FDA Issues Warning About Ibrance, Kisqali, Verzenio Due to Lung Inflammation

The FDA is warning that these drugs used to treat advanced breast cancers may cause rare but severe inflammation of the lungs.

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FDA is warning that Ibrance (palbociclib), Kisqali (ribociclib), and Verzenio (abemaciclib) used to treat some patients with advanced breast cancers may cause rare but severe inflammation of the lungs. FDA has approved new warnings about this risk to the prescribing information and Patient Package Insert for the entire class of these cyclin-dependent kinase 4/6 (CDK 4/6) inhibitor medicines. The overall benefit of CDK 4/6 inhibitors is still greater than the risks when used as prescribed.

CDK 4/6 inhibitors are a class of prescription medicines that are used in combination with hormone therapies to treat adults 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 block certain molecules involved in promoting the growth of cancer cells. FDA approved Ibrance in 2015, and both Kisqali and Verzenio in 2017. CDK 4/6 inhibitors have been shown to improve the amount of time after the start of treatment the cancer does not grow substantially and the patient is alive, called progression-free survival (See List of FDA-Approved CDK 4/6 Inhibitors below).

Patients should notify your health care professional right away if you have any new or worsening symptoms involving your lungs, as they may indicate a rare but life-threatening condition that can lead to death. Symptoms to watch for include:

- Difficulty or discomfort with breathing
- Shortness of breath while at rest or with low activity

Do not stop taking your medicine without first talking to your health care professional. All medicines have side effects even when used correctly as prescribed, but in general the benefits of taking these medicines outweigh these risks. It is important to know that people respond differently to all medicines depending on their health, the diseases they have, genetic factors,

other medicines they are taking, and many other factors. Specific risk factors to determine how likely it is that a particular person will experience severe lung inflammation when taking Ibrance, Kisqali, or Verzenio have not been identified.

Health care professionals should monitor patients regularly for pulmonary symptoms indicative of interstitial lung disease (ILD) and/or pneumonitis. Signs and symptoms may include:

- hypoxia
- cough
- dyspnea
- 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, and permanently discontinue treatment in patients with severe ILD and/or pneumonitis. Healthcare professionals and patients are encouraged to report adverse events or side effects related to the use of these products to the FDA's MedWatch Safety Information and Adverse Event Reporting Program:

- Complete and submit the report online.
- Download form (UCM2007307) or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

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