

**FOR IMMEDIATE RELEASE**

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**Auris Health Announces Publication of Results from BENEFIT Study of MONARCH® Platform in CHEST**

*Data Demonstrates Safety of MONARCH Platform and Effective Localization of Peripheral Nodules*

REDWOOD CITY, CALIF. – January 21, 2021 – Auris Health, Inc., a subsidiary of Ethicon, Inc., part of the Johnson & Johnson Medical Devices Companies\*, today announced results from the world’s first prospective, multicenter study of robotic bronchoscopy. The study, called BENEFIT, evaluated the safety and feasibility of the MONARCH® Platform, a first-of-its-kind robotic technology indicated for use in diagnostic and therapeutic bronchoscopic procedures. Results of the study [were published](#) in CHEST, the official publication of the American College of Chest Physicians.

The study, led by Alexander C. Chen\*\*, M.D., of St. Louis, Mo. and Gerard A. Silvestri\*\*, M.D., M.S. of Charleston, S.C., assessed the safety and feasibility of utilizing the MONARCH robotic system to aid in the diagnosis of peripheral pulmonary lesions. Fifty-five patients were enrolled at five leading institutions across the United States: Washington University in St. Louis, Medical University of South Carolina, the Cleveland Clinic, Henry Ford Hospital, and Inova Fairfax Hospital.

The MONARCH Platform localized targeted nodules using a combination of direct visualization, navigational guidance and radial endobronchial ultrasound (R-EBUS). Results of the study demonstrated safety, with pneumothorax occurring in 2/54 (3.7%) of procedures, and placement of a chest tube required in 1/54 (1.9%) procedure. No additional serious adverse events were reported. In 96.2% of cases, the pre-planned target area was reached and localized as confirmed by ultrasound imaging. An exploratory analysis of overall diagnostic yield in the study was 74.1%. In addition, a diagnostic yield of 70% was achieved in lung nodules located outside of a patient’s airway. Authors noted these results compare favorably to reported yields of 30-40% using non-robotic technology for lesions outside the patient’s airway.

“This study was conducted using strict definitions for diagnostic yield. In previous studies, variations in the definition of yield led to overestimation of a successful bronchoscopy. Given this strict trial design, the diagnostic yield of 74.1% is promising, and we hope this sets the stage for future multicenter trials,” said Dr. Silvestri, Hillenbrand Professor of Thoracic Oncology at Medical University.

“We are thrilled to be making a meaningful impact on the diagnosis of lung conditions, particularly in patients with small and difficult to reach nodules that may progress to something more serious,” said Eric Davidson, President, Flexible Robotics, Auris Health, Inc. “Physicians in the study, using our first-generation MONARCH software, were able to localize and diagnose the most difficult-to-reach nodules

at a higher rate than was previously possible. Since then, we have continued to improve the platform, delivering a higher level of accuracy and ease of use. We continue to build robust clinical evidence in support of the MONARCH Platform and work with our colleagues at the Lung Cancer Initiative at Johnson & Johnson with the goal of transforming the standard of care for this devastating disease.”

Ethicon continues to generate clinical evidence with the December 2019 launch of the TARGET trial, a prospective multicenter study to further characterize the safety and efficacy of the MONARCH Platform.

### **About Ethicon**

Ethicon, part of Johnson & Johnson Medical Devices Companies, has made significant contributions to surgery for more than 100 years from creating the first sutures, to revolutionizing surgery with minimally invasive procedures. Our continuing dedication to Shape the Future of Surgery is built on our commitment to help address the world's most pressing health care issues and improve and save more lives. Through Ethicon's surgical technologies and solutions including sutures, staplers, energy devices, trocars and hemostats and our commitment to treat serious medical conditions like obesity worldwide, we deliver innovation to make a life-changing impact. For more information, visit [www.ethicon.com](http://www.ethicon.com).

### **About Johnson & Johnson Medical Devices Companies**

At Johnson & Johnson Medical Devices Companies, we are helping people live their best lives. Building on more than a century of expertise, we tackle pressing healthcare challenges, and take bold steps that lead to new standards of care while improving people’s healthcare experiences. In surgery, orthopaedics, vision and interventional solutions, we are helping to save lives and paving the way to a healthier future for everyone, everywhere.

\*Comprising the surgery, orthopedics, vision and interventional solutions businesses within Johnson & Johnson’s Medical Devices segment

\*\*Dr. Chen and Dr. Silvestri are paid consultants for Auris Health, Inc.

### *Cautions Concerning Forward-Looking Statements*

This press release contains "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995 regarding MONARCH®. The reader is cautioned not to rely on these forward-looking statements. These statements are based on current expectations of future events. If underlying assumptions prove inaccurate or known or unknown risks or uncertainties materialize, actual results could vary materially from the expectations and projections of Ethicon, any of the other Johnson & Johnson Medical Devices Companies and/or Johnson & Johnson. Risks and uncertainties include, but are not limited to: uncertainty of commercial success; challenges to patents; competition, including technological advances, new products and patents attained by competitors; manufacturing difficulties and delays; product efficacy or safety concerns resulting in product recalls or regulatory action; changes to applicable laws and regulations, including global health care reforms; changes in behavior and spending patterns of purchasers of health care products and services; and trends toward health care cost containment. A further list and descriptions of these risks, uncertainties and other factors can be found in Johnson & Johnson's Annual Report on Form 10-K for the fiscal year ended December 29, 2019, including in the sections captioned “Cautionary Note Regarding Forward-Looking Statements” and “Item 1A. Risk Factors,” and in the company’s most recently filed Quarterly Report on Form 10-Q, and the company’s subsequent filings with the Securities and Exchange Commission. Copies of these filings are

available online at [www.sec.gov](http://www.sec.gov), [www.jnj.com](http://www.jnj.com) or on request from Johnson & Johnson. Neither Ethicon, the Johnson & Johnson Medical Devices Companies nor Johnson & Johnson undertakes to update any forward-looking statement as a result of new information or future events or developments.