



Summary of Investigation Results

Palbociclib

February 12, 2019

Non-proprietary name

Palbociclib

Branded name (Marketing authorization holder)

Ibrance Capsules 25 mg, 125 mg (Pfizer Japan Inc.)

Indications

Unresectable or recurrent breast cancer

Summary of revisions

“Interstitial lung disease” should be added to the Important Precautions and Clinically Significant Adverse Reactions sections.

Investigation results and background of the revision

Cases of interstitial lung disease have been reported in patients treated with palbociclib 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 adverse reactions and patient mortalities reported in Japan during the previous 3 fiscal years

A total of 12 cases involving interstitial lung disease have been reported to date (including 6 cases for which a causal relationship with the product could not be ruled out.)

2 instances of patient mortality has been reported to date (a causal relationship with the product could not be established for these patients.)