Auris Health Announces Late-Breaking Results from First-in-Human Study of Monarch™ Platform

Data Presented at CHEST 2019 Demonstrates Efficacy of Monarch to Successfully Reach Nodules and Biopsy Tissue

NEW ORLEANS – October 23, 2019 – Auris Health, Inc. ("Auris Health"), part of Johnson & Johnson Medical Devices Companies,* today announced results from a study demonstrating the safety and feasibility of the Monarch Platform, a first-of-its-kind robotic technology indicated for use in diagnostic and therapeutic bronchoscopic procedures. Data from the BENEFIT study was presented in a late-breaking session at the CHEST 2019 Conference in New Orleans by Alexander C. Chen, M.D., of St. Louis, Mo.

The BENEFIT study assessed the safety and feasibility of utilizing a robotic system to aid in the diagnosis of peripheral pulmonary lesions 1-5 cm in size. During the study, investigators performed robotic-assisted bronchoscopy using the Monarch Platform on 55 patients across five study sites. The Monarch Platform localized targeted nodules using a combination of direct visualization, navigational guidance and radial endobronchial ultrasound (R-EBUS). The primary effectiveness endpoint, successful localization of targeted pulmonary lesions, was reported in 52/54 (96.3%) of procedures. Pneumothorax occurred in 2/55 (3.6%) of procedures and required tube thoracostomy in 1/55 (1.8%) procedure. No additional serious adverse events were reported.

"This is the first prospective, multicenter study of robot-assisted bronchoscopy in patients with undiagnosed lung lesions," said Gerard A. Silvestri, Hillenbrand Professor of Thoracic Oncology and a lung cancer pulmonologist at the Medical University of South Carolina. "We were able to safely perform the procedure and successfully localize lesions in 96% of cases. This data suggests robot-assisted bronchoscopy is feasible and may improve the bronchoscopists' ability to effectively localize peripheral lesions. The promising results of this study warrant further evaluation in additional prospective studies where yield can be better assessed."

"The results from the BENEFIT study demonstrate the potential of Monarch to help surgeons diagnose these hard-to-reach lesions," said Josh DeFonzo, Chief Operating Officer of Auris Health. "We are very encouraged by the results of the BENEFIT study and are thrilled to be making a positive impact on the diagnosis of lung conditions. We will continue to build robust clinical evidence around the Monarch Platform to support its use in interventional pulmonology."

Since Auris Health commercially launched the Monarch Platform last year, more than 1,000 procedures have been performed using the technology in the United States.

About Auris Health, Inc.

Auris Health, part of Johnson & Johnson Medical Devices Companies, is pioneering the next era of medical intervention by developing platforms that enhance physician capabilities, evolve minimally invasive techniques, and create new categories of care that redefine optimal patient outcomes. The company is committed to transforming medical intervention by integrating robotics, micro-instrumentation, endoscope design, sensing, and data science into one platform. Every element of our technology is driven by patient-specific design aimed at maintaining the integrity of the human body. Learn more at www.aurishealth.com.

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** The Johnson & Johnson Medical Devices Companies comprise the surgery, orthopaedics, vision and interventional solutions businesses within Johnson & Johnson's Medical Devices segment.*

Dr. Silvestri is a paid consultant to Auris Health, Inc.

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