



Summary of Investigation Results

Ipilimumab (genetical recombination)

October 12, 2023

Non-proprietary name

Ipilimumab (genetical recombination)

Brand name (marketing authorization holder)

Yervoy Injection 20 mg, 50 mg (Bristol-Myers Squibb K.K.)

Japanese market launch

Yervoy Injection 50 mg: August 2015

Yervoy Injection 20 mg: November 2021

Indications

- Radically unresectable malignant melanoma
- Radically unresectable or metastatic renal cell carcinoma
- Unresectable, advanced or recurrent microsatellite instability high (MSI-High) colorectal cancer that has progressed after chemotherapy
- Unresectable, advanced or recurrent non-small cell lung cancer
- Unresectable, advanced or recurrent malignant pleural mesothelioma
- Radically unresectable advanced or recurrent esophageal cancer

Summary of revisions

“Encephalitis” should be added to the Clinically Significant Adverse Reactions section in ADVERSE REACTIONS.

Investigation results and background of the revision

Cases involving encephalitis were evaluated. Cases for which a causal relationship

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between ipilimumab (genetical recombination) and encephalitis was reasonably possible have been reported. As a result of consultation with expert advisors regarding the causality assessment of the cases and the necessity of revision of PRECAUTIONS, the MHLW/PMDA concluded that revision of PRECAUTIONS was necessary.

Reference: Number of cases*† and patient mortalities involving encephalitis reported in Japan and overseas

A total of 2 cases have been reported in Japan to date (including 1 case for which a causal relationship between the drug and event was reasonably possible).

No patient mortalities have been reported in Japan to date.

A total of 24 cases have been reported overseas to date (including 14 cases for which a causal relationship between the drug and event was reasonably possible).

A total of 3 patient mortalities have been reported overseas to date. (A causal relationship between the drug and deaths subsequent to the event could not be established for any of these cases.)

*: Cases collected in the PMDA's database for adverse drug reactions, etc. reports

†: Cases retrieved by the following conditions.

- MedDRA SMQ “noninfectious encephalitis (narrow)”
- Cases for which there is no description about administration of anti-PD-1 antibody, anti-PD-L1 antibody or other anti-CTLA-4 antibody drugs in the case forms. Cases are included in which administration of the relevant antibody drugs was confirmed only after the onset of adverse reactions (PT identified as being involved in MedDRA SMQ “noninfectious encephalitis (narrow)).

The expert advisors present at the Expert Discussion regarding the current investigation were nominated based on their conflict of interest declarations concerning the relevant products, pursuant to the “Rules for Convening Expert Discussions, etc., by the Pharmaceuticals and Medical Devices Agency” (PMDA Administrative Rule No. 20-8, dated December 25, 2008).