Intuitive Surgical Brings Stapler Instrumentation to da Vinci Robotic-Assisted Surgical Systems in the U.S., Europe & Asia

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SUNNYVALE, Calif., July 14, 2015 (GLOBE NEWSWIRE) -- Intuitive Surgical, Inc. (Nasdaq:ISRG), the global leader in robotic-assisted minimally invasive surgery, today announced new clearances in Europe and Asia and provided an update on the status of its EndoWrist® Staplers in the United States.

The da Vinci® Si™ and Xi™ Surgical System staplers are the only devices of their type that provide fully wristed articulation and SmartClamp technology that detects when instrument jaws are adequately closed on target tissue. The design enables control of stapling from the surgeon console, creating a more direct relationship between clinical decision-making and instrument action. Intuitive Surgical has received clearance for stapler use on the da Vinci Si and Xi Surgical Systems by various regulatory bodies in the United States, Europe and Asia.

Current regulatory status:

- Received CE Mark to sell the EndoWrist Stapler for the da Vinci Si and Xi Surgical Systems in European markets, April 2015.
- Received 510(k) clearance to sell the EndoWrist Stapler for the da Vinci Si and Xi Surgical Systems in the United States, October 2012 and July 2014, respectively.
- Received clearance to sell the EndoWrist Stapler for the da Vinci Si Surgical System in South Korea, Q1 2015.

"This is robotic-assisted technology at its best. The new robotic stapler allows for full surgeon control, with wristed functionality unlike other products in the market," said Craig Rezac, M.D., Associate Professor and Chief of Robotic Surgery at Rutgers Robert Wood Johnson Medical School and Chief of the Section of Colorectal Surgery at Rutgers Medical School. "The instrument's internal feedback gives the surgeon the certainty that the stapling was performed in the best conditions. Overall, it is a significant enhancement to the technology."

The da Vinci Si and Xi EndoWrist Staplers are designed and intended for resection, transaction and/or creation of anastomoses (surgical connections between vessels or tissues) in general, gynecologic and urologic surgery. Thoracic surgery is a new indication for the da Vinci Xi EndoWrist Stapler with the availability of white staple reloads for thin tissue usage.

Currently, stapler reloads that are white (thin tissue such as vasculature and mesentery), blue (medium-thickness tissue such as colon), and green (thick tissue such as stomach or rectum) are available for the da Vinci Xi System in the United States and Europe. Blue and green reloads are available for the da Vinci Si System in the United States, Europe and Korea. The da Vinci Stapler reload colors correspond to the same closed-staple heights as the equivalent reload colors available in the current market - white (1.0mm closed), blue (1.5mm closed), and green (2.0mm closed).

"The advancements we’ve made with the EndoWrist Stapler further underscore our progress in offering a broad range of tools and resources to surgeons spanning several specialties, including general surgery," said David Stoffel, M.D., Vice President, Marketing and New Business Development at Intuitive Surgical. "We continue to work to obtain approval to offer a full suite of stapler offerings for the da Vinci Xi in Korea and Si and Xi in Japan; clearances are expected later this year."

About Intuitive Surgical, Inc.

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

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 are not programmed to perform surgery on their own. Instead, the procedure is performed entirely by a surgeon who controls the system. 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.

Important Safety Information

Serious complications may occur in any surgery, including da Vinci Surgery, up to and including death. Risks include, but are not limited to, injury to tissues and organs and conversion to other surgical techniques. If your doctor needs to convert the surgery to another surgical technique, this could result in a longer operative time, additional time under anesthesia, additional or larger incisions and/or increased complications. Individual surgical results may vary. Patients who are not candidates for non-robotic minimally invasive surgery are also not candidates for da Vinci Surgery. Patients should talk to their doctors to decide if da Vinci Surgery is right for them. Patients and doctors should review all available information on non-surgical and surgical options in order to make an informed decision. Please also refer to www.daVinciSurgery.com/Safety for Important Safety Information.

Forward-Looking Statement

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, including statements regarding regulatory clearances to market the da Vinci Xi System around the world. These forward-looking statements are necessarily estimates reflecting the best judgment of our 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 those under the heading "Risk Factors" in our annual report on Form 10-K for the year ended December 31, 2013, as updated from time to time by our quarterly reports on Form 10-Q and our 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. We undertake no obligation to publicly update or release any revisions to these forward-looking statements, except as required by law.

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CONTACT: Intuitive Surgical, Inc. (Nasdaq:ISRG)
Corporate Communications
408-523-7337
corpcomm@intusurg.com
http://www.intuitivesurgical.com/
https://twitter.com/IntuSurgNews

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