1364	303 (22.2) Median time to event NA	1384	398 (28.8) Median time to event NA	HR: 0.76 [0.66; 0.89]; < 0.001

Study Outcome category Outcome	abemaciclib + endocrine therapy		endocrine therapy		abemaciclib + endocrine therapy vs. endocrine therapy
	N	Patients with event n (%)	N	Patients with event n (%)	RR [95% CI]; p-value
Side effects					
SAEs	1363	233 (17.1)	1385	141 (10.2)	1.68 [1.38; 2.04]; < 0.001
Severe AEs	1363	694 (50.9)	1385	254 (18.3)	2.78 [2.46; 3.14]; < 0.001
Discontinuation due to AEs	1363	317 (23.3)	1385	18 (1.3)	17.9 [11.2; 28.6]; < 0.001

Study Outcome category Outcome	abemaciclib + endocrine therapy			endocrine therapy			abemaciclib + endocrine therapy vs. endocrine therapy
	N	Values at baseline mean (SD)	Change mean (SE)	N	Values at baseline mean (SD)	Change mean (SE)	MD [95% CI]; p-value; SMD [95% CI]
MONARCH-E							
Morbidity							
Symptoms (FACIT-Fatigue)	1144	39.9 (9.6)	−1.0 (0.2)	1169	39.3 (9.7)	0.3 (0.2)	−1.34 [−1.85; −0.84]; < 0.001; −0.22 [−0.3; −0.13]
Health status (EQ-5D VAS)	1159	77.7 (16.6)	−0.1 (0.3)	1188	78.0 (15.2)	1.2 (0.3)	−1.26 [−2.1; −0.43]; 0.003; −0.12 [−0.2; −0.04]
Health-related quality of life							
FACT-B	1173	108.0 (18.4)	−1.9 (0.4)	1209	107.4 (18.0)	−0.2 (0.4)	−1.71 [−2.68; −0.74]; < 0.001; −0.14 [−0.22; −0.06]

Kaplan-Meier curves on overall survival – research question 2



Behandlung	# Patienten	# Ereignisse (%)	# Zensiert (%)	HR [95% KI]
Abemaciclib+ET	1364	185 (13,6)	1179 (86,4)	0,87 [0,71; 1,06]
ET	1384	220 (15,9)	1164 (84,1)	

Behandlung: Treatment; Ereignisse: Events; Patienten: Patients; Überlebenswahrscheinlichkeit: Probability of survival; Unter Risiko: At risk; Zeit nach Randomisierung (in Monaten): Time since randomization (in months); Zensiert: Censored

References

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Gemeinsamer Bundesausschuss. Nutzenbewertungsverfahren zum Wirkstoff Abemaciclib (Neubewertung nach Fristablauf: Mammakarzinom, HR+, HER2-, früh mit hohem Rezidivrisiko, Adjuvanz, Kombination mit endokriner Therapie) [online]. 2026 [Accessed: 20.08.2026]. URL: https://www.g-ba.de/bewertungsverfahren/nutzenbewertung/1320.

English translations for this project are published at https://www.iqwig.de/en/projects/a26-17.html and https://www.iqwig.de/en/projects/a26-83.html.

Publisher details

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