PUBLIC COMMUNICATION
Health Canada Endorsed Important Safety Information on ACLASTA* (zoledronic acid)

NOVARTIS

October 14, 2010

Subject: **Association of ACLASTA* (zoledronic acid 5 mg/100 mL) solution for intravenous infusion with kidney dysfunction.**

Novartis Pharmaceuticals Canada Inc. ("Novartis"), in collaboration with Health Canada, would like to remind patients of important safety information on kidney dysfunction based on post-marketing experience with ACLASTA*.

The Canadian prescribing information for ACLASTA* is being revised to further emphasize the following safety information:

- ACLASTA* has been associated with kidney dysfunction manifested as worsening of kidney function, and in rare cases, acute kidney failure.
- Kidney impairment has been observed following the administration of ACLASTA*, occasionally after a single administration.
- Kidney failure requiring dialysis or with a fatal outcome has occurred especially in patients with history of kidney impairment or other risk factors. Risk factors include advanced age, some concomitant medicinal products (e.g. any medicines known to be harmful to the kidneys) or dehydration occurring after ACLASTA* administration.

As per the current prescribing and consumer information for ACLASTA*, please note the following important considerations to minimize the risk of renal adverse events:

- Before you take ACLASTA* talk to your doctor or pharmacist if you have, or used to have, a kidney problem.
- Tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including any you have bought without a prescription. It is especially important for your doctor to know if you are taking any medicines known to be potentially harmful to the kidneys (such as nonsteroidal anti-inflammatory drugs (NSAIDs)).
- Make sure that you drink a sufficient amount of water (at least two glasses or 500 mL) before and after your treatment with ACLASTA*.
- ACLASTA*'s infusion should take a minimum of 15 minutes.

Novartis has also sent a letter [novartis.ca] to healthcare professionals to inform them of this new safety information. A copy of that letter is available on the Health Canada website.

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 overdose symptoms or other serious or unexpected adverse reactions in patients receiving ACLASTA* should be reported to Novartis Pharmaceuticals Canada Inc. or Health Canada at the following addresses:

Novartis Pharmaceuticals Canada Inc.
385 Bouchard blvd,
Dorval, Quebec, H9S 1A9
Phone: 1-800-363-8883 (Medical Information)

Any suspected adverse reaction can also be reported to:
Canada Vigilance Program
Marketed Health Products Directorate
HEALTH CANADA
Address Locator: 0701E
Ottawa, Ontario, K1A 0K9
Telephone: 613-957-0337 or Fax: 613-957-0335
CanadaVigilance@hc-sc.gc.ca

To report an Adverse Reaction, consumers and health professionals may call toll free:
Telephone: 1-866-234-2345
Fax: 1-866-678-6789

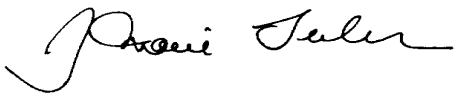
Postage paid labels, the Canada Vigilance Reporting Forms and the Adverse Reaction Reporting Guidelines can be found on the MedEffect™ Canada Web site in the Adverse Reaction Reporting section. The Reporting Form is also in the *Canadian Compendium of Pharmaceuticals and Specialties.*

http://hc-sc.gc.ca/dhp-mps/medeff/report-declaration/index-eng.php

For other health product 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 ACLASTA* (zoledronic acid), please contact Novartis Pharmaceuticals Canada Inc., Medical Information Department at 1-800-363-8883.

Sincerely,



Jean-Marie Leclerc, M.D. FRCP(C)
Chief Scientific Officer and Senior Vice-President Clinical and Regulatory Affairs

*ACLASTA is a registered trademark

References:
ACLASTA* is approved for the treatment and prevention of osteoporosis in postmenopausal women, to increase bone mass in men with osteoporosis, for treatment and prevention of glucocorticoid-induced osteoporosis and for the treatment of Paget's disease of bone.