U. S. FDA Grants Clearance for Ion by Intuitive

February 19, 2019

Flexible robotic catheter helps physicians reach nodules in the peripheral lung

SUNNYVALE, Calif., Feb. 19, 2019 (GLOBE NEWSWIRE) -- Intuitive Surgical, Inc. (Nasdaq: ISRG), a global technology leader in minimally invasive care and the pioneer of robotic-assisted surgery, today announced that the U.S. Food and Drug Administration (FDA) cleared the Ion ™ endoluminal system to enable minimally invasive biopsy in the peripheral lung.

Lung cancer is the world's leading cause of cancer deaths. Many suspicious lesions found in the lung may be small and difficult to access, which can make obtaining a diagnosis challenging.

"Early lung cancer diagnosis can save lives. Intuitive's advanced, robotic-assisted, minimally invasive Ion system helps address a challenging aspect of lung biopsy by enabling physicians to obtain tissue samples from deep within the lung," said Gary Guthart, Intuitive CEO.

The Ion system uses an ultra-thin articulating robotic catheter that can move 180 degrees in all directions. The outer diameter of the catheter is 3.5 mm, which physicians can navigate through small and tortuous airways to reach nodules in any airway segment within the lung. The Ion system's flexible biopsy needle (called the Flexision Biopsy Needle) can also pass through very tight bends via Ion's catheter to collect tissue in the peripheral lung. The catheter's 2mm working channel can also accommodate other biopsy tools, such as biopsy forceps or cytology brushes, if necessary.

Intuitive developed the system's fiber optic shape sensor technology to provide the physician with the precise location and shape information of the catheter throughout the navigation and biopsy process.

Intuitive designed the Ion system to easily integrate into existing lung nodule biopsy workflows, as well as existing imaging technology, including fluoroscopy, radial-endobronchial ultrasound, and cone-beam CT.

"The Ion system represents Intuitive's continued commitment to innovating for minimally invasive care, and extends our focus beyond surgery," said Guthart. "At Intuitive, we innovate for need, and lung cancer is clearly a global health challenge that requires new modalities of care."

Intuitive plans to introduce the Ion system in the U.S. in a measured fashion, with customer shipments beginning in the second quarter of 2019.

Intuitive brings more than two decades of leadership in robotic-assisted surgical technology and solutions to this innovative new platform, which supports the company's mission in the advancement of minimally invasive care.

About Intuitive

Intuitive (Nasdaq: ISRG), headquartered in Sunnyvale, Calif., is the pioneer and a global leader in robotic-assisted, minimally invasive surgery. At Intuitive, 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.

Forward Looking Statements

This press release contains forward-looking statements, including statements regarding the Ion endoluminal system and the company's leadership in the advancement of minimally invasive care. These forward-looking statements are based on current expectations and estimates and involve a number of risks and uncertainties that could cause actual results to differ materially from those suggested by the forward-looking statements. These forward-looking statements should, therefore, be considered in light of various important factors, including, but not limited to, the following: the impact of global and regional economic and credit market conditions on healthcare spending; healthcare reform legislation in the United States and its impact on hospital spending, reimbursement and fees levied on certain medical device revenues; changes in hospital admissions and actions by payers to limit or manage surgical procedures; the timing and success of product development and market acceptance of developed products, including, but not limited to, the recently cleared Ion endoluminal system, da Vinci SP Surgical System and 3rd generation stapling platform; the results of any collaborations, in-licensing arrangements, joint ventures, strategic alliances or partnerships; procedure counts; regulatory approvals, clearances and restrictions or any dispute that may occur with any regulatory body; guidelines and recommendations in the healthcare and patient communities; intellectual property positions and litigation; competition in the medical device industry and in the specific markets of surgery in which the company operates; unanticipated manufacturing disruptions or the inability to meet demand for products; the results of legal proceedings to which the company is or may become a party; product liability and other litigation claims; adverse publicity regarding the company and the safety of the company's products and adequacy of training; the company's ability to expand into foreign markets; the impact of changes to tax legislation, guidance, and interpretations; and other risk factors under the heading "Risk Factors" in the company's annual report on Form 10-K for the year ended December 31, 2018, as updated by the company's other filings with the Securities and Exchange Commission. Statements using words such as "estimates," "projects," "believes," "anticipates," "plans," "expects," "intends," "may," "will," "could," "should," "would," "targeted" and similar words and expressions are intended to identify forward-looking statements. 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.

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PN1057696-A

Source: Intuitive Surgical, Inc.