

Summary of Investigation Results

Alectinib Hydrochloride

Non-proprietary name Brand name	Non-proprietary name	Brand name (marketing authorization holder)
	Alectinib Hydrochloride	ALECENSA Capsules 150 mg (Chugai Pharmaceutical Co., Ltd.)
Japanese market launch	December 2015	
Indications	○ALK-positive, unresectable, advanced or relapsed solid tumour ○Adjuvant treatment of resected ALK-positive non-small cell lung cancer ○Recurrent or refractory ALK-positive anaplastic large cell lymphoma	
Summary of revisions	A cautionary statement regarding severe hypertriglyceridemia with subsequent pancreatitis should be added to the 8. IMPORTANT PRECAUTIONS section	
Investigation results and background of the revision	Cases involving severe hypertriglyceridemia with subsequent pancreatitis were evaluated. Cases in which a causal relationship between alectinib hydrochloride and severe hypertriglyceridemia 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 severe hypertriglyceridemia ^{*2} reported in Japan and overseas	Japan	Overseas
	A total of 0 cases have been reported to date (including 0 cases in which a causal relationship between the drug and the event was reasonably possible). No deaths have been reported to date.	A total of 3 cases have been reported to date (including 3 cases in which a causal relationship between the drug and the event was reasonably possible). No deaths have been reported to date.

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

*2: Among cases that fell under MedDRA ver. 28.1 PTs "Hypertriglyceridemia" and "Blood triglyceride increased", referred to pancreatitis secondary to hypertriglyceridemia 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).