Intuitive Submits New Robotic-Assisted Platform to FDA for Obtaining Lung Biopsies

September 6, 2018

SUNNYVALE, Calif, Sept. 06, 2018 (GLOBE NEWSWIRE) -- Intuitive Surgical, Inc. (Nasdaq: ISRG), the pioneer and a global technology leader in robotic-assisted, minimally invasive surgery, today announced it has submitted a premarket notification to the U.S. Food and Drug Administration (FDA) for the company's new flexible robotic-assisted, catheter-based platform, designed to navigate through very small lung airways to reach peripheral nodules for biopsies.

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

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 leadership in the advancement of minimally invasive care.

Premarket notification is one of the regulatory processes that the FDA uses to review information about medical devices before they are allowed to be marketed in the U.S.

About Intuitive Surgical, Inc.

Intuitive Surgical, Inc. (Nasdaq:ISRG), headquartered in Sunnyvale, Calif., is the pioneer and a global leader in robotic-assisted, minimally invasive surgery. Intuitive Surgical develops, manufactures and markets the da Vinci® surgical system.

Forward Looking Statements

This press release contains forward-looking statements, including statements regarding the flexible robotic-assisted, catheter-based platform's design and the company's leadership in the advancement of minimally invasive care. These forward-looking statements are necessarily estimates reflecting 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. These forward-looking statements should, therefore, be considered in light of various important factors, including, but not limited to, the following: the risk that the FDA will not clear the flexible robotic-assisted, catheter-based platform device for commercial distribution under the premarket notification process or otherwise; other regulatory approvals, clearances and restrictions or any dispute that may occur with any regulatory body; 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 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; 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, 2017, 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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Source: Intuitive Surgical, Inc.