HEALTHCARE PROFESSIONAL COMMUNICATION
Health Canada Recommendation to Suspend RAPTIVA® (efalizumab) in Canada

February 20, 2009

Dear Health Care Professional,

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

EMD Serono Canada Inc., in consultation with Health Canada, has urgent new safety information concerning RAPTIVA (efalizumab).

RAPTIVA is an immunomodulating, humanized monoclonal antibody which was authorized in Canada in 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.

- In consultation with Health Canada, EMD Serono Canada Inc., the company that markets RAPTIVA in Canada will suspend RAPTIVA from the Canadian marketplace due to safety concerns. Although many patients may have benefited or are still benefiting from treatment with RAPTIVA, this action is necessary to ensure patient safety is paramount. Within a few months from now the product will no longer be available on the Canadian market.

- A benefit/risk analysis conducted in Europe by the European Medicines Agency (EMEA) has determined that the benefit/risk in the approved indication for RAPTIVA **has become unfavourable following safety concerns.**

- Three virologically confirmed cases and one suspected case of progressive multifocal leukoencephalopathy (PML) have been reported in patients with chronic plaque psoriasis who had been continuously treated with RAPTIVA for three or more years. In addition to PML RAPTIVA is associated with other serious side effects including Guillain-Barré and Miller-Fisher syndromes, encephalitis, encephalopathy, meningitis, sepsis and opportunistic infections. As a result, the EMEA has determined that the benefits of RAPTIVA no longer outweigh its risks **and has recommended suspension of marketing authorization of RAPTIVA in Europe.** EMD Serono Canada Inc. will suspend RAPTIVA from the Canadian marketplace.

- **Prescribers in Canada are advised not to issue any new prescriptions for RAPTIVA and should review the treatment of patients currently taking this medicine to assess the most appropriate alternatives as soon as possible.**

- Abrupt discontinuation of RAPTIVA without substitution treatment may be followed by recurrence of psoriasis or emergence of new psoriasis morphologies, including erythrodermic and pustular psoriasis. Management of patients discontinuing RAPTIVA should include close observation. In case of disease recurrence, the treating physician should institute the most appropriate psoriasis treatment as necessary.

- Management of patients discontinuing RAPTIVA includes close observation for neurological symptoms and symptoms of infection. The effects on the immune system last for about eight to twelve weeks.

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 the EMD Serono Medical Information/Drug Safety Department at 1-888-737-6668 ×5160.

original signed by

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EMD Serono Canada Inc.