PUBLIC COMMUNICATION
Health Canada Endorsed Important Safety Information on
[RAPTIVA® (efalizumab)]

February 20, 2009

Subject: Communication on the decision to suspend Raptiva® in Canada

EMD Serono Canada Inc., in consultation with Health Canada, has informed Canadian healthcare professionals of important new safety information concerning RAPTIVA (efalizumab).

This Communication is to inform you about the Health Canada recommendation for EMD Serono Canada Inc. to suspend the availability of RAPTIVA in Canada.

RAPTIVA was authorized in October 2005 for the treatment of moderate to severe chronic plaque psoriasis in adult patients (18 years or older) who are candidates for systemic therapy or phototherapy.

Summary:

- In Europe, the European Medicines Agency (EMEA) has determined that the benefits of RAPTIVA no longer outweigh its risks because of **safety concerns including the occurrence of Progressive Multifocal Leukoencephalopathy (PML) in patients taking this medication.**

- In addition to PML, RAPTIVA is associated with other serious infections occurring in people with weakened immune systems

- As a result of these safety concerns, and in keeping with the measures taken by the European Medicines Agency, EMD Serono Canada Inc., the company that markets RAPTIVA in Canada, in consultation with Health Canada, will suspend the marketing of RAPTIVA. Although many patients may have benefited or are still benefiting from treatment with RAPTIVA, this action is necessary to ensure patient safety. Within a few months from now Raptiva will no longer be available in Canada.

You should consult your physician as soon as possible to assess the most appropriate treatment alternative based on your individual medical situation and need. Do not change or stop your treatment without first consulting your doctor. Abrupt discontinuation of RAPTIVA without alternative treatment may be followed by a return of psoriasis or onset of new psoriasis.

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 occurrence of serious and/or unexpected adverse reactions in patients receiving RAPTIVA should be reported to EMD Serono Canada Inc., or Health Canada at the following addresses:

EMD Serono Canada Inc.
2695 North Sheridan Way, Suite 200
Mississauga ON L5K 2N6
Tel: 1 888 737 6668 ×5160
Fax: 905 919 0292
E-mail: drugsafetycanada@merckserono.net

Any suspected adverse reaction can also be reported to:
Canada Vigilance Program
Marketed Health Products Directorate
HEALTH CANADA
Address Locator: 0701C
Ottawa, Ontario, K1A 0K9
Tel: 613-957-0337 or Fax: 613-957-0335
To report an Adverse Reaction, consumers and health professionals may call toll free:
Tel: 866-234-2345
Fax: 866-678-6789
CanadaVigilance@hc-sc.gc.ca

The AR Reporting Form and the AR Guidelines can be found on the Health Canada web site or in *The Canadian Compendium of Pharmaceuticals and Specialties*.

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 regarding the use of RAPTIVA, please call EMD Serono Canada Inc.'s Patient Services at 1-866-440-4245.

Original signed by

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