



Summary of Investigation Results

Palbociclib

July 9, 2019

Non-proprietary name

Palbociclib

Branded name (Marketing authorization holder)

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

Indications

Inoperable or recurrent breast cancer

Inoperable or recurrent breast cancer

Summary of revisions

1. Language concerning interstitial lung disease should be added to the Warnings and Careful Administration sections.
2. Language concerning interstitial lung disease in the Important Precautions and Clinically Significant Adverse Reactions sections should be revised.

Investigation results and background of the revision

A Dear Healthcare Professionals Letter of Rapid Safety Communication (Blue Letter) was issued regarding interstitial lung disease associated with abemaciclib and revision of its package insert was decided in May 2019. Abemaciclib has a CDK4/6 inhibiting effects and palbociclib has such effects as well. Consequently, necessity to enhance the current precaution for interstitial lung disease in palbociclib was investigated. The investigation revealed that several cases of interstitial lung disease had been reported since the revision of the package insert in February 2019 to place a cautionary statement regarding interstitial lung disease in the Important Precautions and Clinically significant Adverse Reactions



sections (A total of 23 cases were identified including those newly reported since the revision in February 2019, and those already assessed at the time of the revision for which additional information has been reported since then. A causal relationship between the drug and event could not be ruled out for 10 of the 23 cases). There was 1 instance of patient mortality among the identified cases, for which it is considered that a causal relationship between this drug and the death subsequent to event could not be ruled out. MHLW/PMDA concluded that precaution regarding interstitial lung disease that will be in line with abemaciclib should be included in the Warnings, Careful Administration, and other appropriate sections in the package insert of palbociclib as well.

Number of cases and patient mortalities reported in Japan during the previous 3 fiscal years

A total of 30 cases involving interstitial lung disease have been reported to date (including 14 cases for which a causal relationship between the drug and event could not be ruled out). 3 instances of patient mortalities have been reported to date (including 1 instance for which a causal relationship between the drug and the death subsequent to event could not be ruled out).