

Backgrounder: TheraSphere®

Tiny beads offer hope to liver cancer patients

TheraSphere® offers physicians innovative alternative to traditional therapies

Tiny radioactive glass beads called TheraSphere® are offering hope to patients with liver cancer. TheraSphere consists of millions of tiny glass microspheres, about one-half the diameter of a human hair, that attack cancerous tumours in the liver while minimizing the impact on healthy tissue.

TheraSphere is a therapeutic medical device for the treatment of liver cancer. Depending on the country in which it is administered, TheraSphere can be used to treat cancer that either starts in the liver, such as hepatocellular carcinoma (HCC), the most common form of primary liver cancer; or that has migrated to the liver from another location known as metastatic or secondary liver cancer. In the U.S., TheraSphere is approved to treat HCC. In other countries, TheraSphere is approved to treat HCC as well as metastatic cancer.

TheraSphere offers important benefit to patients. Unlike chemotherapy, TheraSphere has few side effects. Patients rarely experience the fatigue, nausea and vomiting usually associated with high-dose, systemic chemotherapies. TheraSphere is also minimally embolic in that it does not prevent blood flow through arteries resulting in less toxicity and pain to the patient. This feature also enables physicians to re-treat a patient with either TheraSphere or other conventional arterial therapies providing a wider range of future treatment options.

TheraSphere is ideal for patients where surgery, transplantation or tumour ablation is not a viable option. In addition, TheraSphere can be used to “downstage” tumours, by shrinking them, thus making a patient eligible for surgery or transplantation.

To administer TheraSphere, a physician first makes a small incision in a patient's leg and places a long, flexible plastic tube called a catheter, into the femoral artery, the major blood vessel in the leg. Guided by fluoroscopy – an X-ray imaging technique that projects views of the inside of the body onto a screen – the physician then moves the catheter up through the blood vessels to the hepatic artery, which is one of two blood vessels that feed the liver. The physician guides the catheter into the branch of the hepatic artery that feeds the cancerous tumour in the liver and injects the TheraSphere beads through the catheter into the blood that supplies the tumour. The tiny radioactive beads become permanently lodged in the smallest blood vessels that feed the tumour and emit their radioactive payload.

In the U.S., the treatment can be done on an outpatient basis meaning patients do not have to stay overnight in the hospital. The procedure is usually performed in a hospital's radiology suite and patients remain conscious throughout the treatment.

TheraSphere is approved for use in the United States, Europe, Canada, India, Russia and South Africa. In January of 2007, MDS Nordion announced that TheraSphere had been used for the first time in India, signifying a key step to expansion into the Asian market.

TheraSphere in the United States

TheraSphere is approved by the U.S. Food and Drug Administration (FDA) as a humanitarian device for the treatment of unresectable HCC or as a bridge to surgery or liver transplant. A Center of Excellence for TheraSphere is located at Northwestern Memorial Hospital in Chicago, IL.

MDS Nordion has received FDA approval for an expanded use for TheraSphere to treat patients with HCC who also have partial or branch portal vein thrombosis (PVT). This is an expansion of TheraSphere's existing approval in the U.S. Approximately 30 – 40 percent of HCC patients have portal vein thrombosis. Since TheraSphere does not prevent blood flow; it can be used to treat HCC patients who have this condition. The portal vein and hepatic artery supply blood to the liver. When conventional arterial therapies are used to treat PVT, it can further restrict the already compromised blood flow to healthy liver tissue and cause serious side effects for the patients. Until TheraSphere, there was no approved therapy to treat this subset of HCC patients.

TheraSphere is approved for Medicare reimbursement and is reimbursed at cost under the Hospital Outpatient Prospective Payment System. The majority of the patients identified as suitable for treatment with TheraSphere are Medicare eligible. Other government-sponsored programs such as state Medicaid programs and Tri-Care for military personnel have also provided coverage for TheraSphere treatments. Commercial insurance plans such as Health Maintenance Organizations (HMO), Preferred Provider Organizations (PPO), indemnity, and self-insured employers have also provided reimbursement for the treatment. However, coverage policies sometimes vary based upon the type of plan and location, and individuals are advised to confirm with their insurer.

TheraSphere in Europe

In June 2006, MDS Nordion received approval (CE mark) in Europe to distribute and use TheraSphere to treat primary and secondary liver cancer. MDS Nordion established four TheraSphere Centers of Excellence in Europe to train and educate oncology professionals on the use of this innovative cancer treatment. The Centers are located at the BCLC Group Hospital Clinic in Barcelona, Spain; Centre Eugene Marquis in Rennes, France; University-Hospital Essen in Essen, Germany; and Istituto Tumori, Italy.

TheraSphere in Asia

TheraSphere is used in India at leading cancer centres in Mumbai – the Liliwati Hospital and Research Group and the Jaslok Hospital and Research Centre. Patients have also been treated at the Apollo Hospital in New Delhi – the largest healthcare group in Asia. TheraSphere® is used in India to treat both primary and secondary liver cancer.

The demand for innovative cancer treatment in Asia will continue to grow as cancer rates in Asia increase. Rates of liver cancer are typically higher in regions, such as Asia, where there is less access to sanitation facilities and clean drinking water leading to higher incidence of hepatitis, a precursor to liver cancer. Since the liver acts to filter toxins from the blood, the more stress put on the liver by increased levels of toxins from the environment, the higher the levels of liver disease including cancer.



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About MDS Nordion

MDS Nordion (www.mdsnordion.com) is a world leader in medical isotopes, radiation and related technologies. It is a business unit of MDS Inc. (TSX:MDS)(NYSE:MDZ). MDS Inc. is a global life sciences company that provides market-leading products and services for the development of drugs and diagnosis and treatment of disease. We are a leading global provider of pharmaceutical contract research, medical isotopes for molecular imaging, radiotherapeutics, and analytical instruments. MDS Inc. has more than 6,200 highly skilled people in 28 countries. Find out more at www.mdsinc.com or by calling 1-888-MDS-7222, 24 hours a day.

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