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)

May 9, 2019

Non-proprietary name

Nivolumab (genetical recombination)

Branded name (Marketing authorization holder)

Opdivo Intravenous Infusion 20 mg, 100 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

Summary of revision

1. A cautionary statement for pituitary impairment and adrenal disorder should be added to the language concerning pituitary impairment in the Important Precautions section.
2. “Pituitary impairment” should be added to the Clinically Significant Adverse Reactions section.

Investigation results and background of the revision

Cases of pituitary impairment have been reported in patients treated with nivolumab in Japan. MHLW/PMDA concluded that revision of the package insert was necessary based on the results of their investigation of the currently available evidence and in consultation

3-3-2 Kasumigaseki, Chiyoda-ku, Tokyo 100-0013 Japan
E-mail: safety.info@pmda.go.jp

with expert advisors. Of note, given that a cautionary statement for adrenal disorder is already included in the Clinically Significant Adverse Reactions section and that the test parameters are the same for pituitary impairment and adrenal disorder, MHLW/PMDA also concluded that “adrenal disorder” together with pituitary impairment should be added to the Clinically Significant Adverse Reactions section.

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

A total of 76 cases involving pituitary impairment have been reported to date (including 11 cases for which a causal relationship with the product could not be ruled out). A total of 2 patient mortalities have been reported to date (including 1 case for which a causal relationship with the product could not be ruled out).