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.

Summary of investigation results

Crizotinib

June 2, 2015

Non-proprietary name

crizotinib

Brand name (Marketing authorization holder)

Xalkori Capsules 200 mg and 250 mg (Pfizer Japan Inc.)

Indications

Anaplastic lymphoma kinase (ALK)-positive, unresectable, advanced or relapsed non-small-cell lung cancer

Summary of revision

“Cardiac failure” should be added in the Clinically significant adverse reactions section.

Background of the revision and investigation results

Cases of cardiac failure have been reported in patients treated with crizotinib in Japan. Following an investigation result based on the opinions of expert advisors and the available evidence, the MHLW/PMDA concluded that revision of the package insert was necessary.

The number of reported adverse reactions and fatal cases in the last 3 fiscal years in Japan

A total of 11 cases associated with cardiac failure have been reported (Including 6 cases for which a causal relationship to the product could not be ruled out).

Of the 11 cases, a fatal case has been reported (The causal relationship to the product could be ruled out for the patient).

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