



# Summary of Investigation Results

## Osimertinib mesilate

December 3, 2019

### **Non-proprietary name**

Osimertinib mesilate

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

Tagrisso Tablets 40 mg, 80 mg (AstraZeneca K.K.)

### **Indications**

EGFR gene mutation-positive inoperable or recurrent non-small cell lung cancer

### **Summary of revisions**

“Congestive cardiac failure and decreased left ventricular ejection fraction” should be added to the Clinically Significant Adverse Reactions section.

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

Cases of congestive cardiac failure and decreased left ventricular ejection fraction have been reported in patients treated with osimertinib 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 cases and patient mortalities reported in Japan during the previous 3 fiscal years**

A total of 34 cases involving cardiac failure have been reported to date (including 5 cases for which a causal relationship between the drug and event could not be ruled out).

A total of 7 patient mortalities have been reported to date (a causal relationship between the drug and the death subsequent to event could not be established for any of these cases).

(Japanese market launch: May 2016)