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
Borofalan (^{10}B)

March 23, 2023

Non-proprietary name

Borofalan (^{10}B)

Brand name (marketing authorization holder)

Steboronine 9000 mg/300 mL for infusion (STELLA PHARMA CORPORATION)

Japanese market launch

May 2020

Indications

Unresectable, locally advanced or recurrent head and neck cancer

Summary of revisions

“Pharyngolaryngeal oedema” should be added to the Clinically Significant Adverse Reactions section.

Investigation results and background of the revision

Cases involving pharyngolaryngeal oedema-related events and airway obstruction-related events in the treatment using this drug and a neutron irradiation medical device for boron neutron capture therapy (hereinafter referred to as "this treatment") reported in Japan were evaluated.

Cases for which a causal relationship between this treatment and a pharyngolaryngeal oedema-related event and airway obstruction-related event 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.

Pharmaceuticals and Medical Devices Agency

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Reference: Number of cases and patient mortalities reported in Japan

・Cases***** involving pharyngolaryngeal oedema-related events

A total of 4 cases have been reported to date. (A causal relationship between the drug and event was reasonably possible for all the cases.)

No patient mortalities have been reported to date.

・Cases***** involving airway obstruction-related events

A total of 3 cases have been reported to date (including 2 cases for which a causal relationship between the drug and event was reasonably possible).

No patient mortalities have been reported to date.

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

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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