



Summary of Investigation Results

Avelumab (genetical recombination)

June 4, 2019

Non-proprietary name

Avelumab (genetical recombination)

Branded name (Marketing authorization holder)

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

Indications

Unresectable Merkel cell carcinoma

Summary of revisions

“Pancreatitis” should be added to the Clinically Significant Adverse Reactions section.

Investigation results and background of the revision

Cases of pancreatitis have been reported in patients treated with avelumab overseas. MHLW/PMDA concluded that revision of the package insert was necessary based on their investigation of the currently available evidence and in consultation with expert advisors. Although no corresponding cases have been reported in Japan, revision based on overseas cases was determined appropriate by considering that currently there have been no findings to indicate ethnic differences in the pharmacokinetics and safety profile of the drug between Japanese and overseas patients. In addition, the drug is indicated for “unresectable Merkel cell carcinoma” in Japan for which extremely few patients are found in Japan.

Number of cases and patient mortalities reported in Japan during the previous 3 fiscal years

No cases involving pancreatitis have been reported to date.

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