PUBLIC COMMUNICATION
Important Safety Information on PrEXJADE* (deferasirox)

NOVARTIS

March 9, 2007

SUBJECT: **Severe kidney problems associated with EXJADE* (deferasirox)**
Reports of low blood cell counts *(*cytopenias) with EXJADE* (deferasirox)

Following discussions with Health Canada, Novartis wishes to provide you with updated safety information regarding reports of severe kidney problems and cytopenias (low blood cell counts) with EXJADE*.

EXJADE* is used to treat chronic iron overload caused by blood transfusions for the treatment of anemias for adults, adolescents, and children aged 6 years and over; and in children aged 2 to 5 years who cannot be adequately treated with deferoxamine.

Therapy with EXJADE* should be initiated and maintained by physicians experienced in the treatment of chronic iron overload due to blood transfusions.

- Cases of severe kidney problems (some with fatal outcome) have been reported following the post-marketing use (commercial use) of EXJADE*. For the reports in which the outcome for these critically ill patients was fatal, the involvement of EXJADE* with the kidney problems cannot be excluded, although the fatalities could have been caused by underlying diseases. When EXJADE* was discontinued in the non-fatal cases, the kidney problems improved, which indicates an involvement of EXJADE*.

- Your kidney function (serum creatinine) should be monitored twice before you start taking EXJADE*. Weekly monitoring will then be done for the first month of treatment, or after a change of treatment, and monitored monthly thereafter. A second test for kidney function (proteinuria) will also be performed monthly. You and your doctor should also ensure that you are well hydrated (drink lots of fluid). Tell your doctor if you produce less urine than usual.

- Some patients have developed blood cell counts that are too low (cytopenias) while on EXJADE* therapy. Most of these patients already had diseases that lead to their low blood cell counts, so the relationship to EXJADE* treatment is uncertain. If you have a disease that might result in abnormal blood cell counts, your doctor should continue routine monitoring of your blood cell counts.

A copy of the Health Care Professional letter and this communication are available on the Health Canada website (http://www.hc-sc.gc.ca/dhp-mps/medeff/advisories-avis/prof/2006/index_e.html).

If you have any questions about the above information or about EXJADE* please talk to your doctor, pharmacist, or contact Novartis Pharmaceuticals Canada Inc. at : 1-800-363-8883.

For more information on EXJADE* please consult the Consumer Information document available at www.novartis.ca.

Managing marketed health product-related adverse reactions depends on health care professionals and consumers reporting them, in addition to reports collected from clinical trials. Reporting rates determined on the basis of spontaneously reported post-marketing adverse reactions are generally presumed to underestimate the risks associated with health products. If you have had a serious or unexpected reaction to EXJADE* you may notify either Novartis Pharmaceuticals Canada Inc. or Health Canada as follows:

Novartis Pharmaceuticals Canada Inc.
385 Bouchard Blvd.
Dorval, (QC) H9S 1A9
Phone:1-800-363-8883

Any suspected adverse reaction can also be reported to:
Canadian Adverse Drug Reaction Monitoring Program (CADRMP)
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 (AR), consumers and health professionals may call toll free:
Tel: 866 234-2345 or Fax: 866 678-6789
cadrmp@hc-sc.gc.ca

The AR Reporting Form (http://www.hc-sc.gc.ca/hpfb-dgpsa/tpd-dpt/adverse_e.html) and the AR Guidelines (http://www.hc-sc.gc.ca/hpfb-dgpsa/tpd-dpt/adr_guideline_e.html) can be found on the Therapeutic Products Directorate web site or in The Canadian Compendium of Pharmaceuticals and Specialties.

For media inquiries please contact Jason Jacobs at (514) 633-7872.

Sincerely,

original signed by

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* EXJADE is a registered trademark.