



This English version is intended to be a reference material for the convenience of users. In the event of inconsistency between the Japanese original and this English translation, the former shall prevail.

Summary of Investigation Results

Avelumab (genetical recombination)

April 21, 2026

Non-proprietary name

Avelumab (genetical recombination)

Brand name (marketing authorization holder)

Bavencio intravenous infusion 200 mg (Merck Biopharma Co., Ltd)

Japanese market launch

November 2017

Indications

- Radically unresectable Merkel cell carcinoma
- Radically unresectable or metastatic renal cell carcinoma
- Maintenance treatment of radically unresectable urothelial carcinoma following chemotherapy

Summary of revisions

“Severe skin disorders” should be added to the 11.1 Clinically Significant Adverse Reactions section in 11. ADVERSE REACTIONS.

Investigation results and background of the revision

Cases involving severe skin disorders were evaluated. Cases in which a causal relationship between avelumab (genetical recombination) and severe skin disorders was reasonably possible have been reported. As a result of consultation with expert advisors regarding the causality assessment of the cases and the necessity of revision of PRECAUTIONS, the MHLW/PMDA concluded that revision of PRECAUTIONS was necessary.



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Reference: Number of cases*¹ and patient mortalities involving severe skin disorders reported in Japan and overseas

A total of 16 cases*² have been reported in Japan to date (including 5 cases in which a causal relationship between the drug and the event was reasonably possible).

No patient mortalities have been reported in Japan to date.

A total of 3 cases*³ have been reported overseas to date (including 1 case in which a causal relationship between the drug and the event was reasonably possible).

One instance of patient mortality has been reported overseas to date. (A causal relationship between the drug and the death following the event could not be established for this case.)

*1: Cases collected in the PMDA's safety database for drugs

*2: Cases that fell under MedDRA SOC "Skin and subcutaneous tissue disorders" involving severe skin disorders of grade 3 or higher by Common Terminology Criteria for Adverse Events (CTCAE) Version 6.0 or cases that fell under MedDRA PT "Pemphigoid" or "Pemphigus"

*3: Cases extracted as those that fell under MedDRA PT "Toxic epidermal necrolysis", "Oculomucocutaneous syndrome", "Stevens-Johnson syndrome", or "Erythema multiforme"

The expert advisors present at the Expert Discussion regarding the current investigation were nominated based on their conflict of interest declarations concerning the relevant products, pursuant to the "Rules for Convening Expert Discussions, etc.", by the Pharmaceuticals and Medical Devices Agency" (PMDA Administrative Rule No. 20-8, dated December 25, 2008).