

PUBLIC COMMUNICATION

**Health Canada Endorsed Important Safety Information on
Gamunex[®] (Immune Globulin Intravenous [Human], 10%)**

October 19, 2005

Subject: Association of Gamunex[®] (Immune Globulin Intravenous [Human], 10%) with Hemolytic Reactions

Talecris Biotherapeutics, Inc., in collaboration with Health Canada, is informing healthcare professionals in Canadian hospitals of important new safety information concerning Gamunex[®] (Immune Globulin Intravenous [Human], 10%).

Gamunex[®] belongs to a group of biological medicines derived from human plasma known as IGIV products that treat patients with a compromised immune system or idiopathic thrombocytopenic purpura (ITP). It is administered in hospitals by infusion through the veins.

- **Hemolytic reactions (reactions which involve the breakdown of some red blood cells) have been reported rarely in patients receiving IGIV products.**
- **Cases have now been reported following the use of Gamunex[®].**

Symptoms of hemolytic reactions can vary depending on their severity but may include generalized weakness, lightheadedness and pale complexion and sometimes dark urine and jaundice. Should a patient be experiencing any of these symptoms following treatment with an IGIV product, consult your specialist to confirm the diagnosis and determine if any treatment is necessary.

Any suspected adverse reaction can also be reported to:

Drug Safety and Medical Information
Bayer Inc.
77 Belfield Rd.
Toronto, ON M9W 1G6
Tel: 1-800-265-7382
Fax: 1-866-232-0565

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, consumers and health professionals may call toll free:

Tel: 866-234-2345

Fax: 866-678-6789

cadrmpp@hc-sc.gc.ca

Should you have any questions or require additional information regarding Gamunex[®], please contact your health care provider or Bayer Medical Information at 1-800-265-7382.