Summary of Investigation Results

Ramucirumab (genetical recombination)

August 30, 2022

Non-proprietary name

Ramucirumab (genetical recombination)

Brand name (Marketing authorization holder)

Cyramza Intravenous Injection 100 mg, 500 mg (Eli Lilly Japan K.K.)

Indications

·Incurable, unresectable, advanced or recurrent gastric cancer

·Incurable, unresectable, advanced or recurrent colorectal cancer

·Unresectable advanced or recurrent non-small cell lung cancer

·Unresectable hepatocellular carcinoma with serum AFP greater than 400 ng/mL that has progressed after chemotherapy

Summary of revisions

A cautionary statement regarding thrombotic microangiopathy should be added to the Clinically Significant Adverse Reactions section.

Investigation results and background of the revision

Cases involving thrombotic microangiopathy reported in Japan were evaluated. Cases for which a causal relationship between ramucirumab (genetical recombination) and thrombotic microangiopathy was reasonably possible have been reported in Japan. As a result of consultation with expert advisors, MHLW/PMDA concluded that revision of Precautions was necessary.

Number of cases and patient mortalities involving thrombotic microangiopathy reported in Japan during the previous 3 fiscal years

A total of 17 cases have been reported to date (including 6 cases for which a causal relationship between the drug and event was reasonably possible).

This English version is intended to be a reference material to provide convenience for users. In the event of inconsistency between the Japanese original and this English translation, the former shall prevail.

1 instance of patient mortality has been reported to date. (A causal relationship between the drug and the event could not be established for this case.)

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).

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