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 26, 2021

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

Conditioning treatment prior to allogeneic haematopoietic stem cell transplant

Summary of revisions

1. Language concerning thyroid function tests should be newly added to the IMPORTANT PRECAUTIONS section.
2. “Hypothyroidism, or hyperthyroidism” should be added to “Immune disorder” in the Clinically Significant Adverse Reactions section.

Investigation results and background of the revision

Cases of hypothyroidism or hyperthyroidism have been reported in patients treated with alemtuzumab (genetical recombination) overseas. MHLW/PMDA in consultation with expert advisors concluded that revision of the package insert was necessary.

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

No cases involving abnormal thyroid function have been reported to date.

Pharmaceuticals and Medical Devices Agency

3-3-2 Kasumigaseki, Chiyoda-ku, Tokyo 100-0013 Japan
E-mail: safety.info@pmda.go.jp

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.

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).

Pharmaceuticals and Medical Devices Agency

3-3-2 Kasumigaseki, Chiyoda-ku, Tokyo 100-0013 Japan
E-mail: safety.info@pmda.go.jp