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)

February 12, 2019

Non-proprietary name

Pembrolizumab (genetical recombination)

Branded name (Marketing authorization holder)

Keytruda Injection 20 mg, 100 mg (MSD K.K.)

Indications

Malignant melanoma

Unresectable advanced or recurrent non-small cell lung cancer

Relapsed or refractory classical Hodgkin lymphoma

Unresectable urothelial carcinoma exhibiting progression after chemotherapy

Advanced or recurrent, microsatellite instability-high (MSI-H) solid tumours exhibiting progression after chemotherapy (only when management cannot be achieved with standard therapies)

Summary of revisions

1. “Haemophagocytic syndrome” should be added to the Clinically Significant Adverse Reactions section.
2. Language concerning “Immune thrombocytopenic purpura”, “haemolytic anaemia”, and “pure red cell aplasia“ in the Clinically Significant Adverse Reactions section should be integrated under “serious blood disorder“, and language concerning agranulocytosis should be added.

Investigation results and background of the revision

Cases of haemophagocytic syndrome and agranulocytosis have been reported in patients treated with pembrolizumab in Japan. MHLW/PMDA concluded that revision of the package

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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 9 cases involving haemophagocytic syndrome have been reported to date (including 7 cases for which a causal relationship with the product could not be ruled out.) 1 instance of patient mortality has been reported to date (a causal relationship with the product could not be established in this case.)
2. A total of 7 cases involving neutropenia (including agranulocytosis) have been reported to date (including 4 cases for which a causal relationship with the product could not be ruled out.) No patient mortalities have been reported to date.

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