衞生署藥物辦公室
藥物註冊及進出口管制部
香港九龍南昌街 382 號公共衞生檢測中心三樓
電話號碼 Tel. No.: 2319 8458
詢問處 Enquiries (852) 2319 8458
傳真號碼 Faxline No. (852) 2803 4962
本署檔號 OUR REF.: DH DO PRIE/7-30/15
(來函請緊明此檔案號碼)
(IN REPLY PLEASE QUOTE THIS FILE REF.)

DEPARTMENT OF HEALTH
DRUG OFFICE
DRUG REGISTRATION AND
IMPORT/EXPORT CONTROL DIVISION
3/F., Public Health Laboratory Centre,
382 Nam Cheong Street, Kowloon, Hong Kong
BY FAX

16 April 2013

Dr. Donald LI
President
Hong Kong Academy of Medicine
(Fax Number: 2505 5577)

Dear Dr. LI,

TASIGNA (nilotinib) - Possible Risk of Developing Atherosclerosis-Related Conditions

Your attention is drawn to the announcement of Health Canada on an important information regarding reports of atherosclerosis-related diseases in patients treated with TASIGNA (nilotinib). TASIGNA belongs to the pharmacological class of protein-tyrosine kinase inhibitors and is indicated for the treatment of Philadelphia chromosome positive chronic myeloid leukemia (Ph+CML) in adults.

Cases of atherosclerosis-related diseases had been reported during clinical trials and post marketing experience with the use of TASIGNA. In a Phase III study (A2303) in newly diagnosed Ph+ CML patients, atherosclerosis-related diseases such as peripheral arterial occlusive disease, femoral artery stenosis, coronary artery stenosis, carotid artery stenosis, and cerebrovascular accident were reported in patients taking TASIGNA (5.0% for TASIGNA 300 mg BID and 6.1% for TASIGNA 400 mg BID). Most of the patients had pre-existing documented cardiovascular disease or risk factors for atherosclerotic-related disease. Of the 369 patients treated with TASIGNA, who had no documented pre-existing risk factors for cardiovascular disease, 7 patients (2%) experienced atherosclerotic-related events. Since it was not known whether TASIGNA caused or exacerbated these conditions, patients should be monitored during treatment with TASIGNA for signs of atherosclerotic-related conditions. Administer with caution in patients with pre-existing risk factors for atherosclerosis was recommended. A review of the Novartis global safety database search (between January 1st, 2005 and January 31, 2013) identified a total of 277 cases of atherosclerosis, of which 14 were Canadian cases. The cumulative patient exposure since the first launch of TASIGNA in 2007 is estimated to be approximately 39,299 patient-years.

The Canadian Product Monograph for TASIGNA (nilotinib) had been revised to include the new safety information and recommendation for monitoring for signs of atherosclerotic-related conditions. Health care professionals were recommended to follow current clinical guidelines for the diagnosis and management of patients with signs and symptoms of events due to atherosclerosis.

Please refer to Health Canada's website for details:

http://healthycanadians.gc.ca/recall-alert-rappel-avis/hc-sc/2013/26651a-eng.php

In Hong Kong, there are 2 registered pharmaceutical products containing nilotinib, namely Tasigna Cap 200mg (HK-56797) and Tasigna Cap 150mg (HK-60833). Both products are registered by Novartis for the treatment of Philadelphia chromosome positive chronic myeloid leukaemia and are prescription only medicines. Novartis has informed the Department of Health (DH) that they will submit application for approval to change the package inserts to include the relevant safety information. The DH will keep vigilance against any safety updates of the drugs released by other regulatory authorities.

Please encourage your members to report any adverse events caused by the drugs to the Pharmacovigilance Unit of Department of Health (tel. no.: 2319 2920, fax: 2186 9845 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 drug safety digest of drug safety news and information issued by Drug Office.

Yours sincerely,

(Ms. Pamela Li)

for Assistant Director (Drug)