



Summary of Investigation Results

Osimertinib mesilate

September 24, 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

“Toxic epidermal necrolysis (TEN), oculomucocutaneous syndrome (Stevens-Johnson syndrome), erythema multiforme” should be added to the Clinically Significant Adverse Reactions section.

Investigation results and background of the revision

Cases of TEN, oculomucocutaneous syndrome, or erythema multiforme have been reported in patients treated with osimertinib mesilate in Japan and overseas. 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

1. Toxic epidermal necrolysis

No cases involving TEN have been reported to date.



This English version is intended to be a reference material for the convenience of users. In the event of inconsistency between the Japanese original and this English translation, the former shall prevail.

2. Oculomucocutaneous syndrome

A total of 5 cases involving oculomucocutaneous syndrome have been reported to date (including 2 cases for which a causal relationship between the drug and event could not be ruled out).

No patient mortalities have been reported to date.

3. Cases involving erythema multiforme*

A total of 3 cases involving erythema multiforme have been reported to date (including 3 cases for which a causal relationship between the drug and event could not be ruled out).

No patient mortalities have been reported to date.

*Cases considered erythema multiforme major according to the Guidelines for the Diagnosis and Treatment of Erythema Multiforme Exudativum Major, Stevens-Johnson Syndrome, Toxic Epidermal Necrolysis (TEN) in Japan