Drug assessment at a glance: A25-150[1] **Asciminib (CML, first- and second-line treatment)**

24 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 A25-150. The G-BA decides on the added benefit.

Research question 1 of the benefit assessment

Population	Asciminib in adult patients with Philadelphia chromosome-positive chronic myeloid leukaemia in chronic phase, first-line treatment
Intervention	asciminib
Comparator	▪ imatinib or ▪ nilotinib or ▪ dasatinib or ▪ bosutinib
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	↔	–
Symptoms	↑ (nausea and vomiting) ↑↑ (symptoms)	★
Health-related quality of life	↑ (social functioning, effects on everyday 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: a small advantage with moderate informative value

Evidence base and noteworthy aspects – research question 1

- Evidence base:
  - ASC4FIRST study (an ongoing, open-label, 2-arm RCT comparing asciminib [N = 201] with a tyrosine kinase inhibitor [imatinib, nilotinib, dasatinib or bosutinib] [N = 204])
  - ASC4START study (an ongoing, open-label, 2-arm RCT comparing asciminib [N = 284] with nilotinib [N = 284])
- For the outcomes on symptoms, health status and health-related quality of life, a high proportion of patients were not considered in the analysis due to missing values at the time of randomization. The informative value was therefore limited.

Key study findings – research question 1

Outcome category Outcome Study	asciminib Nb	asciminib Median time to event in months [95% CI] Patients with event n (%)	TKI[a] Nb	TKI[a] Median time to event in months [95% CI] Patients with event n (%)	asciminib vs. TKI[a] HR [95% CI]; p-value[c]
Mortality					
Overall survival					
ASC4FIRST	201	NA 2 (1.0)	204	NA 4 (2.0)	0.49 [0.09; 2.67]; 0.398
ASC4START	284	NA 2 (0.7)	284	NA 1 (0.4)	1.98 [0.18; 21.89]; 0.568
Total					0.79 [0.21; 2.93]; 0.719
Health-related quality of life					
EORTC QLQ-C30 – time to first deterioration by ≥ 10 points					
Global health status					
ASC4FIRST	201	22.2 [22.0; NC] 40 (19.9)	204	22.0 [5.4; NC] 53 (26.0)	0.67 [0.44; 1.02]; 0.029
ASC4START	284	22.1 [11.1; NC] 59 (20.8)	284	NA [11.1; NC] 63 (22.2)	0.89 [0.62; 1.27]; 0.529
Total					0.79 [0.60; 1.04]; 0.058

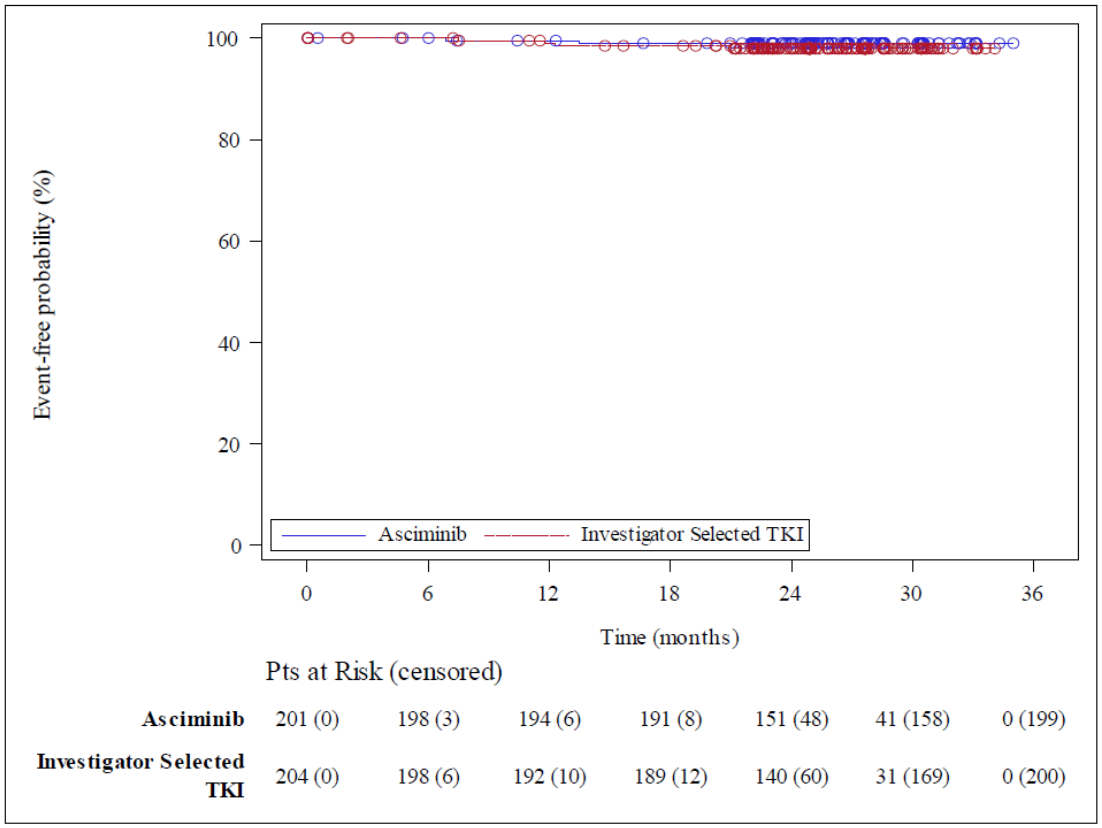
Outcome category Outcome Study	asciminib Nb	asciminib Median time to event in months [95% CI] Patients with event n (%)	TKI[a] Nb	TKI[a] Median time to event in months [95% CI] Patients with event n (%)	asciminib vs. TKI[a] HR [95% CI]; p-value[c]
Physical functioning					
ASC4FIRST	201	NA 25 (12.4)	204	22.1 [22.1; NC] 41 (20.1)	0.50 [0.30; 0.83]; 0.006
ASC4START	284	NA [11.2; NC] 49 (17.3)	284	NA 50 (17.6)	0.91 [0.61; 1.35]; 0.616
Total					0.72 [0.53; 0.98]; 0.036
Role functioning					
ASC4FIRST	201	NA [22.2; NC] 35 (17.4)	204	NA [6.7; NC] 45 (22.1)	0.57 [0.36; 0.90]; 0.018
ASC4START	284	22.1 [11.1; NC] 64 (22.5)	284	22.1 [11.1; NC] 59 (20.8)	1.08 [0.76; 1.55]; 0.587
Total				Heterogeneity:	p-value = 0.029
Emotional functioning					
ASC4FIRST	201	NA 29 (14.4)	204	NA [22.1; NC] 38 (18.6)	0.71 [0.43; 1.15]; 0.149
ASC4START	284	NA [11.2; NC] 47 (16.5)	284	NA [11.1; NC] 59 (20.8)	0.65 [0.44; 0.96]; 0.120
Total					0.69 [0.51; 0.94]; 0.035

Outcome category Outcome Study	asciminib Nb	asciminib Median time to event in months [95% CI] Patients with event n (%)	TKI[a] Nb	TKI[a] Median time to event in months [95% CI] Patients with event n (%)	asciminib vs. TKI[a] HR [95% CI]; p-value[c]
Cognitive functioning					
ASC4FIRST	201	NA [22.1; NC] 40 (20.9)	204	11.1 [10.9; 22.1] 54 (26.5)	0.75 [0.49; 1.13]; 0.151
ASC4START	284	11.1 [11.0; 22.1] 75 (26.4)	284	11.1 [5.6; NC] 77 (27.1)	0.92 [0.67; 1.26]; 0.626
Total					0.85 [0.66; 1.09]; 0.205
Social functioning					
ASC4FIRST	201	NA 35 (17.4)	204	22.1 [2.9; NC] 50 (24.5)	0.62 [0.40; 0.97]; 0.027
ASC4START	284	22.1 [11.2; NC] 58 (20.4)	284	NA [11.0; NC] 64 (22.5)	0.76 [0.53; 1.09]; 0.203
Total					0.71 [0.54; 0.94]; 0.017

Outcome category Outcome Study	asciminib N	asciminib Patients with event n (%)	TKI N	TKI Patients with event n (%)	asciminib vs. TKI RR [95% CI]; p-value
Side effects					
SAEs					
ASC4FIRST	196	29 (14.8)	190	35 (18.4)	0.80 [0.51; 1.26]; 0.530
ASC4START	284	47 (16.5)	282	42 (14.9)	1.11 [0.76; 1.63]; 0.683
Total					0.97 [0.73; 1.30]; 0.839
Severe AEs					
ASC4FIRST	196	87 (44.4)	190	101 (53.2)	0.84 [0.68; 1.03]; 0.088
ASC4START	284	102 (35.9)	282	114 (40.4)	0.89 [0.72; 1.10]; 0.289
Total					0.86 [0.74; 1.00]; 0.051
Discontinuation due to AEs					
ASC4FIRST	196	10 (5.1)	190	25 (13.2)	0.39 [0.19; 0.79]; 0.006
ASC4START	284	23 (8.1)	282	44 (15.6)	0.52 [0.32; 0.70]; 0.006
Total					0.47 [0.32; 0.70]; < 0.001
Vascular disorders (SOC, severe AEs)					
ASC4FIRST	200	14 (7.0)	201	7 (3.5)	2.01 [0.83; 4.87]; 0.127
ASC4START	284	17 (6.0)	282	6 (2.1)	2.81 [1.13; 7.03]; 0.021
Total					2.38 [1.26; 4.50]; 0.007

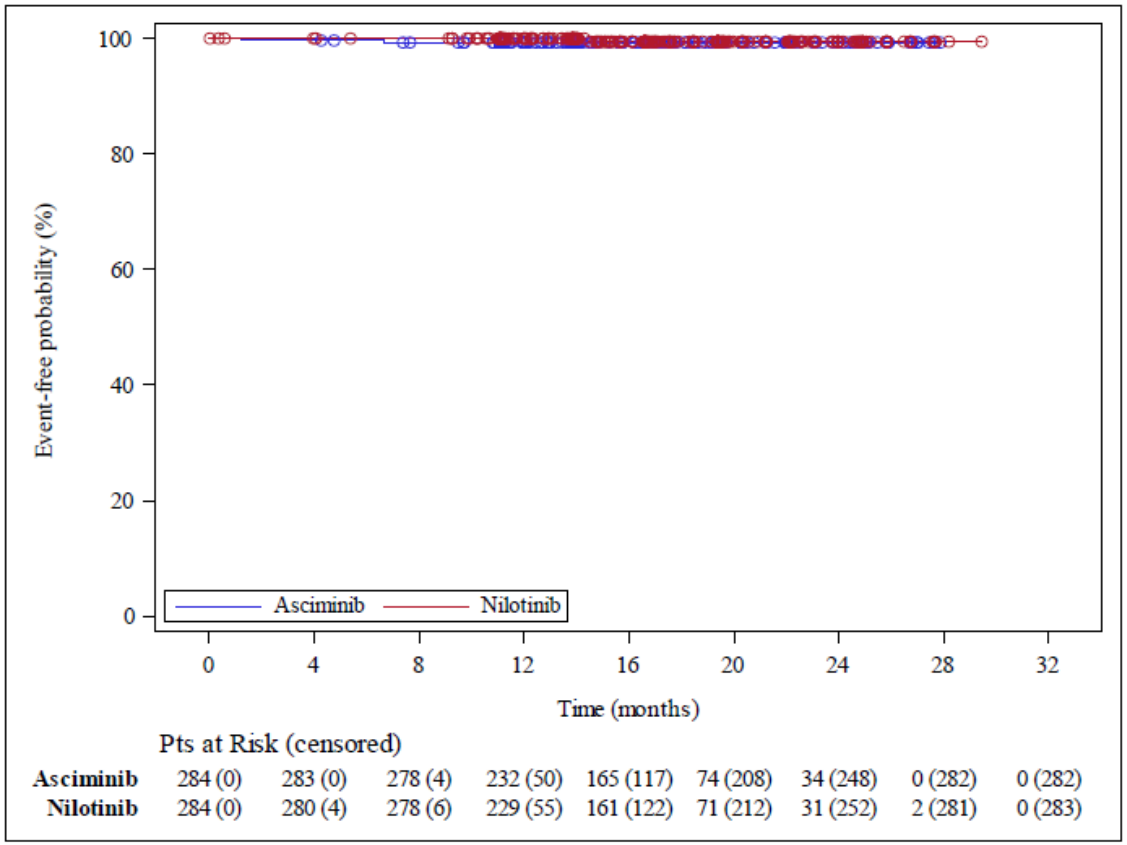
Kaplan-Meier curves on overall survival – research question 1

ASC4FIRST



Note: o = Censored observations
Data Cut/22OCT2024

ASC4START



o = Zensierte Beobachtungen
Datenschnitt: 15.05.2025

Research question 2 of the benefit assessment

Population	Adult patients with Philadelphia chromosome-positive chronic myeloid leukaemia in chronic phase who have previously been treated with a tyrosine kinase inhibitor; second-line treatment
Intervention	asciminib
Comparator	Individualized treatment from a choice of ▪ nilotinib, ▪ dasatinib, ▪ bosutinib, and ▪ ponatinib
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	∅	–
Symptoms	∅	–
Health-related quality of life	∅	–
Side effects	∅	–
	∅ 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 (no suitable data)

Evidence base and noteworthy aspects – research question 2

No suitable data were available.

References

Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen. Asciminib (CML, Erst- und Zweitlinientherapie); Nutzenbewertung gemäß § 35a SGB V; Dossierbewertung [online]. 2026 [Accessed: 19.06.2026]. URL: https://doi.org/10.60584/A25-150.

Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen. Asciminib (CML, Erst- und Zweitlinientherapie); Addendum zum Projekt A25-150 (Dossierbewertung) [online]. 2026 [Accessed: 19.06.2026]. URL: https://doi.org/10.60584/A26-40.

Gemeinsamer Bundesausschuss. Nutzenbewertungsverfahren zum Wirkstoff Asciminib (Neues Anwendungsgebiet: Chronische myeloische Leukämie, Philadelphia-Chromosom-+, chronische Phase Ph+ CML-CP) [online]. 2026 [Accessed: 19.06.2026]. URL: https://www.g-ba.de/bewertungsverfahren/nutzenbewertung/1287/.

English translations for this project are published at https://www.iqwig.de/en/projects/a25-150.html and https://www.iqwig.de/en/projects/a26-40.html.

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