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Pharmaceuticals and Medical Devices Agency

## 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.)

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