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

Pazopanib hydrochloride

March 24, 2015

Non-proprietary name

Pazopanib hydrochloride

Brand name (Marketing authorization holder)

Votrient Tablets 200 mg (GlaxoSmithKline K.K.)

Indications

- Soft tissue sarcoma
- Radically unresectable or metastatic renal cell carcinoma

Summary of revision

'Retinal detachment' should be added in the Clinically significant adverse reactions section.

Background of the revision and investigation results

Cases of adverse events suggestive of retinal detachment have been reported in patients treated with pazopanib hydrochloride in Japan and in foreign countries, and the company core datasheet (CCDS)* has been revised to include information on retinal detachment. Following an investigation based on the opinions of expert advisors and available evidence, the MHLW/PMDA concluded that revision of the package insert was necessary.

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

A total of 3 cases of adverse events suggestive of retinal detachment have been reported (including 2 cases in which causality could not be ruled out). No fatalities have been reported.

NOTE:

*The CCDS is prepared by the marketing authorization holder and covers material relating to safety, indications, dosing, pharmacology, and other information concerning the product.

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