Intuitive Surgical Announces FDA Clearance of da Vinci(R) Sp(TM) Surgical System

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SUNNYVALE, Calif., April 22, 2014 (GLOBE NEWSWIRE) -- Intuitive Surgical, Inc. (Nasdaq:ISRG), the global leader in robotic-assisted minimally invasive surgery, today announced it has received FDA 510(k) clearance for the *da Vinci Sp* Surgical System, which is designed to expand the Company's single-incision product offering. This initial clearance is specific to urologic surgical procedures that are appropriate for a single port approach.

"Our development of this single-port technology represents our foundational commitment to advancing tools for minimally invasive surgery," said Gary Guthart, Intuitive Surgical's President and CEO.

da Vinci Sp technology is a dedicated single-port innovation designed to deliver an articulating 3D HD camera and three fully articulating instruments through a single 25 mm cannula. The fully wristed *EndoWrist® Sp* Instruments have two more degrees of freedom than the *da Vinci Single-Site®* Instruments, which are not wristed and are used in single port surgeries. The surgeon controls the instruments and endoscope while seated at the *da Vinci* Surgical System console.

The Company does not intend to commercialize the *da Vinci Sp* technology until the current technology is engineered to be fully compatible with the newly released *da Vinci Xi* ™ Surgical System, currently projected for the second half of 2015. This will require product refinements, supply chain optimization and additional regulatory clearances.

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 *da Vinci®* Surgical Systems. Intuitive Surgical's mission is to extend the benefits of minimally invasive surgery to those patients who can and should benefit from it. For more information, visit intuitivesurgical.com.

Indications for Use for the *da Vinci Sp* Surgical System and *EndoWrist Sp* Instruments

The Intuitive Surgical Endoscopic Instrument Control System (*da Vinci Sp* Surgical System, Model SP999) is intended to assist in the accurate control of Intuitive Surgical *EndoWrist Sp* Instruments during urologic surgical procedures that are appropriate for a single port approach. The system is indicated for adult use. It is intended for use by trained physicians in an operating room environment in accordance with the representative, specific procedures set forth in the Professional Instructions for Use.

Intuitive Surgical *EndoWrist Sp* Instruments are controlled by the *da Vinci Sp* Surgical System, Model SP999, and include flexible endoscopes, blunt and sharp endoscopic dissectors, scissors, forceps/pick-ups, needle holders, endoscopic retractors, electrocautery and accessories for endoscopic manipulation of tissue, including grasping, cutting, blunt and sharp dissection, approximation, ligation, electrocautery, and suturing through a single incision laparoscopic approach. The system is indicated for urologic surgical procedures that are appropriate for a single port approach. The system is indicated for adult use. It is intended for use by trained physicians in an operating room environment in accordance with the representative, specific procedures set forth in the Professional Instructions for Use.

The safety and effectiveness of this device for use in the performance of general laparoscopic surgery procedures have not been established. This device is only intended to be used for single port urological procedures with the *da Vinci EndoWrist Sp* Instruments and the *da Vinci Sp* Surgical System (SP999).

Surgical Risks

All surgery presents risk, including *da Vinci* Surgery and other minimally invasive procedures. Serious complications may occur in any surgery, up to and including death. Examples of serious and life-threatening complications, which may require hospitalization, include injury to tissues or organs, bleeding, infection, and internal scarring that can cause long-lasting dysfunction or pain.

Forward-Looking Statement

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. 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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