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

Bosutinib hydrate

May 30, 2017

Non-proprietary name

Bosutinib hydrate

Brand name (Marketing authorization holder)

Bosulif Tablets 100 mg (Pfizer Japan Inc.)

Indications

Chronic myelogenous leukemia with resistance or intolerance to prior drug therapies

Summary of revision

“Toxic epidermal necrolysis (TEN), oculomucocutaneous syndrome (Stevens-Johnson syndrome), and erythema multiforme” should be added in the Clinically Significant Adverse Reactions section.

Background of the revision and investigation results

Cases of oculomucocutaneous syndrome have been reported in patients treated with bosutinib hydrate in Japan and the company core data sheet (CCDS) has been revised. In addition, cases of toxic epidermal necrolysis and of erythema multiforme have been reported in Japan as well in patients treated with bostinib hydrate. Following an investigation result based on the opinions of expert advisors and the 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

One case associated with toxic epidermal necrolysis has been reported (including 1 case

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

for which a causal relationship to the product could not be ruled out). No fatality has been reported.

A total of 4 cases associated with oculomucocutaneous syndrome have been reported (including 4 cases for which a causal relationship to the product could not be ruled out). No fatality has been reported.

A totals of 4 cases associated with erythema multiforme have been reported (including 4 cases for which a causal relationship to the product could not be ruled out). No fatality has been reported.