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)

March 31, 2020

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)

Unresectable or metastatic renal cell carcinoma

Recurrent or metastatic head and neck cancer

Summary of revisions

With the addition of “toxic epidermal necrolysis (TEN),” the “Oculomucocutaneous syndrome (Stevens-Johnson syndrome), erythema multiforme” in the Clinically Significant Adverse Reactions section should be revised to “Toxic epidermal necrolysis (TEN), oculomucocutaneous syndrome (Stevens-Johnson syndrome), erythema multiforme”.

Pharmaceuticals and Medical Devices Agency

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Investigation results and background of the revision

Cases of toxic epidermal necrolysis (TEN) have been reported in patients treated with pembrolizumab (genetical recombination) 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 16 cases involving toxic epidermal necrolysis (TEN) have been reported to date (including 7 cases for which a causal relationship between the drug and event could not be ruled out). A totals of 5 patient mortalities have been reported to date (including 1 case for which a causal relationship between the drug and the death subsequent to event could not be ruled out).
(Japanese market launch: February 2017)

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).