Medtronic News

First European Patients Enroll in Medtronic International Lung Cancer Study

NAVIGATE Study Assesses Impact of Minimally Invasive Technology to Aid in Early Diagnosis and Treatment of Lung Cancer

DUBLIN - March 10, 2016 - Committed to technologies that assist in the goal of reducing lung cancer morbidity worldwide, Medtronic (NYSE: MDT) today announced European enrollment in the NAVIGATE clinical trial. This 2,500-patient international study will assess the long-term impact of its superDimension(TM) navigation system as an aid in early detection of lung cancer and subsequent treatment.

The superDimensionsystem uses LungGPS(TM) technology, the first of its kind to enable Electromagnetic Navigation Bronchoscopy (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, can help patients avoid surgery for benign disease and other invasive procedures like transthoracic needle aspiration, and lead to earlier, personalized treatment - potentially saving lives. The superDimension system has received CE Mark in Europe, 510(k) clearance in the US and has also been approved for use in numerous international markets.

"Early detection, diagnosis and intervention are crucial to the survival of people living with lung cancer," said Mag. Petra Lichtenberger, Assistant to Prof. Dr. Lamprecht at the Department of Pulmonology of Kepler University Clinic Linz, Austria, which enrolled the first ENB patient in Europe. "Technology that allows medical professionals to view areas of the lung that could not be accessed before is a major advance that is changing the landscape of lung cancer diagnosis and helping save patient lives."

Up to 75 centers around the world will enroll patients in the single-arm, multi-center post-market observational study designed to evaluate the impact of ENB procedures on early diagnosis and treatment. The NAVIGATE study will also determine the success rate of physicians using the technology to obtain biopsy samples from the surrounding lymph nodes. In addition, the study will assess the effectiveness of physicians' placement of fiducial markers or dyes to guide subsequent procedures to treat or remove lung tumors.

More than 22 sites have been activated to enroll patients since the study first launched in the U.S. in April 2015. Healthcare professionals will follow patients for 24 months.

"The NAVIGATE study represents our commitment to delivering meaningful solutions that support the early detection and treatment of lung cancer to save patient lives," said Vafa Jamali, president, Early Technologies business in the Medtronic Minimally Invasive Therapies Group. "The enrollment of patients in Europe for the NAVIGATE study is a significant milestone and an important step to help establish ENB procedures as the gold standard for detecting lung cancer in the earlier, more curable stages."

According to the World Health Organization, lung cancer is the number one cancer killer in the world, accounting for 1.59 million deaths in 2012.1 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, and long-term survival rates drastically decline. When diagnosed early, an estimated 85 percent of lung cancer cases appear at a more curable stage.2 Early detection and immediate treatment dramatically increases the typical long-term survival rate from 15 percent at five years3 to 88 percent at 10 years.2

To date nearly 100,000 ENB procedures have been performed globally at more than 600 hospitals commercially and as part of prior clinical trials.

Additional information about the NAVIGATE study and enrolling sites can be found at[clinicaltrials.gov/ct2/show/NCT02410837](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/first-european-patients-enroll-medtronic-international-lung-cancer-study.

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 approximately 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.

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1 World Health Organization. Cancer. Fact Sheet. Last updated February 2015. www.who.int/mediacentre/factsheets/fs297/en/. Accessed January 20, 2016.

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

3 Molina JR, Yang P, Cassivi SD, Schild SE, Adjei AA. Non-small cell lung cancer: epidemiology, risk factors, treatment, and survivorship. Mayo Clin Proc. 2008;83(5):584-594. http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2718421/. Accessed January 20, 2016.

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