This English version is intended to be a reference material to provide convenience for users. In the event of inconsistency between the Japanese original and this English translation, the former shall prevail.

Summary of investigation results

imatinib mesilate

September 16, 2014

Non-proprietary Name

imatinib mesilate

Brand Name (Marketing Authorization Holder)

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

Indications

- Chronic myeloid leukaemia
- KIT (CD117)-positive gastrointestinal stromal tumors
- Philadelphia chromosome positive acute lymphocytic leukaemia
- The following Fip-1-like 1-platelet-derived growth factor receptor alpha-positive diseases: Hypereosinophilic syndrome and chronic eosinophilic leukaemia

Summary of revision

In Clinically significant adverse reactions section, haemorrhage (cerebral haemorrhage, subdural haemorrhage, and gastrointestinal haemorrhage) subsection should be divided to haemorrhage (cerebral haemorrhage and subdural haemorrhage) subsection and gastrointestinal haemorrhage subsection. ‘Gastric antral vascular ectasia (GAVE)’ should be added in the new gastrointestinal haemorrhage subsection.

Background of the revision and investigation results

Cases of GAVE have been reported in patients treated with imatinib mesilate in Japan. Following an investigation result based on opinions of expert advisors and available evidence, the MHLW/PMDA concluded that ‘gastrointestinal haemorrhage’ in Clinically significant adverse reactions section should be deleted from the haemorrhage subsection, create a new gastrointestinal haemorrhage subsection, and that GAVE should be added in the new subsection.

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

A total of 5 cases associated with GAVE has been reported. A causal relationship with imatinib mesilate could not be ruled out in 3 cases. No fatalities have been reported.

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