LUNDBECK CANADA LAUNCHES A NEW TREATMENT FOR A RARE FORM OF ACUTE LEUKEMIA:
ACUTE PROMYELOCYTIC LEUKEMIA

Trisenox® is now available in Canada

Montreal, Quebec -- November 13, 2013 – Health Canada has recently approved Trisenox® (arsenic trioxide) for relapsed or refractory acute promyelocytic leukemia (APL). This was made possible by a decision from Health Canada’s Therapeutic Products Directorate to remove a prior regulatory prohibition on arsenic containing drug therapies for use in humans and by granting priority review. Trisenox® has been available since 2000 for the treatment of relapse or refractory APL in over 40 countries.

APL is a cancer of the white blood cells characterized by a rapid accumulation of abnormal white blood cells in the bone marrow and blood, resulting in anemia, susceptibility to infections, bleeding, and hemorrhage. APL is a distinct subtype of acute myeloid leukemia (AML) potentially life threatening, characterized by abnormal promyelocytes and t(15;17) chromosomal translocation in the vast majority of cases. APL is a rare disease and affects approximately 10-15% of AML patients.iii

In Canada, there are approximately 100 to 150 newly diagnosed APL patients each year, with only 20 to 30 who relapse or become refractory to treatment per year.iii The median age for diagnosis is 40 years (versus 70 years for other types of AML) and may include paediatric patients.

“Trisenox® is the only chemo-free targeted therapy that provides an opportunity to cure acute promyelocytic leukemia (APL) patients,” says Dr. Andre Schuh, Head of Leukemia Service, Princess Margaret Hospital, University Health Network, Toronto. “The approval of Trisenox is an important milestone for the treatment of APL patients.”

“The approval of new, highly effective treatments brings hope for the thousands of Canadians living with one of the many types of blood cancers and disorders,” said Lorna Warwick, Senior National Director of Mission Programs, The Leukemia and Lymphoma Society Canada. “We encourage every provincial health authority to ensure that all refractory or relapse APL patients can have access to life saving therapies like Trisenox® when they need them.”

NEW Health Canada Change to Food and Drug Act: Allow Use of Arsenic in Humans
On May 31st, 2013, Health Canada amended the Food and Drug Act to allow the use of arsenic trioxide as a medicinal ingredient in humans. This practice changing decision came about after arsenic trioxide was reviewed by Health Canada’s Drug Status Scheduling Committee (DSSC) against a set of established and publicly available factors that include, but are not limited to, toxicity, pharmacological properties and therapeutic uses.
ABOUT TRISENOX®
Approved Indication
TRISENOX® (arsenic trioxide) is indicated for induction of remission and consolidation in patients with acute promyelocytic leukemia (APL), which is refractory to or has relapsed from retinoid and anthracycline therapy, and whose APL is characterized by the presence of the t(15;17) translocation or promyelocytic leukemia-retinoic-acid-receptor alpha (PML-RARα) gene expression.

Important Safety Information
Trisenox® has serious warning and precautions.

APL Differentiation Syndrome: Some patients with APL treated with TRISENOX® have experienced symptoms similar to a syndrome called the retinoic acid-APL syndrome or APL differentiation syndrome.

Acute Cardiac Toxicities (Rhythm Disturbance): Arsenic trioxide can cause QT prolongation and complete atrioventricular block. QT prolongation can lead to torsade de pointes, a polymorphic ventricular tachyarrhythmia, which can be fatal.

TRISENOX® should be administered under the supervision of a physician who is experienced in the management of patients with acute leukemia.

For more information, please refer to the complete product monograph.

Lundbeck Canada in Oncology
“I am very pleased that we are able to make Trisenox® available to Canadians living with refractory or relapsed APL,” said Patrick Cashman, President and CEO of Lundbeck Canada. “With a growing hematology-oncology portfolio, Lundbeck Canada is a patient-centric company that strives to give hope, strength and humanity to Canadian cancer patients.”

Montreal-based Lundbeck Canada is a subsidiary of H. Lundbeck A/S, a leading international research-based pharmaceutical company. Lundbeck has built its reputation as a leader in specialty treatments. For decades, we’ve concentrated our expertise on helping people everywhere fight CNS disorders such as Alzheimer, depression, anxiety and schizophrenia. Now, we’re directing that same focus and energy to help cancer patients. In addition to the approval of Trisenox®, Lundbeck also brought Treanda® (bendamustine hydrochloride for injection) to market for people living with chronic lymphocytic leukemia and non-Hodgkin lymphoma. For more information, visit lundbeck.ca.
In February 2011, Lundbeck announced that the company had been granted exclusive rights to Trisenox® in Canada, as well as the commercial rights to several Cephalon Inc. products in Canada and Latin America. Cephalon Inc. is a wholly owned subsidiary of Teva Pharmaceutical Industries Ltd.

Media enquiries:

Celeste Brown 
Achieve Communications Group
Celeste.brown@gmail.com
(416) 301-9957

Dan McCarthy
Lundbeck Canada
DMY@lundbeck.com
(514) 844-8515

Trisenox® is a registered trademark of Lundbeck Canada Inc.

---


iii Trisenox® product monograph. www.lundbeck.com/ca/en