



Summary of investigation results

Afatinib maleate

April 21, 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

Unresectable or recurrent *EGFR* mutation-positive non-small-cell lung cancer

Summary of revision

“Acute pancreatitis” should be added in the Clinically significant adverse reaction section.

Background of the revision and investigation results

Cases of acute pancreatitis have been reported in patients treated with this drug in Japan. 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 4 cases associated with acute pancreatitis have been reported (including 2 cases for which a causal relationship to the product could not be ruled out). No fatality has been reported.