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)

June 21, 2021

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

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

Unresectable advanced or recurrent esophageal cancer that has progressed after chemotherapy

Summary of revisions

1. A cautionary statement should be added to the IMPORTANT PRECAUTIONS section concerning febrile neutropenia when this drug is co-administered with carboplatin, paclitaxel, and bevacizumab (genetical recombination).

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2. “Febrile neutropenia” should be added to the cautionary statement concerning “Serious blood disorder” in the Clinically Significant Adverse Reactions section.
3. Results of the clinical study (ONO-4538-52 Study) in which this drug was co-administered with carboplatin, paclitaxel, and bevacizumab (genetical recombination) in patients with unresectable advanced or recurrent non-squamous non-small cell lung cancer should be added to the Clinical Results section.

Investigation results and background of the revision

Results of the clinical study in which this drug was co-administered with carboplatin, paclitaxel, and bevacizumab (genetical recombination) in patients with unresectable advanced or recurrent non-squamous non-small cell lung cancer showed clinical effectiveness of the co-administration. Considering the results of the study and the incidence of febrile neutropenia when this drug was co-administered with these drugs, MHLW/PMDA in consultation with expert advisors concluded that revision of the package insert was necessary.

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).