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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.)

30 Oct 2024

Dear Healthcare Professionals,

Gavreto® (pralsetinib): New warning and precaution of severe and fatal infections

Your attention is drawn to the Singapore Health Sciences Authority's (HSA) announcement that a Dear Healthcare Professional Letter has been issued by Roche Singapore Pte Ltd to update healthcare professionals that severe and fatal infections, including opportunistic infections, have been reported in patients treated with Gavreto®. An ad hoc analysis of results from the ongoing phase III trial AcceleRET-Lung demonstrated an imbalance regarding the risk of severe and fatal infection, including severe opportunistic infections, between the pralsetinib and standard of care arms. Healthcare professionals are advised to monitor patients closely for signs and symptoms of infection and treat appropriately. They are also advised to withhold Gavreto® in the presence of active infection and discontinue Gavreto® permanently if infections are life-threatening.

Please refer to the following website in HSA for details:
https://www.hsa.gov.sg/announcements/dear-healthcare-professional-letter/gavreto--(pralsetinib)---new-warning-and-precaution-of-severe-and-fatal-infections

In Hong Kong, there is one registered pharmaceutical product containing pralsetinib, namely Gavreto Capsules 100mg (HK-67499). The product is registered by Cstone Pharm (HK) Holding Limited. It is a prescription-only medicine. So far, the Department of Health (DH) has received 2 cases of adverse drug reaction with regard to pralsetinib, of which one case was reported as pneumonia (lung infection). In light of the above HSA's announcement, the DH will remain vigilant on safety update of the drug issued by other overseas drug regulatory authorities.

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)