

Summary of Investigation Results

Osimertinib mesilate

Non-proprietary name Brand name	Non-proprietary name	Brand name (marketing authorization holder)
	Osimertinib mesilate	Tagrisso Tablets 40 mg, 80 mg (AstraZeneca K.K.)
Japanese market launch	May 2016	
Indications	OEGFR mutation-positive inoperable or recurrent non-small cell lung cancer OAdjuvant therapy for EGFR mutation-positive non-small cell lung cancer OMaintenance treatment for unresectable, locally advanced EGFR mutation-positive non-small cell lung cancer following definitive chemoradiation therapy	
Summary of revisions	1. A cautionary statement regarding aplastic anemia should be added to the 8. IMPORTANT PRECAUTIONS section. 2. “Aplastic anemia” should be added to the 11.1 Clinically Significant Adverse Reactions section in 11. ADVERSE REACTIONS.	
Investigation results and background of the revision	Cases involving aplastic anemia were evaluated. Cases in which a causal relationship between Osimertinib mesilate and aplastic anemia was reasonably possible have been reported. As a result of consultation with expert advisors regarding the causality assessment of the cases and the necessity of revision of PRECAUTIONS, the MHLW/PMDA concluded that revision of PRECAUTIONS was necessary.	
Reference: Number of cases ^{*1} involving aplastic anemia ^{*2} reported in Japan	A total of 8 cases have been reported to date (including 3 cases in which a causal relationship between the drug and the event was reasonably possible). A total of 1 death has been reported to date (including 0 cases in which a causal relationship between the drug and the death following the event was reasonably possible).	

*1: Cases collected in PMDA's safety database for drugs.

*2: Among cases that fell under MedDRA ver. 28.1 PTs "Aplastic anaemia", cases with information relevant to the diagnostic criteria (laboratory values for haemoglobin, neutrophils, and platelets) were retrieved.

The expert advisors present at the Expert Discussion regarding the current investigation were nominated based on their conflict of interest declarations concerning the relevant products, pursuant to the "Rules for Convening Expert Discussions, etc., by the Pharmaceuticals and Medical Devices Agency" (PMDA Administrative Rule No. 20-8, dated December 25, 2008).