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

Nivolumab (genetical recombination)

November 5, 2020

Non-proprietary name

Nivolumab (genetical recombination)

Branded name (Marketing authorization holder)

Opdivo Intravenous Infusion 20 mg, 100 mg, 120 mg, 240 mg (Ono Pharmaceutical Co., Ltd.)

Indications

Malignant melanoma

Unresectable advanced or recurrent non-small cell lung cancer

Unresectable or metastatic renal cell carcinoma

Relapsed or refractory classical Hodgkin lymphoma

Relapsed or metastatic head and neck cancer

Unresectable, advanced or recurrent gastric cancer that has progressed after cancer chemotherapy

Unresectable, advanced or recurrent malignant pleural mesothelioma that has progressed after cancer chemotherapy

Microsatellite instability high (MSI-High) unresectable advanced or recurrent colorectal cancer that has progressed after chemotherapy

Unresectable advanced or recurrent oesophageal carcinoma that has progressed after chemotherapy

Pharmaceuticals and Medical Devices Agency

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Summary of revisions

1. A statement that patients should be monitored through periodic liver function tests should be added to the Important Precautions section.

2. “Fulminant hepatitis” should be added to the description “Hepatic failure, hepatic function disorder, hepatitis, and cholangitis sclerosing” currently listed in the Clinically Significant Adverse Reactions section.

Investigation results and background of the revision

Cases of fulminant hepatitis have been reported in patients treated with nivolumab 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 18 cases involving fulminant hepatitis have been reported to date (including 3 cases for which a causal relationship between the drug and event was reasonably possible). A total of 10 patient mortalities have been reported to date (including 3 cases for which a causal relationship between the drug and 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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