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

Riociguat

August 3, 2017

Non-proprietary name

Riociguat

Brand name (Marketing authorization holder)

Adempas Tablets 0.5 mg, 1.0 mg, 2.5 mg (Bayer Yakuhin, Ltd.)

Indications

Inoperable chronic thromboembolic pulmonary hypertension (CTEPH) or postoperative persistent or recurrent CTEPH

Pulmonary arterial hypertension

Summary of revision

In the Important Precautions section, increased incidences of serious adverse events and fatal outcomes observed in patients receiving riociguat in a clinical study in patients with symptomatic pulmonary hypertension associated with idiopathic interstitial pneumonias should be added, as well as a precaution regarding patients with pulmonary arterial hypertension associated with interstitial pneumopathy.

Background of the revision and investigation results

The clinical study in patients with symptomatic pulmonary hypertension associated with idiopathic interstitial pneumonias (RISE-IIP Study) was terminated early due to increased incidences of serious adverse events and fatal outcomes observed in patients receiving riociguat compared with patients receiving placebo, and the necessity for measures was considered. Following investigation results based on the opinions of expert advisors and the available evidence, the MHLW/PMDA concluded that revision of the package insert was necessary considering:

・Similar risks are expected in patients with pulmonary arterial hypertension associated with

interstitial pneumopathy and the risks may outweigh the benefits in some patients.

・Therefore, it is important that a decision on administration is made for each patient by a physician versed in the treatment of interstitial lung disease.

The number of reported adverse reactions and fatal cases in the last 3 fiscal years in Japan

One case* associated with adverse reactions has been reported in patients with symptomatic pulmonary hypertension associated with idiopathic interstitial pneumonias.

No fatality has been reported.

*Causality of adverse reactions and the product has not been evaluated.

Pharmaceuticals and Medical Devices Agency
Office of Safety I
3-3-2 Kasumigaseki, Chiyoda-ku, Tokyo 100-0013 Japan
E-mail: safety.info@pmda.go.jp