



PRECISE Clinical Study Preliminary Results Favorable for Intuitive’s Ion Endoluminal System for Peripheral Nodule Lung Biopsy

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SUNNYVALE, Calif., Oct. 18, 2021 (GLOBE NEWSWIRE) -- Intuitive (Nasdaq: ISRG), a global technology leader in minimally invasive care and the pioneer of robotic-assisted surgery, today announced the release of preliminary data from 69 subjects participating in the Prospective, Multi-Center Evaluation of the Clinical Utility (PRECISE) – a post-market, multi-center clinical trial of its Ion endoluminal system.

Use of the Ion system for pulmonary nodule biopsy resulted in an 83% diagnostic yield, which represents the likelihood that tissue samples obtained during the procedure will provide physicians with information needed to establish a diagnosis. PRECISE is the first multi-center study of the Ion system’s shape-sensing, robotic-assisted technology. Among the initial results of the ongoing study reported Sunday at the American College of Chest Physicians (CHEST) conference, the Ion system showed:

- Encouraging diagnostic yield for both smaller and larger nodules: Ion-enabled biopsies helped investigators obtain a diagnosis in 82% of cases with nodules between 1-2 centimeters, 85% with nodules between 2-3 cm. The similarity between yield rates for both smaller and larger nodules biopsied with Ion is a favorable result for clinicians seeking to sample smaller nodules.
- A strong safety profile: the Ion system had no serious adverse events reported in this subset of patients in the study, and no pneumothorax events requiring a chest tube.
- Sensitivity for malignancy from samples obtained from nodule biopsy was 84%-88%. Sensitivity is an indicator of the number of malignant conditions found from the tissue samples obtained.

“This study is another step to help confirm what we’ve seen and heard from physicians using Ion—that our technology helps them safely gain access to the appropriate portions of the lung to biopsy small nodules,” said Intuitive CEO Gary Guthart. “The Ion system’s progress further demonstrates how minimally invasive technologies can help create better outcomes for patients, surgeons, and care teams.”

These preliminary results of 69 subjects with up to 14-month follow up for applicable subjects are a subset of the study’s total of 365 patients, who were enrolled across six medical centers beginning in March 2019. The Ion system was used by investigators to sample nodules 10-30mm in diameter with Ion’s flexible articulating catheter that, combined with PlanPoint mapping software, enables the users to access the peripheral portions of the lungs, where many nodules are typically found.

“We’ve been waiting to see if the multi-center clinical evidence shows that shape-sensing robotic-assisted bronchoscopy can provide answers earlier in lung cancer,” said Dr. David Ost of The University of Texas MD Anderson Cancer Center in Houston, the study’s presenting author. “These are encouraging results on the potential for this technology to help safely biopsy small lung nodules.”

During a procedure using the Ion system, a physician will insert the Ion fully articulating catheter into the patient’s lung via the mouth and throat through an endotracheal tube, which may have fewer complications than biopsy approaches that use a needle inserted from outside the body.

The Ion system’s ability to navigate to small nodules and enable biopsies may help physicians get answers for patients, potentially enabling more time to consider medical management options. There are currently more than 70 Ion systems installed in U.S. hospitals as of the second quarter of 2021, and Intuitive continues to explore its applications in other countries.

About Intuitive

Intuitive (Nasdaq: ISRG), headquartered in Sunnyvale, California, is a global technology leader in minimally invasive care and the pioneer of robotic-assisted surgery. As part of our mission, we believe that minimally invasive care is life-enhancing care. Through ingenuity and intelligent technology, we expand the potential of physicians to heal without constraints.

Intuitive brings more than two decades of leadership in robotic-assisted surgical technology and solutions to its offerings and develops, manufactures, and markets the da Vinci Surgical System and the Ion endoluminal system.

Da Vinci® and Ion™ are trademarks or registered trademarks of Intuitive Surgical, Inc.

For more information, please visit the Company’s website at www.intuitive.com.

About the da Vinci Surgical System

There are several models of the da Vinci Surgical System. The da Vinci surgical systems are designed to help surgeons perform minimally invasive surgery. Da Vinci systems offer surgeons high-definition 3D vision, a magnified view, and robotic and computer assistance. They use specialized instrumentation, including a miniaturized surgical camera and wristed instruments (i.e., scissors, scalpels and forceps) that are designed to help with precise dissection and reconstruction deep inside the body.

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About Ion

Ion is Intuitive's robotic-assisted platform for minimally invasive biopsy in the lung. The system features an ultra-thin, ultra-maneuverable catheter that allows navigation far into the peripheral lung and provides the unprecedented stability necessary for precision in biopsy. Visit www.intuitive.com/en-us/products-and-services/ion

Important Safety Information

Risk associated with bronchoscopy through an endotracheal tube and under general anesthesia are infrequent and typically minor, and may include but are not limited to: sore throat, hoarseness, respiratory complications including dyspnea or hypoxemia, airway injury, bronchospasm, laryngospasm, fever, hemoptysis, chest or lung infection including pneumonia, lung abscess or an adverse reaction to anesthesia.

Although rare, the following complications may also occur: bleeding, pneumothorax (collapsed lung), cardiac related complications, respiratory failure, air embolism, or death.

As with other medical procedures, there may be additional risks associated with the use of general anesthesia and/or endotracheal intubation which are not listed above; you should consult a health care professional regarding these and other potential risks.

Procedures using the Ion Endoluminal System may be associated with longer procedure and/or longer anesthesia time.

Forward-Looking Statements

This press release contains forward-looking statements, including statements regarding the performance of the Ion Endoluminal System. These statements reflect the best judgment of the Company's management and involve a number of risks and uncertainties that could cause actual results to differ materially from those suggested by the forward-looking statements, including the risk that our products may not achieve market acceptance. These forward-looking statements should, therefore, be considered in light of the risk factors under the heading "Risk Factors" in our report on Form 10-K for the year ended December 31, 2020, as updated by the Company's other filings with the Securities and Exchange Commission. You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date of this press release. The Company undertakes no obligation to publicly update or release any revisions to these forward-looking statements, except as required by law. For more information, please visit the company's website at www.intuitive.com.

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