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

Daprodustat

July 17, 2024

Non-proprietary name

Daprodustat

Brand name (marketing authorization holder)

Duvroq Tablets 1 mg, 2 mg, 4 mg, 6 mg (GlaxoSmithKline K.K.)

Japanese market launch

August 2020

Indications

Nephrogenic anaemia

Summary of revisions

“Patients with cardiac failure or a history of the disease” should be added to the 9.1 Patients with Complication or History of Diseases, etc. section of 9 PRECAUTIONS CONCERNING PATIENTS WITH SPECIFIC BACKGROUNDS, and a cautionary statement regarding cardiac failure should be added.

Investigation results and background of the revision

Concerning the occurrences of cardiac failure in post-hoc analyses of overseas clinical studies, the results of subgroup analyses by the presence or absence of “cardiac failure or a history of the disease” were evaluated. In the subgroup containing “patients with cardiac failure or a history of the disease” for both the clinical study in patients with chronic kidney disease on dialysis and the clinical study in those not on dialysis, it was shown that the incidence ratio of the first hospitalization due to cardiac failure tended to be higher in the daprodustat group than in the erythropoietin stimulating agents group. Therefore, as a result

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of consultation with expert advisors, the MHLW/PMDA concluded that revision of PRECAUTIONS was necessary.

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).