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FDA warns about rare but severe lung inflammation with Ibrance, Kisqali, and Verzenio for breast cancer

Cyclin-dependent kinase 4/6 (CDK 4/6) inhibitors are a class of medicines used in combination with hormonal therapies to treat adult patients with hormone receptor (HR)-positive, human epidermal growth factor 2 (HER2)-negative advanced or metastatic breast cancer that has spread to other parts of the body.

CDK 4/6 inhibitors include: Ibrance (palbociclib), Kisqali (ribociclib), and Verzenio (abemaciclib).

The FDA evaluated data from manufacturer's clinical trials and discovered that 13% of patients treated with CDK 4/6 Inhibitors developed interstitial lung disease (ILD) or pneumonitis. Less than 1% of these cases were fatal. The FDA concludes that the overall benefit of CDK 4/6 inhibitors is greater than the risks when used as prescribed.

FDA has included the risk of ILD or pneumonitis as a new warning in the package inserts.

Health care professionals should monitor patients regularly for pulmonary symptoms indicative of ILD and/or pneumonitis.

Signs and symptoms may include hypoxia, cough, dyspnea, or interstitial infiltrates on radiologic exams in patients in whom infectious, neoplastic, and other causes have been excluded.

Interrupt CDK 4/6 inhibitor treatment in patients who have new or worsening respiratory symptoms.

Permanently discontinue treatment in patients with severe ILD and/or pneumonitis.

The full drug safety communication can is attached and can be found on the FDA website.