



# Summary of investigation results

## Lenvatinib mesilate

May 9, 2019

### **Non-proprietary name**

Lenvatinib mesilate

### **Branded name (Marketing authorization holder)**

Lenvima Capsules 4 mg, 10 mg (Eisai Co., Ltd.)

### **Indications**

Unresectable thyroid cancer, unresectable hepatocellular carcinoma

### **Summary of revision**

“Interstitial lung disease” should be added to the Clinically Significant Adverse Reactions section.

### **Investigation results and background of the revision**

Cases of interstitial lung disease have been reported in patients treated with lenvatinib mesilate in Japan. MHLW/PMDA concluded that revision of the package insert was necessary based on the results of their investigation of the currently available evidence and in consultation with expert advisors.

### **Number of adverse reactions and patient mortalities reported in Japan during the previous 3 fiscal years**

A total of 11 cases involving interstitial lung disease have been reported to date (including 4 cases for which a causal relationship with the product could not be ruled out). A total of 4 patient mortalities have been reported to date (including 1 case for which a causal relationship with the product could not be ruled out).