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

Ipilimumab

(genetical recombination)

January 11, 2018

Non-proprietary name

Ipilimumab (genetical recombination)

Brand name (Marketing authorization holder)

Yervoy Injection 50 mg (Bristol-Myers Squibb K.K.)

Indications

Unresectable malignant melanoma

Summary of revision

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

Background of the revision and investigation results

Although no myositis cases have been reported in Japan for which a causal relationship to ipilimumab could not be ruled out, by considering that EU and US package inserts include precautions regarding myositis, mechanisms of action of the product, and that cases of myositis have been reported in patients treated with the product overseas, the MHLW/PMDA concluded that revision of the package insert was necessary following investigation results based on the opinions of expert advisors and the available evidence.

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

A total of 2 cases associated with myositis have been reported (including 0 cases for which a causal relationship to the product could not be ruled out). No fatality has been reported.

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