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)

April 20, 2017

Non-proprietary name

Pembrolizumab (genetical recombination)

Brand name (Marketing authorization holder)

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

Indications

Treatment of unresectable malignant melanoma

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

Summary of revision

“Myocarditis” should be newly added in the Clinically Significant Adverse Reactions section.

Background of the revision and investigation results

Cases of myocarditis have been reported overseas and the company core data sheet (CCDS)* has been revised. Following an investigation result based on the opinions of expert advisors and the available evidence, the MHLW/PMDA concluded that revision of the package insert was necessary.

The number of reported adverse reactions and fatal cases in the last 3 fiscal years in Japan

No case associated with myocarditis has been reported.

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NOTE:

*CCDS is prepared by the marketing authorization holder and covers material relating to safety, indications, dosing, pharmacology, and other information concerning the product.

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