PUBLIC COMMUNICATION
Health Canada Endorsed Important Safety Information on
PrTASIGNA* (nilotinib)

April 12, 2013

Subject: **Updated information regarding the possible risk of developing atherosclerosis-related conditions with the use of TASIGNA* (nilotinib)**

Novartis Pharmaceuticals Canada, Inc. (Novartis), in collaboration with Health Canada, would like to inform you about important safety information regarding reports of atherosclerosis-related conditions in patients treated with TASIGNA* (nilotinib).

TASIGNA* is a prescription medicine used to treat adult patients at different stages of a type of leukemia called Philadelphia chromosome positive chronic myeloid leukemia (Ph+CML).

- Cases of atherosclerosis-related conditions have been reported during clinical trials and post marketing experience with the use of TASIGNA*.
- Patients should tell their healthcare professional if they have or have had any conditions that could cause atherosclerosis-related conditions such as a heart problem, high blood pressure, high cholesterol, or high glucose before starting TASIGNA* treatment.
- During treatment with TASIGNA*, healthcare professionals will check for signs of atherosclerosis. Healthcare professional will also check cholesterol and blood sugar levels before starting treatment and periodically thereafter.
- Patients should not stop treatment with TASIGNA* or change the dosage without discussing their condition with their healthcare professional.

Atherosclerosis is a disease that occurs in arterial blood vessels (arteries) and occurs more frequently in older adults. In atherosclerosis the walls of the arteries become thickened and hardened by plaque buildup. Plaque is made from fatty deposits and cells that can build up in the walls of your arteries over many years. As plaque builds up, the arteries narrow and become less flexible and the blood flow through the arteries can be reduced. Possible complications of atherosclerosis include heart attacks and strokes.

In patients taking TASIGNA*, the following side effects related to atherosclerosis have been reported during clinical trials: peripheral arterial occlusive disease (hardening and narrowing of the arteries that supply blood to the arms and legs), femoral artery stenosis (hardening and narrowing of the arteries located in the upper thigh), coronary artery stenosis (narrowing or hardening of the arteries supplying the heart that causes angina (chest pain)), carotid artery stenosis (narrowing or hardening of the carotid artery in the neck), and cerebrovascular accident (stroke). 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.

Novartis Canada has worked with Health Canada to include the new safety information for TASIGNA* (nilotinib) regarding atherosclerosis-related conditions into the Canadian Product Monograph (CPM), the reference document that healthcare professionals use when prescribing a drug, and the Consumer Information Leaflet (CIL).These documents can be found at www.novartis.ca or by contacting Novartis Canada, at 1-800-363-8883 or on the Health Canada website.

Managing marketed health product-related adverse reactions depends on health care professionals and consumers reporting them. Reporting rates determined on the basis of spontaneously reported post-marketing adverse reactions are generally presumed to underestimate the risks associated with health product treatments. Any case of atherosclerosis or other serious or unexpected adverse reactions in patients receiving TASIGNA* should be reported to Novartis or Health Canada at the following addresses:

Novartis Pharmaceuticals Canada Inc.
385 Bouchard Blvd.
Dorval, (QC) H9S 1A9
Phone: 1-800-363-8883 (Medical Information)

You can report any suspected side effect associated with the use of health products to Health Canada by:

- Calling toll-free at 1-866-234-2345; or
- Visiting MedEffect Canada's Web page on Adverse Reaction Reporting (http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/index-eng.php) for information on how to report online, by mail or by fax

For other health product inquiries related to this communication, please contact Health Canada at:
Marketed Health Products Directorate
E-mail: mhpd_dpsc@hc-sc.gc.ca
Telephone: 613-954-6522
Fax: 613-952-7738

Novartis will continue to monitor the side effects related to atherosclerosis and appreciates your help in ensuring the continued reporting of this and any potential side effects.

Should you have any questions or require additional information regarding the use of TASIGNA*, please contact Novartis Pharmaceuticals Canada Inc., Medical Information Department at 1-800-363-8883.

Sincerely,

Jean Godin, M.D.
Chief Scientific Officer and Vice-President Clinical and Regulatory Affairs

*TASIGNA is a registered trademark