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

Bortezomib

July 20, 2022

Non-proprietary name

Bortezomib

Brand name (Marketing authorization holder)

Velcade Injection 3 mg (Janssen Pharmaceutical K.K.), and the others

Indications

·Multiple myeloma

·Mantle cell lymphoma

·Primary macroglobulinaemia and lymphoplasmacytic lymphoma

·Systemic AL amyloidosis

Summary of revisions

“Guillain-Barré syndrome, demyelinating polyneuropathy” should be added in the Clinically Significant Adverse Reactions section.

Investigation results and background of the revision

Cases involving Guillain-Barré syndrome or demyelinating polyneuropathy reported in Japan and overseas were evaluated. Cases for which a causal relationship of bortezomib to Guillain-Barré syndrome or demyelinating polyneuropathy was reasonably possible have been reported overseas. As a result of consultation with expert advisors, MHLW/PMDA concluded that revision of Precautions was necessary.

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Number of cases and patient mortalities of Guillain-Barré syndrome, demyelinating polyneuropathy reported in Japan and overseas during the previous 3 fiscal years

1 case involving Guillain-Barré syndrome has been reported in Japan to date. (A causal relationship between the drug and event could not be established for this case.)
No patient mortalities have been reported in Japan to date.
A total of 8 cases involving Guillain-Barré syndrome have been reported overseas to date (including 2 cases for which a causal relationship between the drug and event was reasonably possible).
No patient mortalities have been reported overseas to date.

No cases involving demyelinating polyneuropathy have been reported in Japan to date.
A total of 20 cases involving demyelinating polyneuropathy have been reported overseas to date (including 13 cases for which a causal relationship between the drug and event was reasonably possible).
No patient mortalities have been reported overseas to date.

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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