独立行政法人 医薬品医療機器総合機構
Pharmaceuticals and Medical Devices Agency

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Summary of Investigation Results

Avelumab (genetical recombination)

July 30, 2025

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

1. Precautions for sclerosing cholangitis should be added to the language concerning hepatic failure, hepatic impairment, and hepatitis in 8. IMPORTANT PRECAUTIONS.
2. “Sclerosing cholangitis” should be added to “hepatic failure, hepatic impairment, hepatitis” in the 11.1 Clinically Significant Adverse Reactions section in 11. ADVERSE REACTIONS.

Investigation results and background of the revision

Cases involving sclerosing cholangitis were evaluated. Cases for which a causal relationship between avelumab (genetical recombination) and sclerosing cholangitis 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.

Reference: Number of cases* and patient mortalities involving sclerosing cholangitis reported in Japan

A total of 8 cases have been reported to date (including 4 cases for which a causal relationship between the drug and the event was reasonably possible).

No patient mortalities have been reported to date.

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

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).