Health Canada Endorsed Important Safety Information on VECTIBIX® (panitumumab)

27 May 2014

Dear Healthcare Professional:

Subject: Rare cases of Stevens-Johnson syndrome and Toxic Epidermal Necrolysis have been reported in patients treated with VECTIBIX® (panitumumab)

Amgen Canada Inc., in consultation with Health Canada, would like to inform you of important updates to safety information regarding the risk of Stevens-Johnson syndrome (SJS) and Toxic Epidermal Necrolysis (TEN) associated with the use of VECTIBIX®.

VECTIBIX is indicated as monotherapy for the treatment of patients with epidermal growth factor receptor (EGFR)-expressing metastatic colorectal carcinoma with non-mutated (wild-type) *KRAS* after failure of fluoropyrimidine-, oxaliplatin-, and irinotecan-containing chemotherapy regimens. VECTIBIX has been issued a marketing authorization with conditions (NOC/c), pending the results of studies to verify its clinical benefit.

- Cases of Stevens-Johnson syndrome (SJS) and Toxic Epidermal Necrolysis (TEN) have been reported rarely (≥1/10,000 patients and <1/1000 patients) in the post-market setting, in patients receiving VECTIBIX.
- The Product Monograph of VECTIBIX is being updated to include the risk of SJS and TEN.
- In case of the occurrence of SJS or TEN, VECTIBIX treatment should be discontinued.

Monitor for dermatologic and soft tissue signs or symptoms and consider withholding or discontinuing VECTIBIX in patients with severe or life-threatening and inflammatory or infectious complications.

Events such as skin exfoliation, exfoliative rash, erythema, skin necrosis and mucosal events such as stomatitis and mucosal inflammation have previously been reported with the administration of VECTIBIX. Serious complications that have been observed include events of cellulitis, necrotizing fasciitis (some with a fatal outcome), and other soft tissue complications.

A copy of this letter and the Canadian Product Monograph can be accessed at the Health Canada website (http://www.hc-sc.gc.ca/dhp-mps/medeff/advisories-avis/index-eng.php). This information is also available at www.amgen.ca.

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 SJS or TEN, or other serious or unexpected adverse reactions, in patients receiving VECTIBIX should be reported to Amgen Canada Inc. or Health Canada.

Amgen Canada Inc.
6775 Financial Drive, Suite 100
Mississauga, Ontario L5N 0A4
Safety Tel: 1-866-512-6436 or Fax: 1-888-264-3655
Safety e-mail: safetycanada@amgen.com

To correct your mailing address or fax number, contact Amgen Canada Inc.

You can report any suspected adverse reactions 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, contact Health Canada at:
Marketed Health Products Directorate
E-mail: mhpd_dpsc.public@hc-sc.gc.ca
Telephone: 613-954-6522
Fax: 613-952-7738

Sincerely,

Clive Ward-Able, MD
Executive Medical Director
Amgen Canada Inc.