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

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

Pembrolizumab (genetical recombination)

July 30, 2025

Non-proprietary name

Pembrolizumab (genetical recombination)

Brand name (marketing authorization holder)

Keytruda Injection 100 mg (MSD K.K.)

Japanese market launch

February 2017

Indications

•Malignant melanoma
•Unresectable, advanced or recurrent non-small cell lung cancer
•Pre- and postoperative adjuvant therapy for non-small cell lung cancer
•Relapsed or refractory classical Hodgkin lymphoma
•Radically unresectable urothelial carcinoma
•Advanced or recurrent microsatellite instability-high (MSI-High) solid tumours that have progressed after cancer chemotherapy (limited to patients who are refractory or intolerant to standard treatments)
•Radically unresectable or metastatic renal cell carcinoma
•Postoperative adjuvant therapy for renal cell carcinoma
•Recurrent or metastatic head and neck cancer
•Radically unresectable advanced or recurrent oesophageal carcinoma
•Unresectable, advanced or recurrent microsatellite instability-high (MSI-High) colorectal cancer
•PD-L1-positive, hormone receptor-negative and HER2-negative inoperable or recurrent breast cancer

- Pre- and postoperative drug therapy for hormone receptor-negative and HER2-negative breast cancer at high risk of recurrence
- Advanced or recurrent endometrial carcinoma
- Advanced or recurrent, tumour mutational burden-high (TMB-High) solid tumours that have progressed after cancer chemotherapy (limited to patients who are refractory or intolerant to standard treatments)
- Advanced or recurrent cervical cancer
- Locally advanced cervical cancer
- Recurrent or refractory primary mediastinal large B-cell lymphoma
- Unresectable, advanced or recurrent gastric cancer
- Unresectable biliary tract cancer
- Unresectable, advanced or recurrent malignant pleural mesothelioma

Summary of revisions

"Vasculitis" 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 vasculitis were evaluated. Cases for which a causal relationship between pembrolizumab (genetical recombination) and vasculitis 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 vasculitis reported in Japan

A total of 35 cases have been reported to date (including 11 cases for which a causal relationship between the drug and the event was reasonably possible).

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

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

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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).