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

Belimumab (genetical recombination)

October 29, 2019

Non-proprietary name

Belimumab (genetical recombination)

Branded name (Marketing authorization holder)

Benlysta for I.V. infusion 120 mg, 400 mg

Benlysta for S.C. injection 200 mg auto-injector, 200 mg syringe (Glaxo Smith Kline K.K.)

Indications

Systemic lupus erythematosus in patients who have had an inadequate response to conventional treatments

Summary of revisions

1. A statement should be added to the Important Precautions section that patients and their families or other caregivers should be informed of the risks of depression, suicidal ideation, and suicide attempt and instructed to contact the attending physician immediately if patients experience any symptoms related to these events.
2. “Depression, suicidal ideation, and suicide attempt” should be added to the Clinically Significant Adverse Reactions section.

Investigation results and background of the revision

Results of the post-marketing clinical study conducted in systemic lupus erythematosus patients suggested higher incidences of depression, suicide and/or self-injury in the group administered belimumab plus standard therapy such as steroid therapy compared to the group administered placebo plus standard therapy, and necessity of regulatory measures was discussed. Considering the importance for patients themselves and their families or other caregivers as well as physicians to be alert to changes in the psychiatric status of

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patients in the risk management of depression, suicidal ideation, and suicide attempt, MHLW/PMDA concluded that it was appropriate to provide a precaution regarding these events in the Important Precautions and Clinically Significant Adverse Reactions sections 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 depression, suicidal ideation, and suicidal attempt has been reported to date (a causal relationship between the drug and events could not be established for this case).

No patient mortalities have been reported to date.