Medtronic News

Medtronic Announces NAVABLATE Study Results Released in Late-Breaking Podium Presentation at European Respiratory Society International Congress 2021

Results Demonstrate Feasibility of Bronchoscopic Microwave Ablation for Certain Patients with Malignant Lung Nodules

DUBLIN, Sept. 7, 2021 /PRNewswire/ -- Medtronic plc (NYSE:MDT), the global leader in medical technology, today announced new clinical data from the NAVABLATE study, which highlights the much anticipated safety and performance results on microwave ablation used bronchoscopically with the Emprint™ Ablation Catheter Kit with Thermosphere™ Technology in conjunction with the Medtronic electromagnetic navigation bronchoscopy system. Results were reported as a late-breaking presentation at the virtual European Respiratory Society International Congress 2021, September 5, 2021.

"Patients with malignant lesions in the lung often have limited therapy options due to lesion locations, comorbidities, and treatment side effects," said Kelvin Lau, M.A., DPhil, FRCS(CTh), a consultant thoracic surgeon at St. Bartholomew's Hospital, London, and a principal investigator for the NAVABLATE study. "The results from the NAVABLATE study explore the potential benefit of a more individualized treatment for patients and offer a new option for surgeons and physicians to provide a minimally invasive, localized treatment of malignant lesions in the lung."

NAVABLATE is a prospective, multi-center study that enrolled 30 subjects in theUnited Kingdom and Hong Kong to characterize the safety and performance of the CE Marked Emprint Ablation Catheter Kit. All patients underwent a bronchoscopic ablation procedure using the Emprint Ablation Catheter Kit and were followed for one month post procedure.

"Despite advances in treatment that can extend survival, the challenges of long-term management of tumors in the lung have been a significant barrier to improving outcomes, quality of life, and extended time with loved ones," said Emily Elswick, vice president and general manager, Lung Health & Visualization, within the Surgical Innovations business, which is part of the Medical Surgical Portfolio at Medtronic. "Medtronic continues to take a broad transformative approach to the care continuum for the treatment of lung disease to improve diagnostics, optimize therapy and accelerate recovery."

Results of the NAVABLATE study demonstrated bronchoscopic microwave ablation is an option for primary and oligometastatic malignant lung nodules ≤30mm in patients who decline or are not candidates for both surgery and stereotactic body radiation therapy (SBRT). Ablation using the Emprint Ablation Catheter Kit achieved 100% technical success (nodule reached and ablated in accordance with the study protocol) in all 30 subjects immediately post-procedure. One-month imaging showed satisfactory ablation of the nodule in 100% of subjects. The composite rate of adverse events related to the Emprint Ablation Catheter Kit was 3.3% (one subject with mild hemoptysis). There were no deaths or pneumothoraces.

The Emprint Ablation Catheter Kit is in development and recently received Breakthrough Device Designation status from the U.S. Food and Drug Administration (FDA) in April 2021. This device is not approved or cleared by FDA and is not available for sale in the U.S. The catheter is intended to be used in conjunction with the Emprint™ microwave generator and Medtronic electromagnetic navigation bronchoscopy system to provide a highly localized treatment of malignant lesions in the lung, and it can be used together with standard of care therapy when indicated. Medtronic will continue to study the safety and efficacy of the Emprint ablation catheter kit under an upcoming FDA investigational device exemption (IDE) study, with the intent to submit for device approval or clearance at a future date.

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 90,000 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.

Contacts:

Kira Jastive	Ryan Weispfenning
Public Relations	Investor Relations
+1-508-452-4238	+1-763-505-4626

SOURCE Medtronic plc

---

https://news.medtronic.com/2021-09-07-Medtronic-Announces-NAVABLATE-Study-Results-Released-in-Late-Breaking-Podium-Presentation-at-European-Respiratory-Society-International-Congress-2021?sf150363465=1