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Summary of Investigation Results Pembrolizumab (genetical recombination)

April 19, 2018

Non-proprietary name

Pembrolizumab (genetical recombination)

Brand name (Marketing authorization holder)

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

Indications

Treatment of unresectable melanoma

Treatment of patients with PD-L1 positive, unresectable, recurrent or advanced non-small cell lung cancer

Treatment of relapsed or refractory classical Hodgkin lymphoma

Treatment of unresectable urothelial carcinoma which has progressed after cancer chemotherapy

Summary of revision

1. Precaution for sclerosing cholangitis should be added to the language concerning hepatic impairment in the Important Precautions section.
2. “Sclerosing cholangitis” should be added to the language concerning hepatic impairment and hepatitis in the Clinically Significant Adverse Reactions section.

Investigation results and background of the revision

Cases of sclerosing cholangitis have been reported in patients treated with pembrolizumab (genetical recombination) in Japan. Based on the results of their investigation of the evidence currently available and in consultation with expert advisors, MHLW/PMDA concluded that revision of the package insert was necessary.

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

A total of 7 cases associated with sclerosing cholangitis have been reported to date. (including 3 cases for which a causal relationship with the product could not be ruled out.)

One patient mortality has been reported to date (including no cases for which a causal relationship with the product could not be ruled out.)

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