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)

July 4, 2017

Non-proprietary name

Nivolumab (genetical recombination)

Brand name (Marketing authorization holder)

Opdivo Intravenous Infusions 20 mg, 100 mg (Ono Pharmaceutical Co., Ltd.)

Indications

Treatment of unresectable malignant melanoma
Treatment of unresectable, advanced, or recurrent non-small cell lung cancer
Treatment of unresectable or metastatic renal cell carcinoma
Treatment of relapsed or refractory classical Hodgkin lymphoma
Treatment of relapsed or metastatic head and neck cancer

Summary of revision

“Sclerosing cholangitis” should be added in the Clinically Significant Adverse Reactions section with regard to “Hepatic dysfunction, hepatitis”.

Background of the revision and investigation results

Cases of sclerosing cholangitis have been reported in patients treated with nivolumab in Japan. Following investigation results 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

A total of 10 cases associated with sclerosing cholangitis have been reported (including 6 cases for which a causal relationship to the product could not be ruled out). One fatal case

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

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