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

Afatinib maleate

September 13, 2016

Non-proprietary name

Afatinib maleate

Brand name (Marketing authorization holder)

Giotrif Tablets 20 mg, 30 mg, 40 mg, 50 mg (Nippon Boehringer Ingelheim Co., Ltd.)

Indications

EGFR mutation-positive unresectable or relapsed non–small-cell lung cancer

Summary of revision

“Toxic epidermal necrolysis (TEN), erythema multiforme” should be added to the “Oculomucocutaneous syndrome (Stevens–Johnson syndrome)” subsection in the Clinically significant adverse reaction section.

Background of the revision and investigation results

Cases of toxic epidermal necrolysis and erythema multiforme have been reported in patients treated with afatinib maleate in Japan and overseas. In addition, the company core datasheet (CCDS)* has been updated regarding toxic epidermal necrolysis. 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

A total of 3 cases associated with toxic epidermal necrolysis has been reported (including 2 cases for which a causal relationship to the product could not be ruled out). No fatality has been reported.

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

A case associated with erythema multiforme has been reported (a causal relationship to the product could not be ruled out for this case). No fatality has been reported.

Note:
*CCDS is prepared by the marketing authorization holder and covers materials 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