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)

June 15, 2021

Non-proprietary name

Pembrolizumab (genetical recombination)

Branded name (Marketing authorization holder)

Keytruda Injection 100 mg (MSD K.K.)

Indications

Malignant melanoma

Unresectable advanced or recurrent non-small cell lung cancer

Relapsed or refractory classical Hodgkin lymphoma

Radically unresectable urothelial carcinoma that has progressed after cancer chemotherapy

Advanced or recurrent, microsatellite instability-high (MSI-H) 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

Recurrent or metastatic head and neck cancer

Radically unresectable advanced or recurrent PD-L1-positive esophageal squamous cell cancer that has progressed after cancer chemotherapy

Summary of revisions

1. “Fulminant hepatitis, hepatic failure” should be added to the cautionary statement regarding hepatic impairment and sclerosing cholangitis in the IMPORTANT PRECAUTIONS section.

Pharmaceuticals and Medical Devices Agency

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2. “Fulminant hepatitis, hepatic failure” should be added to “hepatic impairment, hepatitis, sclerosing cholangitis” in the cautionary statement in the Clinically Significant Adverse Reactions section.

Investigation results and background of the revision

Cases of fulminant hepatitis or hepatic failure have been reported in patients treated with pembrolizumab (genetical recombination) in Japan. MHLW/PMDA in consultation with expert advisors concluded that revision of the package insert was necessary.

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

A total of 29 cases involving hepatic failure have been reported to date (including 5 cases for which a causal relationship between the drug and event was reasonably possible).
A total of 18 patient mortalities have been reported to date (including 3 cases for which a causal relationship between the drug and deaths subsequent to the event was reasonably possible).

The above includes the following cases of fulminant hepatitis.
A total of 7 cases reported to date (including 2 cases for which a causal relationship between the drug and event was reasonably possible).
A total of 6 patient mortalities reported to date (including 2 cases for which a causal relationship between the drug and deaths subsequent to the event was reasonably possible).

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).

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