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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.)

13 Sep 2024

Dear Healthcare Professionals,

Lunsumio (mosunetuzumab): New important identified risk of Hemophagocytic Lymphohistiocytosis

Your attention is drawn to the Singapore Health Sciences Authority (HSA)'s announcement that a Dear Healthcare Professional Letter has been issued by Roche Singapore Pte Ltd to inform healthcare professionals that Hemophagocytic Lymphohistiocytosis (HLH) is a new important identified risk for LUNSUMIO.

HLH is a life-threatening syndrome, and early detection and management is essential. HLH, including immune effector cell-associated HLH-like syndrome (IEC-HS), may resemble severe cytokine release syndrome (CRS), but with clinical differences from CRS including a delayed onset, rapid increases in serum ferritin, and differences in cytokine profile.

For any case of suspected HLH, LUNSUMIO should be interrupted and treatment should be considered per current practice guidelines or ASTCT expert consensus guidelines. Consensus guidelines recommend frontline treatment with anakinra (an interleukin1 receptor antagonist), with or without corticosteroids. Expert consultation is recommended if HLH is suspected. The prescribing information of LUNSUMIO will be updated accordingly.

Please refer to the following website in HSA for details:
https://www.hsa.gov.sg/announcements/dear-healthcare-professional-letter/lunsumio-(mosunetuzumab)--new-important-identified-risk-of-hemophagocytic-lymphohistiocytosis

In Hong Kong there are 2 registered pharmaceutical products containing mosunetuzumab. All products are prescription-only medicines. So far, the Department of Health (DH) has not received any

case of adverse drug reaction with regard to mosunetuzumab. In light of the above HSA'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,

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(Terence MAN)
for Assistant Director (Drug)