Medtronic News

Medtronic Announces Positive Results from the Largest ENB Study to Aid in Lung Cancer Diagnosis, Staging, and Treatment Preparation in a Single Minimally Invasive Procedure

Company Is Committed to Leading Evidence Generation Across the Lung Cancer Care Continuum
Medtronic Initiates Separate Study to Evaluate the Safety and Performance of the Emprint(TM) Ablation Catheter with the superDimension(TM) Navigation System for Lung Ablation Procedures

DUBLIN - January 30, 2019 - Medtronic plc (NYSE:MDT) today announced that the*Journal of Thoracic Oncology* has published 12-month results of the NAVIGATE study, the largest, prospective, multicenter trial evaluating electromagnetic navigation bronchoscopy (ENB) procedures using the superDimension(TM) navigation system to aid in lung cancer diagnosis, staging and treatment. NAVIGATE included a key finding that 65 percent of patients diagnosed by physicians with primary lung cancer were at early stages (Stage I or II) of the disease. Early detection of lung cancer is critical to improving patient outcomes long term.

According to the American Cancer Society, lung cancer is the leading cause of cancer-related deaths in the United States.1 Today, the majority of lung cancer patients are diagnosed in the late stages (Stage III or IV), during which long-term survival rates drastically decline.1 When diagnosed at Stage I, the estimated 10-year survival rate climbs to 88 percent.2 Early detection and immediate treatment dramatically increases the typical long-term survival rate.1

"These data demonstrate that, for the first time, both academic and community-based care clinicians can safely obtain a diagnosis in small, peripheral lung lesions, and then stage and prepare for future treatment in a single minimally invasive procedure," said Erik Folch, M.D., M.Sc., chief of the Complex Chest Disease Center and co-director of Interventional Pulmonology at Massachusetts General Hospital in Boston, and co-lead investigator of the NAVIGATE study. "NAVIGATE is the first large, multicenter study to evaluate ENB diagnostic yield and complication rates with prospective, long-term follow up of negative cases. Because we looked at all cases-not just those with easily accessible lesions-NAVIGATE replicates real-world conditions and demonstrates that ENB has the potential to significantly accelerate lung cancer detection, and consequently improve the likelihood of a successful intervention."

Advancing the Lung Cancer Care Continuum Through Real-World Diagnostic Data

ENB procedures provide a minimally invasive, GPS-like approach to access difficult-to-reach areas of the lung, which can aid in the diagnosis of lung disease and potentially lead to earlier, personalized treatment. Earlier treatment has been associated with improved survival.1

NAVIGATE enrolled subjects at 37 sites in the United States and Europe. The*Journal of Thoracic Oncology*publication presents 12 month follow up for 1,215 patients at 29 medical centers in the United States.

The NAVIGATE study results showed the diagnostic yield of ENB (the proportion of patients who obtain an ENB-aided diagnosis) as supported by one-year follow-up. The ENB procedure was successfully completed in 94 percent of study patients and an ENB-aided diagnosis was obtained in 73 percent.3 Compared to published diagnostic yields of 65-73 percent in previous small, single-center, and retrospective studies across different devices,4,5 the one-year diagnostic yield in NAVIGATE is consistent and generalizable across diverse operators. A key finding in the NAVIGATE data was that 65 percent of patients diagnosed by physicians with primary lung cancer were at early stages of the disease (Stage I-II). With 49 percent of lesions less than 20 mm in diameter, NAVIGATE confirms that ENB is suitable for evaluating small peripheral lesions. The procedure had lower complication rates than previously published for transthoracic needle biopsies; specifically, pneumothorax (collapsed lung caused by injury to the lung wall) occurred in only 4.3 percent of NAVIGATE patients, which is lower than 19-25 percent rates typically seen with transthoracic needle biopsies.6

Building on the NAVIGATE results, Medtronic continues to advance lung cancer diagnostics. The latest generation of ENB, the superDimension(TM) Navigation System Version 7.2 with Fluoroscopic Navigation Technology, uses advanced software to enhance the visibility of lung lesions in real-time and aid in improved diagnostic accuracy. Medtronic has recently launched a new prospective study evaluating this technology at two United States centers.

Expanding the Care Continuum Through the New NAVABLATE Clinical Study

Medtronic is also committed to optimizing minimally invasive treatment solutions that accelerate recovery. A third study, NAVABLATE, will characterize the safety and performance of bronchoscopic thermal ablation using the Emprint(TM) ablation catheter kit with Thermosphere(TM) technology guided by the superDimension navigation system. The prospective, multi-center NAVABLATE study will be conducted in up to 30 patients globally.

"We are dedicated to improving lung cancer care across the continuum with platform technologies that identify and manage patients, improve diagnostics, optimize treatment and accelerate recovery," said Emily Elswick, vice president and general manager of Lung Health, which is part of the Minimally Invasive Therapies Group at Medtronic. "At Medtronic, we are setting the standard for clinical and economic evidence that substantiates the value of our innovative platforms for patients, providers and payers worldwide. Lung cancer remains the deadliest cancer and Medtronic is uniquely positioned to innovate, invent and disrupt with products and services that contribute to longer term survival."

The superDimension system has FDA 510(k) clearance in the United States, CE Mark in Europe, and it has also been approved for use in numerous international markets including Japan, Korea, and China. The Emprint ablation catheter kit has CE Mark only, not available in the United States.

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 86,000 people worldwide, serving physicians, hospitals and patients in more than 150 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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