



Summary of investigation results Nivolumab (genetical recombination)

November 24, 2015

Non-proprietary name

Nivolumab (genetical recombination)

Brand name (Marketing authorization holder)

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

Indications

Radically unresectable malignant melanoma

Summary of revision

“Type 1 diabetes mellitus” should be newly added in the Clinically significant adverse reaction section.

Background of the revision and investigation results

Cases of type 1 diabetes mellitus including fulminant type 1 diabetes mellitus have been reported in patients treated with nivolumab in Japan. 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

A total of 5 cases associated with type 1 diabetes mellitus have been reported (including 4 cases for which a causal relationship to the product could not be ruled out). No fatality has been reported.