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(來函請敍明此檔案號碼) DH DO DIMC/7-30/1
(IN REPLY PLEASE QUOTE THIS FILE REF.)

28 Mar 2024

Dear Healthcare Professionals,

Ibrance (palbociclib): Assessing the potential risk of venous thromboembolism

Your attention is drawn to the Health Canada's announcement that it reviewed the potential risk of venous thromboembolism (VTE) with the use of Ibrance. The safety review was triggered by the 2020 publication of a study that found a higher risk of VTE with the use of cyclin-dependent kinase inhibitors (CDKIs), a class of drugs to which Ibrance belongs.

Venous thromboembolism, which includes deep vein thrombosis (DVT) and pulmonary embolism (PE), is a condition where a blood clot forms in a vein blocking the flow of blood through parts of the body. Deep vein thrombosis is a blood clot in a deep vein of the body, usually in the legs. A PE occurs when a DVT dislodges and travels to the lung artery, blocking blood flow and oxygen to the lungs. If not treated quickly, VTE can lead to disability and death.

At the time of the review, the Canadian Product Monograph (CPM) for the other CDKIs, Verzenio (abemaciclib) and Kisqali (ribociclib), included warnings for the risk of VTE, but not the CPM for Ibrance.

Health Canada reviewed information provided by the manufacturer and from the scientific literature. Health Canada reviewed 7 randomized controlled trials (RCTs) involving Ibrance, which included 8,793 patients. The majority (>95%) of these patients had early or metastatic breast cancer. Analysis of data across the 7 RCTs showed a higher risk of VTE with Ibrance treatment. Specifically, in the more relevant trials in metastatic breast cancer patients, VTE was reported in 3.4% of patients treated with Ibrance plus an endocrine therapy (medicine that either blocks the effects or interferes with the production of estrogen in the body), compared with 1.9% of patients treated with the endocrine therapy alone. The evidence reviewed supports a probable link between the risk of VTE and the use of Ibrance. This finding is consistent with the VTE findings for the other CDKIs marketed in Canada.

Health Canada's review of the available information concluded that there is a probable link between the use of Ibrance and the risk of VTE. Health Canada is working with the manufacturer to update the CPM for Ibrance to include the risk of VTE.

Please refer to the following website in Health Canada for details:
https://dhpp.hpfb-dgpsa.ca/review-documents/resource/SSR1707157428464

In Hong Kong, there are registered pharmaceutical products containing palbociclib (6 products), abemaciclib (3 products) and ribociclib (one product). All products are prescription-only medicines.

So far, the Department of Health (DH) has received adverse drug reaction related to palbociclib (145 cases) and ribociclib (26 cases), but these cases were not related to VTE. With regard to abemaciclib, the DH has received 17 cases of adverse drug reaction, of which one case was reported as VTE and one case was reported as PE.

Currently, the product insert of the locally registered abemaciclib-containing products include safety information about the risk of VTE. The current registered product insert of palbociclib- and ribociclib-containing products do not include the relevant information.

In light of the above Health Canada's announcement, the matter will be discussed by the Registration Committee of the Pharmacy and Poisons Board.

Please note that this letter serves as a means for the DH to communicate important new safety information about registered pharmaceutical products with healthcare professionals in Hong Kong and is not intended to serve as guidelines or to replace professional clinical judgement. Healthcare professionals are advised to balance the risk of possible adverse effects against the benefit of treatment.

Please report any adverse events caused by drugs to the Clinical Trials and Pharmacovigilance Unit of the DH (tel. no.: 2319 2920, fax: 2319 6319 or email: adr@dh.gov.hk). For details, please refer to the website at Drug Office under "ADR Reporting": http://www.drugoffice.gov.hk/adr.html. You may wish to visit the Drug Office's website for subscription and browsing of "Drug News" which is a monthly digest of drug safety news and information issued by Drug Office.

Yours faithfully,

(Terence MAN)
for Assistant Director (Drug)