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*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.*

# Revision of Precautions

## Afatinib maleate

April 21, 2016

### **Non-proprietary name**

Afatinib maleate

### **Safety measure**

Precautions should be revised in the package insert.

In the Clinically significant adverse reaction subsection of the Adverse reaction section, the following text should be added (underlined parts are revised):

#### Acute pancreatitis:

Acute pancreatitis may occur. Patients should be carefully monitored. If abnormalities, such as abdominal pain and increased serum amylase, are observed, administration of this drug should be discontinued, and appropriate measures should be adopted.