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

Baricitinib

September 24, 2019

Non-proprietary name

Baricitinib

Branded name (Marketing authorization holder)

Olumiant tablets 2 mg, 4 mg (Eli Lilly Japan K.K.)

Indications

Rheumatoid arthritis in patients who have had an inadequate response to conventional treatments (including the prevention of structural joint damage)

Summary of revisions

“Venous thromboembolism” should be added to the Clinically Significant Adverse Reactions section.

Investigation results and background of the revision

Venous thromboembolism was observed only in patients in the baricitinib group of the clinical studies submitted for the review of marketing authorization along with an instance of patient mortality from pulmonary embolism. In view of the fact that a causal relationship could not be established in any of these cases, venous thromboembolism has been alerted only in the IMPORTANT PRECAUTIONS section of the package insert to date. Considering a post-market case of the event reported in patients treated with baricitinib in Japan in which a causal relationship between the drug and event could not be ruled out, 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.

Pharmaceuticals and Medical Devices Agency

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

A total of 5 cases involving venous thromboembolism have been reported to date (including 1 case for which a causal relationship between the drug and event could not be ruled out).

No patient mortalities have been reported to date.

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