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)

February 12, 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 revisions

1. “Haemophagocytic syndrome” should be added to the Clinically Significant Adverse Reactions section.
2. “Immune thrombocytopenic purpura” in the Clinically Significant Adverse Reactions section should be revised to “serious blood disorder“, and language concerning haemolytic anaemia and agranulocytosis should be added within.

Investigation results and background of the revision

Cases of haemophagocytic syndrome, haemolytic anaemia, and agranulocytosis have

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

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 with expert advisors.

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

1. A total of 10 cases involving haemophagocytic syndrome have been reported to date (including 3 cases for which a causal relationship with the product could not be ruled out.) No patient mortalities have been reported to date.
2. A total of 15 cases involving haemolytic anaemia have been reported to date (including 3 cases for which a causal relationship with the product could not be ruled out.) One instance of patient mortality has been reported to date (a causal relationship with the product could not be established in this case.)
   A total of 33 cases involving neutropenia (including agranulocytosis) have been reported to date (including 12 cases for which a causal relationship with the product could not be ruled out.) No patient mortalities have been reported to date.

3-3-2 Kasumigaseki, Chiyoda-ku, Tokyo 100-0013 Japan
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