Public Communication -
Health Canada Endorsed Important Safety Information on Neupogen® and Neulasta®

April 10, 2014

Subject: Neupogen® (filgrastim) and Neulasta® (pegfilgrastim) are associated with a risk of Capillary Leak Syndrome

Amgen Canada Inc., in consultation with Health Canada, would like to inform you of new important safety information concerning the risk of a condition called Capillary Leak Syndrome (CLS) associated with the granulocyte colony stimulating factors (G-CSF) NEUPOGEN and NEULASTA.

- Cases of Capillary Leak Syndrome (CLS), which causes blood to leak from the small blood vessels into your body, have been reported in:
  - patients undergoing chemotherapy who were receiving NEUPOGEN or NEULASTA, and
  - donors undergoing peripheral blood progenitor cell mobilization who were receiving NEUPOGEN.
- Symptoms of CLS include swelling or puffiness, which may be associated with passing water less frequently, difficulty breathing, abdominal swelling and feeling of fullness, and a general feeling of tiredness. These symptoms generally develop in a rapid fashion. Episodes vary in severity and frequency and may be fatal.
- Please tell your doctor immediately if you have any of the side effects described above. These could be symptoms of CLS and may need urgent medical attention.

NEUPOGEN and NEULASTA are used to treat neutropenia, a condition where the body makes too few neutrophils. Neutropenia predisposes your body to infections and prevents you from fighting them. Neutropenia may be a long-standing condition or it may be caused by drugs used to treat cancer. Neutropenia is the most serious common side-effect of chemotherapy.

Amgen Canada has worked with Health Canada to update the safety information in the Product Monograph for NEUPOGEN AND NEULASTA and has sent a letter to health care professionals to inform them of this new important safety information. A copy of this letter is available on the Health Canada website (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 side effects depends on health care professionals and consumers reporting them. Reporting rates determined on the basis of spontaneously reported post-marketing side effects are generally presumed to underestimate the risks associated with health product treatments. Any case of serious Capillary Leak Syndrome or other serious or unexpected side effects in patients receiving NEUPOGEN or NEULASTA should be reported to Amgen Canada Inc. or Health Canada.

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Safety e-mail: safetycanada@amgen.com

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

You can report any suspected side effects 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
E-mail: MHPD_DPSC@hc-sc.gc.ca
Telephone: 613-954-6522
Fax: 613-952-7738

Sincerely,

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