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Dear Healthcare Professional,

SEVERE BUT RARE LUNG INFLAMMATION WITH IBRANCE

The Food and Drugs Authority (FDA) wishes to bring to your attention new safety information relating to rare but severe lung inflammation with Ibrance (Palbociclib). Ibrance is a prescription only medicine belonging to a group of drugs known as cyclin-dependent kinase 4/6 inhibitors (CDK4/6) used for the treatment of hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer in combination with other drugs. It has been registered for use in Ghana by the Food and Drugs Authority (FDA) since 2017.

Patients are advised to notify their healthcare professionals immediately if they have any of the following symptoms:

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

Healthcare professionals are advised to:

- Monitor patients regularly for pulmonary signs or symptoms indicative of Inflammatory Lung Disease (ILD) / pneumonitis. Symptoms may include hypoxia, cough, dyspnea, or interstitial infiltrates on radiologic exams in patients in whom infectious, neoplastic or other causes have been excluded.
- Interrupt Ibrance treatment immediately and evaluate patients who have new or worsening respiratory symptoms or are suspected to have developed pneumonitis
- Permanently discontinue the Ibrance in all patients with severe ILD or pneumonitis.
- Advise patients to immediately report new or worsening respiratory symptoms.
- Encourage patients to read the Patient Package Insert they receive with their Ibrance prescriptions, which explain the safety risks and provides other important information.

Meanwhile, the FDA has not received any reports of severe lung inflammation or any other adverse drug reaction associated with the use of Ibrance.

The Food and Drugs Authority will like to advice healthcare professionals to report adverse drug reactions to Ibrance and all other medicines to the FDA by completing the Adverse Reaction Reporting Form or online using the link http://adr.fdaghana.gov.gh/ or call 024 431 0297 or send an email to drug.safety@fdaghana.gov.gh or through the Med Safety Mobile App.

Yours faithfully,

Signed

SETH K. SEANEKE (MR.)
AG. DCE DRUG REGISTRATION AND INSPECTORATE DIVISION
FOR: CHIEF EXECUTIVE OFFICER