PUBLIC COMMUNICATION
Health Canada Endorsed Important Safety Information on AVASTIN® (bevacizumab)

August 23, 2010

Subject: Association of AVASTIN® (bevacizumab) with Allergic Reactions

Hoffmann-La Roche Limited (Roche), in consultation with Health Canada, has informed Canadian healthcare providers of important new safety information concerning the association of AVASTIN with allergic reactions.

AVASTIN is authorized, in combination with other cancer drugs, for the treatment of people diagnosed with:

- colon and rectal cancer that has spread to other parts of the body,
- lung cancer that has spread to other parts of the body, and
- breast cancer that has spread to other parts of the body (this use has conditions required by Health Canada).

AVASTIN, as a single agent, is authorized for the treatment of a particular type of brain cancer called glioblastoma (this use has conditions required by Health Canada).

- Serious allergic reactions have been reported in patients receiving AVASTIN therapy.
- Patients taking AVASTIN who have any of the following signs and symptoms should contact their doctor immediately:
  - Difficulty breathing,
  - Redness or flushing of the skin (such as a rash),
  - Low or high blood pressure,
  - Shivering,
  - Chest pain,
  - Nausea/vomiting.
- In the event of an allergic reaction, AVASTIN treatment should be interrupted and appropriate medical treatment administered.

AVASTIN has been given to over 500,000 patients for cancer worldwide. A review of available safety information found that serious allergic reactions have been reported in up to 5% of patients from clinical studies for cancer. In addition, cases of allergic reactions have been reported from post-market use. Healthcare providers should decide on a case-by-case basis whether the use of medications to prevent such reactions before administration of AVASTIN is warranted.

The Canadian Product Monograph (the Prescribing Information) for AVASTIN has been updated to include this new safety information.

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 serious or unexpected adverse reactions in patients receiving AVASTIN should be reported to Hoffmann-La Roche Limited or Health Canada at the following addresses:

Hoffmann-La Roche Limited
Drug Safety Department
2455 Meadowpine Boulevard
Mississauga, Ontario, L5N 6L7
or call toll free at: 1-888-762-4388
or fax at: 905-542-5864
or email to: mississauga.drug_safety@roche.com

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:
•Report online at www.healthcanada.gc.ca/medeffect
•Call toll-free at 1-866-234-2345
•Complete a Reporting Form and:
- ◦ Fax toll-free to 1-866-678-6789, or
- ◦ Mail to: Canada Vigilance Program
  Health Canada
  Postal Locator 0701E
  Ottawa, Ontario K1A 0K9

The Reporting Forms, postage paid labels, and Guidelines can be found on the MedEffect™ Canada Web site in the Adverse Reaction Reporting section (http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/index-eng.php).

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

Should you have any questions or require additional information regarding the use of AVASTIN, please contact the Drug Information Department at Hoffmann-La Roche Limited at 1-888-762-4388, Monday to Friday, between 8:30 a.m. and 4:30 p.m. (Eastern Standard Time).

Sincerely,

original signed by

Lorenzo Biondi,
Vice President, Medical and Regulatory Affairs
Hoffmann-La Roche Limited