Drug assessment at a glance: A26-65[1]

Nivolumab/relatlimab (melanoma)

11 November 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 A26-65. The GBA decides on the added benefit.

Research question for the benefit assessment

Population	Adults and adolescents 12 years of age and older with advanced (unresectable or metastatic) melanoma with tumour cell PD-L1 expression <1%; first-line treatment
Intervention	nivolumab/relatlimab
Comparator	▪ cobimetinib in combination with vemurafenib (only suitable for adult patients with BRAF V600 mutation) or ▪ dabrafenib in combination with trametinib (only suitable for patients with BRAF V600 mutation) or ▪ encorafenib in combination with binimetinib (only suitable for adult patients with BRAF V600 mutation) or ▪ nivolumab (monotherapy) or ▪ pembrolizumab (monotherapy) or ▪ nivolumab in combination with ipilimumab
Outcomes	At least one patient-relevant outcome

Overview of positive and negative effects

	Size of the effects	Informative value of the effects
Mortality	Adults: ↑ Adolescents 12 years of age and older: Ø	Adults: ★ Adolescents 12 years of age and older: –
Morbidity	Ø	–
Symptoms	Ø	–
Health-related quality of life	Ø	–
Side effects	Adults: ↑, ↓↓ Adolescents 12 years of age and older: Ø	Adults: ★ Adolescents 12 years of age and older: –
	Ø No (suitable) data ↔ No advantage or disadvantage ↑ / ↓ Small advantage/disadvantage ↑↑ / ↓↓ Moderate advantage/disadvantage ↑↑↑ / ↓↓↓ Large advantage/disadvantage	– Not applicable ★ Low ★★ Moderate ★★★ High

Overall:

- Adults: a small advantage with low informative value
- Adolescents 12 years of age and older: no advantage or disadvantage (no suitable data)

Evidence base and noteworthy aspects

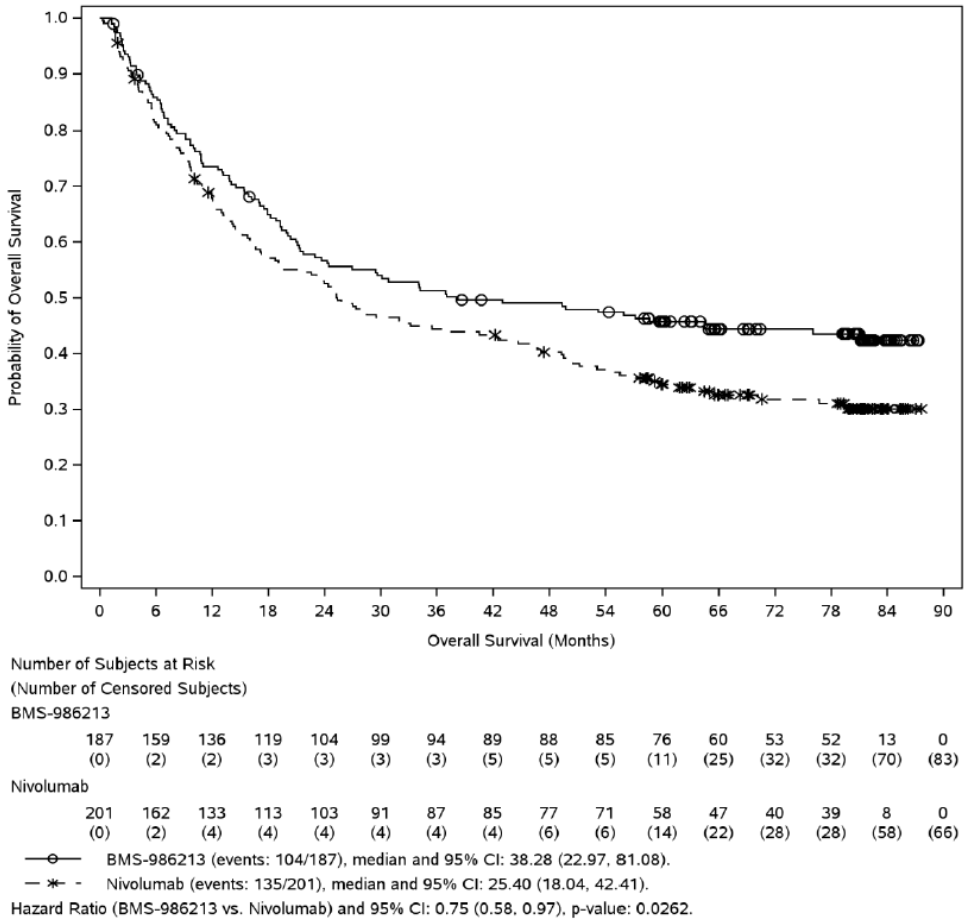
- Evidence base: the double-blind RCT RELATIVITY-047 comparing nivolumab/relatlimab (N=355) versus nivolumab (N=359); relevant subpopulation: nivolumab/relatlimab (n=187) versus nivolumab (n=201)
- The informative value of the study results for the outcome of overall survival was reduced due to uncertainties regarding subsequent therapies
- No suitable data were available on patient-reported outcomes in the categories of morbidity and health-related quality of life, as the questionnaire return rates were too low at an early stage

Key study findings

Study Outcome category Outcome	nivolumab/relatlimab N	nivolumab/relatlimab Median time to event in months [95% CI] Patients with event n (%)	nivolumab N	nivolumab Median time to event in months [95% CI] Patients with event n (%)	nivolumab/relatlimab vs. nivolumab HR [95% CI]; p-value
RELATIVITY-047					
Mortality					
Overall survival	187	38.3 [23.0; 81.1] 104 (55.6)	201	25.4 [18.0; 42.4] 135 (67.2)	0.75 [0.58; 0.97]; 0.026

Study Outcome category Outcome	nivolumab/relatlimab N	 Patients with event n (%)	nivolumab N	 Patients with event n (%)	nivolumab/relatlimab vs. nivolumab RR [95% CI]; p-value
RELATIVITY-047					
Side effects					
SAEs	187	78 (41.7)	201	80 (39.8)	1.05 [0.82; 1.33]; 0.751
Severe AEs	187	95 (50.8)	201	97 (48.3)	1.05 [0.86; 1.29]; 0.711
Discontinuation due to AEs	187	45 (24.1)	201	38 (18.9)	1.27 [0.87; 1.87]; 0.257
Immune-mediated SAEs	187	29 (15.5)	201	13 (6.5)	2.40 [1.29; 4.47]; 0.004
Immune-mediated severe AEs	187	34 (18.2)	201	22 (10.9)	1.66 [1.01; 2.73]; 0.044

Kaplan-Meier curves on overall survival



ITT population, subpopulation with PD-L1 <1%; database lock 11/2025

References

Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen. Nivolumab/Relatlimab (Melanom); Nutzenbewertung gemäß § 35a SGB V; Dossierbewertung [online]. 2026 [Accessed: 02.11.2026]. URL: https://doi.org/10.60584/A26-65.

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English translations for this project are published at https://www.iqwig.de/en/projects/a26-65.html and https://www.iqwig.de/en/projects/a26-120.html.

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