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

Alemtuzumab

(genetical recombination)

January 21, 2020

Non-proprietary name

Alemtuzumab (genetical recombination)

Branded name (Marketing authorization holder)

MabCampath 30 mg I.V. Infusion (Sanofi K.K.)

Indications

Recurrent or refractory chronic lymphocytic leukemia

Summary of revisions

“Cervicocephalic arterial dissection” should be added to the Clinically Significant Adverse Reactions section.

Investigation results and background of the revision

Cases of cervicocephalic arterial dissection have been reported in patients treated with alemtuzumab (genetical recombination) overseas. MHLW/PMDA concluded that revision of the package insert was necessary based on the results of their investigation of the currently available evidence and in consultation with expert advisors,

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

1 case involving cervicocephalic arterial dissection and ischaemic stroke has been reported to date (A causal relationship the drug and event could not be established for this case.) No patient mortalities have been reported to date.

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