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

Peficitinib hydrobromide

August 29, 2023

Non-proprietary name

Peficitinib hydrobromide

Brand name (marketing authorization holder)

Smyraf Tablets 50 mg, 100 mg (Astellas Pharma Inc.)

Japanese market launch

July 2019

Indications

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

Summary of revisions

1. “Patients with risk factors for venous thromboembolism” should be added to the PRECAUTIONS CONCERNING PATIENTS WITH SPECIFIC BACKGROUNDS section.
2. “Venous thromboembolism” should be added to the Clinically Significant Adverse Reactions section.

Investigation results and background of the revision

Cases involving venous thromboembolism reported in Japan were evaluated. Cases for which a causal relationship between peficitinib hydrobromide and venous thromboembolism was reasonably possible have been confirmed in Japan. In addition, the precaution concerning the events has already been included in the package inserts of

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similar drugs. On the basis of these facts and others, the MHLW/PMDA in consultation with expert advisors regarding the causality assessment of the cases and the necessity of revision of PRECAUTIONS concluded that revision of PRECAUTIONS was necessary.

Reference: Number of cases* and patient mortalities involving venous thromboembolism reported in Japan

A total of 5 cases have been reported to date (including 1 case for which a causal relationship between the drug and event was reasonably possible).
No patient mortalities have been reported to date.

*Cases collected in the PMDA's database for adverse drug reactions, etc. reports

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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