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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

## Lenvatinib mesilate

October 23, 2018

### **Non-proprietary name**

Lenvatinib mesilate

### **Safety measure**

Precautions should be revised in the package insert.

The following language should be added to the Careful Administration section (revised language is underlined):

#### Patients with lung metastasis

The language concerning gastrointestinal perforation and fistula formation in the Clinically Significant Adverse Reactions subsection of the Adverse Reactions section should be revised as follows (revised language is underlined):

Gastrointestinal perforation, fistula formation, and pneumothorax:

Intestinal perforation, anal fistula, enterovesical fistula, and pneumothorax, etc. may occur. Patients should be carefully monitored, and if any abnormalities are observed, appropriate measures such as discontinuing administration should be taken.