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

Sorafenib tosilate

December 17, 2024

Non-proprietary name

Sorafenib tosilate

Brand name (marketing authorization holder)

Nexavar tablets 200 mg (Bayer Yakuhin, Ltd.)

Japanese market launch

April 2008

Indications

•Radically unresectable or metastatic renal cell carcinoma

•Unresectable hepatocellular carcinoma

•Radically unresectable thyroid cancer

Summary of revisions

1. A statement regarding tumour lysis syndrome should be added to the 8. IMPORTANT PRECAUTIONS section.
2. “Tumour lysis syndrome” should be added to the 11.1 Clinically Significant Adverse Reactions section in 11. ADVERSE REACTIONS.

Investigation results and background of the revision

Cases involving tumour lysis syndrome were evaluated. Cases for which a causal relationship between tumour lysis syndrome and sorafenib tosilate was reasonably possible have been reported. As a result of consultation with expert advisors regarding the causality assessment of the cases and the necessity of revision of PRECAUTIONS, the MHLW/PMDA concluded that revision of PRECAUTIONS was necessary.

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Reference: Number of cases*† and patient mortalities involving tumour lysis syndrome reported in Japan and overseas

A total of 10 cases have been reported in Japan to date (including 2 cases for which a causal relationship between the drug and the event was reasonably possible).
One instance of patient mortality has been reported in Japan to date. (A causal relationship between the drug and the death subsequent to the event could not be established for this case.)

A total of 12 cases have been reported overseas to date. (A causal relationship between the drug and the event was reasonably possible for 3 cases, including 1 case in which the drug was administered outside the approved dosage and administration.)
A total of 6 patient mortalities have been reported overseas to date. (A causal relationship between the drug and the death subsequent to the event could not be established for any of these cases.)

* Cases collected in the PMDA's database for adverse drug reactions, etc. reports
† Cases with information on laboratory test values (uric acid, potassium, phosphorus, or calcium) related to the diagnostic criteria for tumour lysis syndrome, as documented in the case report form

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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