Important Safety Information on BLINCYTO™ (blinatumomab) and Pancreatitis

2016/07/13

Audience
Healthcare professionals working in the following settings: Hematology, Medical Oncology, and Oncology Pharmacy

Key Messages

- **There have been reported cases of life-threatening, sometimes fatal pancreatitis associated with the use of BLINCYTO (blinatumomab).**
- **The diagnosis of pancreatitis should be considered in patients taking BLINCYTO who experience severe upper abdominal pain accompanied with nausea, vomiting or abdominal tenderness.**
- **If pancreatitis is suspected, BLINCYTO should be either temporarily interrupted or discontinued.**
- **The Canadian Product Monograph has been updated to reflect this new safety information.**

What is the issue?
There have been reported cases of life-threatening, sometimes fatal pancreatitis associated with the use of BLINCYTO (blinatumomab) in clinical trial and post-market settings.

Products affected
BLINCYTO (blinatumomab) for injection

Background information
BLINCYTO is indicated for the treatment of adults with Philadelphia chromosome-negative relapsed or refractory B precursor acute lymphoblastic leukemia (ALL).

In clinical trials, 6 cases suggestive of pancreatitis were reported in patients receiving BLINCYTO. Of these, one case of pancreatitis was serious. It occurred in a patient who had elevations of lipase and total bilirubin before starting treatment with BLINCYTO; the pancreatitis did not resolve with the discontinuation of BLINCYTO. Two remaining cases described increases in pancreatic enzymes (such as increased lipase) with associated symptoms. The three other remaining cases were reported as non-serious pancreatitis.

Globally in the post-market setting, 4 cases of pancreatitis have been reported in patients receiving BLINCYTO. Of these, one case of necrotizing pancreatitis, with a

fatal outcome, was reported in a patient receiving dexamethasone and prior treatment with multiple chemotherapy regimens. In this patient, increases in lipase levels coincided with the dexamethasone dosing during the administration of BLINCYTO; the patient's course was complicated by colitis and sepsis. In one of the cases, the symptoms of pancreatitis subsided upon temporary withdrawal of BLINCYTO and recurred after resuming treatment (positive dechallenge/positive rechallenge). The remaining cases described 1 patient with an event of pancreatitis in the context of leukemic infiltration; and 1 patient with an event of acute pancreatitis in the setting of concurrent appendicitis.

Advice for consumers
BLINCYTO is a prescription medicine used to treat a type of blood cancer called acute lymphoblastic leukemia, also known as ALL. It is used when the cancer has come back after a previous treatment or if there was no response to the first treatment.

Patients should tell their doctor, nurse, or pharmacist immediately if they have stomach pain, with or without nausea and vomiting, as these may be symptoms of a serious and potentially fatal condition known as pancreatitis (inflammation of the pancreas).

Information for health care professionals
If pancreatitis is suspected, BLINCYTO should be temporarily interrupted or discontinued.

For the complete prescribing information and information available for the patients/caregivers please consult the BLINCYTO Product Monograph. The Product Monograph can be found at: www.amgen.ca or www.hc-sc.gc.ca/dhp-mps/prodpharma/databasdon/index-eng.php.

Action taken by Health Canada
Health Canada, in collaboration with Amgen Canada Inc., has updated the Canadian Product Monograph (CPM) for BLINCYTO. Health Canada is communicating this important safety information to health care professionals and to the public through its Healthy Canadians Web site and MedEffect™ e-Notice.

Report health or safety concerns
Managing marketed health product-related side effects depends on health care professionals and consumers reporting them. Any case of pancreatitis or other serious or unexpected side effects in patients receiving BLINCYTO should be reported to Amgen Canada Inc. or Health Canada.

Amgen Canada Inc.
6775 Financial Drive, Suite 100
Mississauga, Ontario L5N 0A4
Safety Tel: 1-866-512-6436 or Fax: 1-888-264-3655
Safety e-mail: safetycanada@amgen.com

You can report any suspected adverse reactions associated with the use of health products to Health Canada by:

- Calling toll-free at 1-866-234-2345; or
- Visiting MedEffect Canada's Web page on Adverse Reaction Reporting (http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/index-eng.php) for information on how to report online, by mail or by fax.

For other health product inquiries related to this communication, contact Health Canada at:

Marketed Health Products Directorate
E-mail: mailto:mhpd_dpsc.public@hc-sc.gc.ca
Telephone: 613-954-6522
Fax: 613-952-7738

Sincerely,

Clive Ward-Able, MD
Executive Medical Director
AMGEN Canada Inc.