Gemeinsamer Bundesausschuss

Resolution

of the Federal Joint Committee on an Amendment of the Pharmaceuticals Directive:
Annex XII – Benefit Assessment of Medicinal Products with New Active Ingredients according to Section 35a SGB V

Asciminib (new therapeutic indication: chronic myeloid leukaemia, Ph+, chronic phase)

From 21 May 2026

At their session on 21 May 2026, the Federal Joint Committee (G-BA) resolved to amend the Pharmaceuticals Directive (AM-RL) in the version dated 18 December 2008 / 22 January 2009 (Federal Gazette, BAnz. No. 49a of 31 March 2009), as last amended by the publication of the resolution of D Month YYYY (Federal Gazette, BAnz AT DD.MM.YYYY BX), as follows:

I. In Annex XII, the following information shall be added after No. 5 to the information on the benefit assessment of Asciminib in accordance with the resolution of 20.11.2025:

Asciminib

Resolution of: 21 May 2026
Entry into force on: 21 May 2026
Federal Gazette, BAnz AT DD. MM YYYY Bx

New therapeutic indication (according to the marketing authorisation of 17 November 2025):

Scemblix is indicated for the treatment of adult patients with Philadelphia chromosome-positive chronic myeloid leukaemia in chronic phase (Ph+ CML-CP).

Therapeutic indication of the resolution (resolution of 21 May 2026):

Treatment of adults with newly diagnosed Philadelphia chromosome-positive chronic myeloid leukaemia in chronic phase (Ph+ CML-CP).

Treatment of adults with Philadelphia chromosome-positive chronic myeloid leukaemia in chronic phase (Ph+ CML-CP) who have previously been treated with a tyrosine kinase inhibitor.

1. Additional benefit of the medicinal product in relation to the appropriate comparator therapy

a) Adults with newly diagnosed Philadelphia chromosome-positive chronic myeloid leukaemia in chronic phase (Ph+ CML-CP), first-line therapy

Appropriate comparator therapy:

- imatinib
  or
- nilotinib
  or
- dasatinib
  or
- bosutinib

The extent and probability of the additional benefit of asciminib compared with imatinib or nilotinib or dasatinib or bosutinib:

Hint for a considerable additional benefit

b) Adults with Philadelphia chromosome-positive chronic myeloid leukaemia in chronic phase (Ph+ CML-CP) who have previously been treated with a TKI; second-line therapy

Appropriate comparator therapy:

An individualised therapy with selection of

- nilotinib,
- dasatinib,
- bosutinib and
- ponatinib

Extent and probability of the additional benefit of asciminib compared to the appropriate comparator therapy:

An additional benefit is not proven.

Study results according to endpoints:[1]

a) Adults with newly diagnosed Philadelphia chromosome-positive chronic myeloid leukaemia in chronic phase (Ph+ CML-CP), first-line therapy

Summary of results for relevant clinical endpoints

Endpoint category	Direction of effect/ risk of bias	Summary
Mortality	↔	No relevant differences for the benefit assessment
Morbidity	↑	Advantages in terms of fatigue, nausea and vomiting, constipation, symptomatology
Health-related quality of life	↑	Advantages in terms of social functioning, impact on daily life
Side effects	↑↑	Advantages in the endpoints of severe AEs (CTCAE grade 3 or 4) and therapy discontinuation due to AEs
Explanations: ↑: statistically significant and relevant positive effect with low/unclear reliability of data ↓: statistically significant and relevant negative effect with low/unclear reliability of data ↑↑: statistically significant and relevant positive effect with high reliability of data ↓↓: statistically significant and relevant negative effect with high reliability of data ↔: no statistically significant or relevant difference ∅: No data available. n.a.: not assessable		

ASC4FIRST study:

- Ongoing, open-label RCT
- Asciminib versus tyrosine kinase inhibitor (imatinib, nilotinib, dasatinib or bosutinib)
- Data cut-off from 22.10.2024

ASC4START study:

- Ongoing, open-label RCT
- Asciminib versus nilotinib
- Data cut-off from 15.05.2025

[1] Data from the dossier assessment of the IQWiG (A25-150) and from the addendum (A26-40), unless otherwise indicated.

Mortality

Endpoint	Asciminib		Tyrosine kinase inhibitor[a]		Asciminib vs tyrosine kinase inhibitor
	N	Median survival time in months [95% CI] *Patients with event n (%)*	N	Median survival time in months [95% CI] *Patients with event n (%)*	HR [95% CI] p value[b]
Overall survival					
ASC4FIRST	201	n.r. 2 (1.0)	204	n.r. 4 (2.0)	0.49 [0.09; 2.67]; 0.398
ASC4START	284	n.r. 2 (0.7)	284	n.r. 1 (0.4)	1.98 [0.18; 21.89]; 0.568
Total					0.79 [0.21; 2.93]; 0.719[c]

Morbidity

Endpoint	Asciminib		Tyrosine kinase inhibitor[a]		Asciminib vs tyrosine kinase inhibitor
	N[d]	Median time to event in months [95% CI] *Patients with event n (%)*	N[d]	Median time to event in months [95% CI] *Patients with event n (%)*	HR [95% CI] p value[b] Absolute difference (AD)[e]
Progression to blast phase					
ASC4FIRST	201	n.r. 1 (0.5)	204	n.r. 2 (1.0)	0.44 [0.04; 4.92]; 0.494
ASC4START	284	n.r. 3 (1.1)	284	n.r. 0 (0)	6.99 [0.23; 214.0]; 0.083
Total					1.89 [0.35; 10.37]; 0.455[c]

Endpoint	**Asciminib**		**Tyrosine kinase inhibitor**[a]		Asciminib vs tyrosine kinase inhibitor
	N[d]	Median time to event in months [95% CI] *Patients with event n (%)*	N[d]	Median time to event in months [95% CI] *Patients with event n (%)*	HR [95% CI] p value[b] Absolute difference (AD)[e]
Symptomatology (EORTC QLQ-C30 – Time to 1st deterioration)[f]					
Fatigue					
ASC4FIRST	201	22.1 [5.5; n.c.] 50 (25.9)	204	2.8 [1.8; 11.1] 65 (31.9)	0.65 [0.45; 0.95]; 0.021 AD: + 19.3 months
ASC4START	284	n.r. [11.2; n.c.] 50 (17.6)	284	22.1 [11.8; n.c.] 58 (20.4)	0.74 [0.51; 1.09]; 0.214
Total					0.70 [0.54; 0.91]; 0.012[c]
Nausea and vomiting					
ASC4FIRST	201	n.r. 24 (11.7)	204	22.1 [10.9; n.c.] 46 (22.5)	0.41 [0.25; 0.68]; < 0.001
ASC4START	284	22.1 [22.1; n.c.] 39 (13.7)	284	n.r. [22.0; n.c.] 47 (16.5)	0.75 [0.49; 1.16]; 0.176
Total					0.58 [0.42; 0.80]; < 0.001[c]
Pain					
ASC4FIRST	201	n.r. [22.1; n.c.] 38 (18.9)	204	5.6 [2.7; n.c.] 59 (28.9)	0.49 [0.32; 0.74]; < 0.001
ASC4START	284	11.1 [5.6; n.c.] 76 (26.8)	284	11.1 [2.8; n.c.] 79 (27.8)	0.90 [0.66; 1.23]; 0.453
Total	Heterogeneity: p value = 0.025				
Dyspnoea					
ASC4FIRST	201	22.2 [22.2; n.c.] 26 (12.9)	204	n.r. [22.1; n.c.] 37 (18.1)	0.58 [0.34; 0.97]; 0.033
ASC4START	284	22.1 [22.1; n.c.] 45 (15.8)	284	n.r. [11.8; n.c.] 50 (17.6)	0.86 [0.57; 1.29]; 0.524

Total					0.74 [0.54; 1.01]; 0.067[c]
Insomnia					
ASC4FIRST	201	n.r. 33 (16.4)	204	n.r. [11.1; n.c.] 43 (21.1)	0.61 [0.39; 0.96]; 0.072
ASC4START	284	22.1 [11.1; n.c.] 55 (19.4)	284	22.0 [11.1; n.c.] 64 (22.5)	0.74 [0.52; 1.07]; 0.122
Total					0.69 [0.52; 0.92]; 0.020[c]
Total Sensitivity analysis 1					0.76 [0.58; 0.98]; 0.064
Total Sensitivity analysis 2					0.79 [0.63; 0.99]; 0.226
Appetite loss					
ASC4FIRST	201	n.r. [22.2; n.c.] 20 (10.0)	204	n.r. [22.1; n.c.] 38 (18.6)	0.36 [0.21; 0.64]; < 0.001
ASC4START	284	22.1 [22.1; n.c.] 31 (10.9)	284	n.r. [22.1; n.c.] 39 (13.7)	0.78 [0.48; 1.25]; 0.229
Total	Heterogeneity: p value: 0.045				
Constipation					
ASC4FIRST	201	n.r. 36 (17.9)	204	n.r. [11.1; n.c.] 38 (18.6)	0.76 [0.47; 1.22]; 0.396
ASC4START	284	22.1 [11.3; n.c.] 44 (15.5)	284	n.r. [11.1; n.c.] 60 (21.1)	0.63 [0.42; 0.93]; 0.026
Total					0.68 [0.50; 0.92]; 0.024[c]
Diarrhoea					
ASC4FIRST	201	n.r. 29 (14.4)	204	22.0 [5.6; n.c.] 49 (24.0)	0.44 [0.27; 0.71]; < 0.001
ASC4START	284	n.r. [22.0; n.c.] 39 (13.7)	284	n.r. [22.2; n.c.] 53 (18.7)	0.72 [0.48; 1.09]; 0.055
Total					0.59 [0.42; 0.79]; < 0.001[c]
Total Sensitivity analysis 1					0.63 [0.48; 0.83]; < 0.001

Total Sensitivity analysis 2					0.86 [0.69; 1.09]; 0.409
Symptomatology					
EORTC QLQ-CML24 – Time to first deterioration[f]					
ASC4FIRST	201	n.r. 24 (11.9)	204	11.0 [5.5; n.r.] 53 (26.0)	0.34 [0.21; 0.56]; < 0.001
ASC4START	284	n.r. [22.1; n.c.] 27 (9.5)	284	n.r. 44 (15.5)	0.55 [0.34; 0.89]; 0.023
Total					0.44 [0.31; 0.61]; < 0.001[c]
Health status (EQ-5D VAS – Time to first deterioration[g])					
ASC4FIRST	201	n.r. [22.2; n.c.] 20 (10.0)	204	n.r. [22.1; n.c.] 34 (16.7)	0.47 [0.27; 0.83]; 0.007
Total Sensitivity analysis 1					0.55 [0.35; 0.87]; 0.008
Total Sensitivity analysis 2					0.77 [0.53; 1.13]; 0.343
ASC4START	Endpoint not assessed				

Health-related quality of life

	Asciminib		**Tyrosine kinase inhibitor**[a]		Asciminib vs tyrosine kinase inhibitor
	N[d]	Median time to event in months [95% CI] *Patients with event n (%)*	N[d]	Median time to event in months [95% CI] *Patients with event n (%)*	HR [95% CI] p value[b] Absolute difference (AD)[e]
EORTC QLQ-C30 – Time to first deterioration[h]					
Global health status					
ASC4FIRST	201	22.2 [22.0; n.c.] 40 (19.9)	204	22.0 [5.4; n.c.] 53 (26.0)	0.67 [0.44; 1.02]; 0.029
ASC4START	284	22.1 [11.1; n.c.] 59 (20.8)	284	n.r. [11.1; n.c.] 63 (22.2)	0.89 [0.62; 1.27]; 0.529
Total					0.79 [0.60; 1.04]; 0.058[c]
Physical functioning					
ASC4FIRST	201	n.r. 25 (12.4)	204	22.1 [22.1; n.c.] 41 (20.1)	0.50 [0.30; 0.83]; 0.006
ASC4START	284	n.r. [11.2; n.c.] 49 (17.3)	284	n.r. 50 (17.6)	0.91 [0.61; 1.35]; 0.616
Total					0.72 [0.53; 0.98]; 0.036[c]
Total Sensitivity analysis 1					0.71 [0.52; 0.95]; 0.018
Total Sensitivity analysis 2					0.75 [0.58; 0.96]; 0.053
Role functioning					
ASC4FIRST	201	n.r. [22.2; n.c.] 35 (17.4)	204	n.r. [6.7; n.c.] 45 (22.1)	0.57 [0.36; 0.90]; 0.018
ASC4START	284	22.1 [11.1; n.c.] 64 (22.5)	284	22.1 [11.1; n.c.] 59 (20.8)	1.08 [0.76; 1.55]; 0.587
Total	Heterogeneity: p value = 0.029				
Emotional functioning					
ASC4FIRST	201	n.r. 29 (14.4)	204	n.r. [22.1; n.c.] 38 (18.6)	0.71 [0.43; 1.15]; 0.149

ASC4START	284	n.r. [11.2; n.c.] 47 (16.5)	284	n.r. [11.1; n.c.] 59 (20.8)	0.65 [0.44; 0.96]; 0.120
Total					0.69 [0.51; 0.94]; 0.035[c]
Total Sensitivity analysis 1					0.73 [0.55; 0.97]; 0.028
Total Sensitivity analysis 2					0.78 [0.62; 0.98]; 0.210
Cognitive functioning					
ASC4FIRST	201	n.r. [22.1; n.c.] 40 (20.3)	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; n.c.] 77 (27.1)	0.92 [0.67; 1.26]; 0.626
Total					0.85 [0.66; 1.09]; 0.205[c]
Social functioning					
ASC4FIRST	201	n.r. 35 (17.4)	204	22.1 [2.9; n.c.] 50 (24.5)	0.62 [0.40; 0.97]; 0.027
ASC4START	284	22.1 [11.2; n.c.] 58 (20.4)	284	n.r. [11.0; n.c.] 64 (22.5)	0.76 [0.53; 1.09]; 0.203
Total					0.71 [0.54; 0.94]; 0.017[c]
EORTC QLQ-CML24 - Time to 1st deterioration[i]					
Impact on worries/ mood					
ASC4FIRST	201	22.2 [22.2; n.c.] 28 (13.9)	204	n.r. [22.0; n.c.] 36 (17.6)	0.64 [0.38; 1.06]; 0.087
ASC4START	284	n.r. 45 (15.8)	284	n.r. 44 (15.5)	0.92 [0.60; 1.39]; 0.904
Total					0.79 [0.57; 1.09]; 0.235[c]
Impact on daily life					
ASC4FIRST	201	n.r. [11.1; n.c.] 41 (20.4)	204	5.6 [2.8; n.r.] 56 (27.5)	0.64 [0.43; 0.97]; 0.021
ASC4START	284	n.r. 42 (14.8)	284	n.r. [11.3; n.c.] 54 (19.0)	0.67 [0.44; 1.00]; 0.106

Total					0.65 [0.49; 0.87]; 0.006[c]
Body image issues					
ASC4FIRST	201	22.2 [22.2; n.c.] 33 (16.4)	204	n.r. [11.1; n.c.] 42 (20.6)	0.65 [0.41; 1.04]; 0.045
ASC4START	284	n.r. [11.1; n.c.] 62 (21.8)	284	22.1 [11.1; n.c.] 57 (20.1)	1.03 [0.72; 1.48]; 0.874
Total					0.87 [0.65; 1.15]; 0.267[c]
Satisfaction with healthcare/ information					
ASC4FIRST	201	11.0 [2.8; n.c.] 54 (26.9)	204	n.r. [11.1; n.c.] 38 (18.6)	1.06 [0.68; 1.65]; 0.079
ASC4START	284	11.1 [8.3; 22.1] 76 (26.8)	284	n.r. [5.7; n.c.] 63 (22.2)	1.07 [0.76; 1.49]; 0.505
Total					1.08 [0.83; 1.41]; 0.105[c]
Satisfaction with social life					
ASC4FIRST	201	n.r. [21.9; n.c.] 41 (20.4)	204	25.7 [22.1; n.c.] 36 (17.6)	1.10 [0.68; 1.76]; 0.717
ASC4START	284	11.1 [5.6; n.c.] 79 (27.8)	284	11.3 [3.0; n.c.] 70 (24.6)	1.10 [0.80; 1.52]; 0.599
Total					1.10 [0.84; 1.44]; 0.523[c]

Side effects

Endpoint	Asciminib		Tyrosine kinase inhibitor[a]		Asciminib vs tyrosine kinase inhibitor
	N	*Patients with event n (%)*	N	*Patients with event n (%)*	RR [95% CI] p value[j]
Total adverse events (presented additionally)					
ASC4FIRST	200	191 (95.9)	201	197 (98.0)	–
ASC4START	284	249 (87.7)	282	257 (91.1)	–
Serious adverse events (SAEs)					
ASC4FIRST	200	29 (14.5)	201	41 (20.4)	0.71 [0.46; 1.10]; 0.127
ASC4START	284	47 (16.5)	282	42 (14.9)	1.11 [0.76; 1.63]; 0.683
Total[k]					0.91 [0.69; 1.22]; 0.536
Severe adverse events (CTCAE grade 3 or 4)					
ASC4FIRST	200	89 (44.5)	201	110 (54.7)	0.81 [0.67; 0.99]; 0.044
ASC4START	284	102 (35.9)	282	114 (40.4)	0.89 [0.72; 1.10]; 0.289
Total[k]					0.85 [0.74; 0.98]; 0.030
Therapy discontinuation due to adverse events					
ASC4FIRST	200	10 (5.0)	201	26 (12.9)	0.39 [0.19; 0.78]; 0.006
ASC4START	284	23 (8.1)	282	44 (15.6)	0.52 [0.32; 0.84]; 0.006
Total[k]					0.47 [0.32; 0.70]; < 0.001
PRO-CTCAE	No suitable data				
Specific adverse events					
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

[a] ASC4FIRST study: with selection of imatinib, nilotinib or dasatinib; ASC4START study: nilotinib

[b] ASC4FIRST study: HR + 95% CI values from a stratified Cox proportional hazards model with stratification factors of ELTS score (IRT), selected TKI (IRT) and the covariate of treatment arm; p value from a stratified log-rank test with factors of ELTS score (IRT) and selected TKI (IRT); ASC4START study: HR + 95% CI values from a stratified Cox proportional hazards model with stratification factors of ELTS score (IRT) and the covariate of treatment arm; p value from a stratified log-rank test with the factors of ELTS score (IRT).

[c] Calculated by meta-analysis: HR + 95% CI values from a stratified Cox proportional hazards model with stratification factors of ELTS score (IRT), TKI selected prior to randomisation (IRT) and study, as well as the covariant of treatment arm and baseline score; p value from stratified log-rank test with stratification factors of ELTS score (IRT), TKI selected prior to randomisation (IRT) and study

[d] For the patient-reported endpoints: primary analysis, in which patients without a baseline value were censored at randomisation on day 1. In the ASC4FIRST study, the number of patients who had a baseline value at randomisation in the intervention arm versus the control arm was 112 (55.7%) versus 115 (56.4%) for the EORTC QLQ-C30, 109 (54.2%) versus 110 (53.9%) for the EORTC QLQ-CML24 and 108 (53.7%) versus 109 (53.4%) for the EQ-5D VAS; in the ASC4START study, the number of patients who had a baseline value at randomisation in the intervention arm versus the control arm was 168 (59.2%) versus 165 (58.1%) for the EORTC QLQ-C30 and 161 (56.7%) versus 157 (55.3%) for the EORTC QLQ-CML24.

[e] Indication of absolute difference (AD) only in case of statistically significant difference; own calculation

[f] An increase in score by ≥ 10 points compared to the start of the study is considered as clinically relevant deterioration (scale range: 0 to 100).

[g] A decrease in score by ≥ 15 points compared to the start of the study is considered as clinically relevant deterioration (scale range: 0 to 100).

[h] A decrease in score by ≥ 10 points compared to the start of the study is considered as clinically relevant deterioration (scale range: 0 to 100).

[i] An increase in score by ≥ 10 points compared to the start of the study for the scales - impact on worries/ mood, impact on daily life and body image issues - as well as a decrease in score by ≥ 10 points compared to the start of the study for the scales - satisfaction with healthcare/ information and satisfaction with social life - is considered as clinically relevant deterioration (scale range: 0 to 100).

[j] IQWiG calculation of RR, CI (asymptotic) and p value (unconditional exact test, CSZ method).

[k] IQWiG calculation: meta-analysis with fixed effect according to Mantel-Haenszel.

Abbreviations used:
AD = absolute difference; CTCAE = Common Terminology Criteria for Adverse Events; ELTS = European Treatment and Outcome Study Long-Term Survival Score; EORTC = European Organisation for Research and Treatment of Cancer; HR = hazard ratio; IRT = Interactive Response Technology; CI = confidence interval; N = number of patients evaluated; n = number of patients with (at least one) event; n.c. = not calculable; n.r. = not reached; PRO-CTCAE = Patient-Reported Outcomes version of the Common Terminology Criteria for Adverse Events; QLQ-C30 = Quality of Life Questionnaire – Core 30; QLQ-CML24 = Quality of Life Questionnaire for Chronic Myeloid Leukaemia 24 items; RR = relative risk; VAS = visual analogue scale; vs = versus.

b) Adults with Philadelphia chromosome-positive chronic myeloid leukaemia in chronic phase (Ph+ CML-CP) who have previously been treated with a TKI; second-line therapy

There are no assessable data.

Summary of results for relevant clinical endpoints

Endpoint category	Direction of effect/ risk of bias	Summary
Mortality	n.a.	There are no assessable data.
Morbidity	n.a.	There are no assessable data.
Health-related quality of life	n.a.	There are no assessable data.
Side effects	n.a.	There are no assessable data.
Explanations: ↑: statistically significant and relevant positive effect with low/unclear reliability of data ↓: statistically significant and relevant negative effect with low/unclear reliability of data ↑↑: statistically significant and relevant positive effect with high reliability of data ↓↓: statistically significant and relevant negative effect with high reliability of data ↔: no statistically significant or relevant difference ∅: No data available. n.a.: not assessable		

2. Number of patients or demarcation of patient groups eligible for treatment

a) Adults with newly diagnosed Philadelphia chromosome-positive chronic myeloid leukaemia in chronic phase (Ph+ CML-CP), first-line therapy

Approx. 5,050 - 5,810 patients

b) Adults with Philadelphia chromosome-positive chronic myeloid leukaemia in chronic phase (Ph+ CML-CP) who have previously been treated with a TKI; second-line therapy

Approx. 1,320 – 1,520 patients

3. Requirements for a quality-assured application

The requirements in the product information are to be taken into account. The European Medicines Agency (EMA) provides the contents of the product information (summary of product characteristics, SmPC) for Scemblix (active ingredient: asciminib) at the following publicly accessible link (last access: 9 February 2026):

https://www.ema.europa.eu/en/documents/product-information/scemblix-epar-product-information_en.pdf

Treatment with asciminib should only be initiated and monitored by specialists in internal medicine, haematology and oncology experienced in the treatment of patients with chronic myeloid leukaemia.

4. Treatment costs

Annual treatment costs:

a) Adults with newly diagnosed Philadelphia chromosome-positive chronic myeloid leukaemia in chronic phase (Ph+ CML-CP), first-line therapy

Designation of the therapy	Annual treatment costs/ patient
Medicinal product to be assessed:	
Asciminib	€ 60,350.97
Appropriate comparator therapy:	
imatinib	€ 2,007.01
nilotinib	€ 28,460.74
dasatinib	€ 9,517.86
bosutinib	€ 18,332.39

Costs after deduction of statutory rebates (LAUER-TAXE® as last revised: 15 March 2026)

Costs for additionally required SHI services: not applicable

b) Adults with Philadelphia chromosome-positive chronic myeloid leukaemia in chronic phase (Ph+ CML-CP) who have previously been treated with a TKI; second-line therapy

Designation of the therapy	Annual treatment costs/ patient
Medicinal product to be assessed:	
Asciminib	€ 60,350.97
Appropriate comparator therapy:	
An individualised therapy with selection of	
nilotinib	€ 37,790.93
dasatinib	€ 9,517.86
bosutinib	€ 22,915.48
ponatinib	€ 76,811.57

Costs after deduction of statutory rebates (LAUER-TAXE® as last revised: 15 March 2026)

Costs for additionally required SHI services: not applicable

5. Designation of medicinal products with new active ingredients according to Section 35a, paragraph 3, sentence 4 SGB V that can be used in a combination therapy with the assessed medicinal product

In the context of the designation of medicinal products with new active ingredients pursuant to Section 35a, paragraph 3, sentence 4 SGB V, the following findings are made:

a) Adults with newly diagnosed Philadelphia chromosome-positive chronic myeloid leukaemia in chronic phase (Ph+ CML-CP), first-line therapy

- No medicinal product with new active ingredients for use in combination therapy in compliance with the requirements of Section 35a, paragraph 3, sentence 4 SGB V.

b) Adults with Philadelphia chromosome-positive chronic myeloid leukaemia in chronic phase (Ph+ CML-CP) who have previously been treated with a TKI; second-line therapy

- No medicinal product with new active ingredients for use in combination therapy in compliance with the requirements of Section 35a, paragraph 3, sentence 4 SGB V.

The designation of combinations exclusively serves the implementation of the combination discount according to Section 130e SGB V between health insurance funds and pharmaceutical companies. The findings made neither restrict the scope of treatment required to fulfil the medical treatment mandate, nor do they make statements about expediency or economic feasibility.

II. The resolution entered into force on the day of its publication on the G-BA website on 21 May 2026.

The justification for this resolution will be published on the G-BA website at www.g-ba.de.

Berlin, 21 May 2026

Federal Joint Committee
in accordance with Section 91 SGB V
The Chair

Prof. Hecken