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

Amenamevir

March 31, 2020

Non-proprietary name

Amenamevir

Branded name (Marketing authorization holder)

Amenalief Tab. 200 mg (Maruho Co., Ltd.)

Indications

Herpes zoster

Summary of revisions

A Clinically Significant Adverse Reactions section should be newly added and “erythema multiforme” should be added therein.

Investigation results and background of the revision

Cases of erythema multiforme have been reported in patients treated with amenamevir in Japan for which a causal relationship between the drug and event could not be ruled out. MHLW/PMDA in consultation with expert advisors concluded that revision of the package insert was necessary.

Addition of “toxic epidermal necrolysis” and “oculomucocutaneous syndrome” along with “erythema multiforme” to the Clinically Significant Adverse Reactions section was also considered based on the cases of these events reported in Japan as well. MHLW/PMDA in consultation with expert advisors and considering the paucity of cases reported for which a

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causal relationship between the drug and event could not be ruled out, concluded that revision of the package insert was not necessary at this time with respect to toxic epidermal necrolysis and oculomucocutaneous syndrome.

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

Cases involving erythema multiforme

A total of 10 cases have been reported to date (including 5 cases for which a causal relationship between the drug and event could not be ruled out). No patient mortalities have been reported to date.

(Japanese market launch: September 2017)

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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