Nordion Provides Update on Europe-Focused Phase III Clinical Trial for TheraSphere® Yttrium-90 Liver Cancer Treatment

The Associated Press

OTTAWA, Ontario--(BUSINESS WIRE)--Sep 6, 2012--Nordion Inc. (TSX: NDN) (NYSE: NDZ), a leading provider of products and services for the prevention, diagnosis and treatment of disease, today provided an update on its YES-P clinical trial for TheraSphere ®, the company's Yttrium-90 (Y-90) glass microsphere liver cancer treatment, by naming the principal investigators (PI) and contract research organization (CRO) for the study.

The co-PIs are Professor Vincenzo Mazzaferro and Dr. Riad Salem. Professor Mazzaferro is Director and Vice-Scientific Director, Gastro-Intestinal Surgery and Liver Transplantation, Istituto Nazionale Tumori, Milan, one of the largest comprehensive cancer centers in Europe. Dr. Salem is Professor of Radiology, Medicine and Surgery; Chief, Section of Vascular and Interventional Radiology; Director, Interventional Oncology; and Vice-Chairman, Image-Guided Therapy Department of Radiology, Northwestern University. The trial will be conducted in collaboration with Theorem Clinical Research, a global full-service CRO, which is also conducting Nordion's two other Phase III clinical trials – EPOCH and STOP-HCC.

YES-P is a randomized, multi-centre Phase III clinical trial to evaluate the safety and efficacy of TheraSphere ® vs. sorafenib in the treatment of patients with portal vein thrombosis (PVT) associated with unresectable hepatocellular carcinoma (HCC), the most common form of primary liver cancer.

"HCC patients with PVT have limited treatment options and, as a result, life expectancy remains unacceptably low," said Mason Ross, MD, Nordion's Vice President of Medical Affairs. "Nordion is pleased to be working with two world renowned liver cancer experts and an internationally recognized CRO to assess whether TheraSphere ® can extend the lives of these patients and to provide physicians with additional data to support their clinical decisions." The YES-P trial is targeting enrollment of 350 patients at approximately 24 sites in Europe, with additional sites to be identified globally. The study will follow a randomized two-armed design – in one arm, patients will undergo Y-90 radioembolization treatment with TheraSphere ®, while patients in the other arm will receive sorafenib, the standard of care for advanced unresectable HCC.

About TheraSphere® TheraSphere ® is a liver cancer therapy that consists of millions of small glass beads (20 to 30 micrometers in diameter) containing radioactive Y-90. The product is injected by physicians into the artery of the patient's liver through a catheter, which allows the treatment to be delivered directly to the tumour via blood flow.

TheraSphere ® is used in the European Union and in Canada for the treatment of hepatic neoplasia in patients who have appropriately positioned arterial catheters.

In the US, TheraSphere ® is used to treat patients with hepatocellular carcinoma (HCC) who can have appropriately positioned hepatic arterial catheters, and can be used as a bridge to surgery or transplantation in these patients. It is also indicated for the treatment of HCC patients with partial or branch portal vein thrombosis or occlusion when clinical evaluation warrants the treatment. TheraSphere ® is approved by the U.S. Food and Drug Administration (FDA) under a Humanitarian Device Exemption (HDE). HDE approvals are based on demonstrated safety and probable clinical benefit. However, effectiveness of the indication for use has not been established.

Common side effects include mild to moderate fatigue, pain and nausea for about a week. Physicians describe these symptoms as similar to those of the flu. Some patients experience some loss of appetite and temporary changes in several blood tests. For details on rare or more severe side effects, please refer to the TheraSphere ® package insert/instructions for use at www.nordion.com/therasphere.

About Nordion Inc. Nordion Inc. (TSX: NDN) (NYSE: NDZ) is a global health science company that provides market-leading products used for the prevention, diagnosis and treatment of disease. We are a leading provider of medical isotopes, targeted therapies and sterilization technologies that benefit the lives of millions of people in more than 60 countries around the world. Our products are used daily by pharmaceutical and biotechnology companies, medical-device manufacturers, hospitals, clinics and research laboratories. Nordion has more than 500 highly skilled employees in three locations. Find out more at www.nordion.com and follow us at http://twitter.com/NordionInc.

As noted on : Theorem Clinical Research is a leading midsized provider of comprehensive clinical research and development services with offices in more than 30 countries and a customer base comprised of some of the world's leading pharmaceutical, biotech and medical device companies. A world leader in the most complex medical device and drug-device combination trials in addition to a notable capability in pharmaceuticals and biologics, Theorem has deep expertise in a broad range of therapeutic areas and in all phases of development. Some of the industry's top scientists and most advanced clinical analytics capabilities help ensure smooth-running, successful trials. For a full-service, right-size global research partner, don't think twice.

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