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
Imatinib mesilate

January 17, 2023

Non-proprietary name

Imatinib mesylate

Brand name (marketing authorization holder)

Glivec Tablets 100 mg (Novartis Pharma K.K.), and the others

Japanese market launch

July 2005

Indications

· Chronic myeloid leukaemia

· KIT (CD117)-positive gastrointestinal stromal tumor

· Philadelphia chromosome-positive acute lymphocytic leukaemia

· The following FIP-1-like-1-platelet-derived growth factor receptor alpha (FIP1L1-PDGFRα)-positive diseases:

Hypereosinophilic syndrome, chronic eosinophilic leukaemia

Summary of revisions

“Pemphigus” should be added to the Clinically Significant Adverse Reactions section.

Investigation results and background of the revision

Cases involving pemphigus reported overseas were evaluated. Cases for which a causal relationship between imatinib mesilate and pemphigus was reasonably possible have been reported overseas. As a result of consultation with expert advisors regarding the causality assessment of the cases and the necessity of revision of Precautions, MHLW/PMDA concluded that revision of Precautions was necessary.

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Reference: Number of cases* and patient mortalities involving pemphigus reported in Japan and overseas

No cases have been reported in Japan to date.

A total of 6 cases have been reported overseas to date (including 5 cases for which a causal relationship between the drug and event was reasonably possible).

No patient mortalities have been reported overseas 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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