

Medtronic Initiates Global Study of Minimally Invasive Technology to Aid Lung Cancer Diagnosis

September 22, 2015 6:58 AM CT



*Demonstrating Commitment To Reduce Lung Cancer Morbidity,
Study Will Enroll Up To 2,500 Patients Globally*

As the #1 Cancer Killer, Lung Cancer Deaths Surpass Breast, Colon and Prostate Cancer Combined

DUBLIN - September 22, 2015 - Committed to reducing lung cancer morbidity around the world, Medtronic's (NYSE: MDT) Minimally Invasive Therapies Group recently launched a 2,500-patient, international study to assess real-world impact of its superDimension(TM) navigation system. The Company developed the study to support and validate the superDimension system, which the Company hopes will become the global standard-of-care for obtaining lung tissue biopsies from the periphery of the lungs¹.

The LungGPS(TM) technology used in the superDimension system is the first of its kind to enable Electromagnetic Navigation Bronchoscopy procedures (also known as ENB procedures). ENB procedures provide a minimally invasive approach to access difficult-to-reach areas of the lung, which can aid in the diagnosis of lung disease and thereby lead to earlier, personalized treatment - potentially saving lives.

With a historical lack of effective, non-invasive diagnostic technologies, lung cancer remains the number one cancer killer in the world, accounting for more cancer deaths than breast, colon and prostate cancer combined².

Up to 75 centers around the globe will enroll patients in the single-arm, multi-center post-market observational study, known as [NAVIGATE](#), to evaluate the diagnostic performance of ENB procedures. The study will also determine how often physicians use the technology to successfully obtain biopsy samples from the surrounding lymph nodes and place fiducial markers or dyes to guide subsequent procedures to ablate or remove lung tumors.

The first enrolled patient underwent an ENB procedure at Pulmonary and Critical Care Associates of Baltimore, in Maryland on April 16, 2015. Patients will be followed for 24 months.

"With the introduction of ENB procedures, we can now navigate through the lung allowing us to screen for cancer and other diseases without surgery," said Erik Folch, MD, interventional pulmonologist at Beth Israel Deaconess Medical Center in Boston, and co-National Lead Investigator of the NAVIGATE study. "With this minimally invasive diagnostic approach now available, we are able to manage thousands of patients with suspicious lung nodules that show up on computerized tomography (CT) scans without resorting to surgery. This important study holds the key to determining the real-world impact of this minimally invasive approach that, I believe, could significantly reduce the mortality of lung cancer."

The ENB procedure allows patients to avoid surgery for benign disease and other invasive procedures like transthoracic needle aspiration.

"As lung cancer screening initiatives increase and we find more suspicious lung nodules, it is especially critical to provide minimally invasive diagnostic options earlier so patients can receive treatment sooner and have better chances of long-term survival," said Sandeep Khandhar, MD, a CVTSA thoracic, surgical director of thoracic oncology at Inova in Falls Church, Virginia and co-National Lead Investigator of the NAVIGATE study. "We are at a crucial time where diagnostic and surgical technologies have advanced to a level where I believe there could be a significant shift in patient outcomes and many patients can go on to lead long, active and healthy lives after a lung cancer diagnosis, which was almost unheard of even 10 years ago."

"Medtronic is committed to providing innovative diagnostic and therapeutic solutions for lung disease that have the potential to transform care and improve outcomes for patients worldwide," said Michael Tarnoff, MD, vice president and chief medical officer, Minimally Invasive Therapies Group at Medtronic. "We hope the NAVIGATE study will help confirm the impact of ENB procedures that we have seen in over 50,000 cases performed at more than 600 hospitals commercially and as part of prior clinical trials. Given the results seen to date, we are confident that this approach has the potential to become a recommended global standard of care to aid in diagnosis of peripheral lung lesions."

According to the American Lung Association, lung cancer is the leading cause of cancer-related deaths in the United States³. In its early stages, lung cancer presents few, if any, symptoms. As a result, diagnosis for the vast majority of lung cancer patients happens in the late stages, causing long-term survival rates to drastically decline. When diagnosed early, an estimated 85 percent of lung cancer cases appear at a more curable stage⁴. Early detection and immediate treatment dramatically increases the typical long-term survival rate from 15 percent at five years³ to 88 percent at 10 years⁴.

The superDimension system has received FDA 510(k) clearance in the United States, CE Mark in Europe and it has also been approved for use in numerous international markets.

Additional information about the NAVIGATE study and sites enrolling can be found at <https://clinicaltrials.gov/ct2/show/NCT02410837>.

Multimedia Release

A multimedia version of this release, with video and links to graphics can be found at: <https://medtronicmediacap.gcs-web.com/medtronic-initiates-global-study-minimally-invasive-technology-aid-lung-cancer-diagnosis>.

About Medtronic

Medtronic plc (www.medtronic.com), headquartered in Dublin, Ireland, is among the world's largest medical technology, services and solutions companies - alleviating pain, restoring health and extending life for millions of people around the world. Medtronic employs more than 85,000 people worldwide, serving physicians, hospitals and patients in more than 160 countries. The company is focused on collaborating with stakeholders around the world to take healthcare Further, Together.

Any forward-looking statements are subject to risks and uncertainties such as those described in Medtronic's periodic reports on file with the Securities and Exchange Commission. Actual results may differ materially from anticipated results.

-end-

1 May 2013; 143(5_suppl) Diagnosis and Management of Lung Cancer, 3rd ed: American College of Chest Physicians Evidence-Based Clinical Practice Guidelines

2 American Cancer Society: Cancer Facts & Figures 2013

3 The International Early Lung Cancer Action Program Investigators. N Engl J Med 2006; 355:1763-1771.

4 American Cancer Society: Cancer Facts & Figures 2014

Contacts:

John Jordan

Public Relations

+1-508-452-4891

Ryan Weispfenning
Investor Relations
+1-763-505-4626

HUG#1953617