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Two New Analyses Demonstrate That Robotic-Assisted Surgery Results in Fewer Complications Compared With Open Surgery for Urologic Cancers

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SUNNYVALE, Calif., Oct. 24, 2013 (GLOBE NEWSWIRE) -- In two independent analyses comparing robotic-assisted surgery and open surgery performed on patients with urologic cancers, researchers found that robotic-assisted surgery results in fewer overall complications during and after surgery, less blood loss and shorter length of hospital stay.

In the first analysis, which was published in this month's issue of *Cancer Treatment Reviews*, the authors (Li K, Tianxin L, Xinxiang F, et. al.) reviewed the available literature on the efficacy and advantages of robotic-assisted radical cystectomy (RARC) versus open radical cystectomy (ORC) performed for bladder cancer. Included in the analysis (962 patients in total) were one randomized controlled trial, eight retrospective studies with prospectively collected data and four retrospective studies.

Radical cystectomy, which is the removal of the entire bladder, nearby lymph nodes, part of the urethra, and nearby organs that may contain cancer cells, is a common procedure performed for patients with stage 2 or stage 3 bladder cancer. According to the National Cancer Institute, bladder cancer is the sixth most common cancer in the United States.[1] It is the third most common cancer in men and the eleventh most common cancer in women, and causes approximately 15,000 deaths each year.

The analysis shows that although RARC was associated with longer operative time ($p < 0.001$), it may result in fewer overall complications during surgery ($p = 0.04$), more lymph node yield ($p = 0.009$), less estimated blood loss ($p < 0.001$), a lower need for a blood transfusion ($p < 0.001$) and a shorter length of hospital stay ($p < 0.001$). Positive surgical margins (leftover cancer cells) did not differ significantly between the surgical techniques. Sensitivity analysis on the prospective studies showed similar results except that no significant difference was seen for lymph node yield and length of stay between the two surgical techniques.

The second analysis, published in the World Journal of Urology by Dr. Gianni Vittori from the Universita` di Firenze, compared kidney cancer patients who had received robotic-assisted partial kidney removal with those who had received open partial kidney removal. The two-year observational multicenter analysis was promoted by the "Associazione GIovani Laparoscopisti Endoscopisti" (AGILE), a non-profit foundation that involved six Italian urologic centers.

This year, there will be an estimated 65,000 new cases and 14,000 deaths related to kidney cancer in the United States. Since a majority of patients are diagnosed when the tumor is still relatively localized (stage 1 and 2) and are able to have surgery to remove the tumor, approximately 40 percent survive for at least five years.

Dr. Vittori's analysis involved a total of 198 and 105 patients enrolled in either open or robotic-assisted surgery groups, respectively. Prior to surgery, the patients undergoing robotic-assisted partial kidney removal were sicker ($p = 0.04$) and had tumors of smaller size ($p = 0.002$). While the surgical results indicated the robotic-assisted patient group had longer operative times ($p<0.001$), they benefited from less blood loss, fewer surgical complications after surgery ($p<0.001$), fewer surgical complications that required additional interventions or were life-threatening ($p=0.001$), and shorter hospitalization times than the open surgery patients.

"As individuals and agencies seek to understand the impact of robotic-assisted surgery on healthcare outcomes, evidence-based medicine and all peer-reviewed clinical publications become increasingly important in understanding appropriate treatment options," said Myriam Curet, MD, Chief Medical Advisor, Intuitive Surgical. "Robotic-assisted surgery, while prevalent in urology and gynecology, is now being utilized for other important procedures such as cystectomy and partial nephrectomy where patients may benefit from a minimally-invasive option over open surgery."

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. Intuitive Surgical's mission is to extend the benefits of minimally invasive surgery to those patients who can and should benefit from it.

About the *da Vinci* Surgical System

The *da Vinci* Surgical System is a surgical platform designed to enable complex surgery using a minimally invasive approach. The *da Vinci* Surgical System consists of an ergonomic surgeon console or consoles, a patient-side cart with three or four interactive arms, a high-performance vision system and proprietary *EndoWrist*® instruments. Powered by state-of-the-art technology, the *da Vinci* Surgical System is designed to scale, filter and seamlessly translate the surgeon's hand movements into more precise movements of the *EndoWrist* instruments. The net result is an intuitive interface with improved surgical capabilities. By providing surgeons with superior visualization, enhanced dexterity, greater precision and ergonomic comfort, the *da Vinci* Surgical System makes it possible for skilled surgeons to perform more minimally invasive procedures involving complex dissection or reconstruction. For more information about clinical evidence related to *da Vinci* Surgery, please visit www.intuitivesurgical.com/company/clinical-evidence/.

All surgery presents risk, including *da Vinci* Surgery. Results, including cosmetic results, may vary. 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. Temporary pain or nerve injury has been linked to the inverted position often used during abdominal and pelvic surgery. Patients should understand that risks of surgery include potential for human error and potential for equipment failure. Risk specific to minimally invasive surgery may include: a longer operative time; the need to convert the procedure to an open approach; or the need for additional or larger incision sites. Converting the procedure to open could mean a longer operative time, long time under anesthesia, and could lead to increased complications. Research suggests that there may be an increased risk of incision-site hernia with

single-incision surgery. Patients who bleed easily, have abnormal blood clotting, are pregnant or morbidly obese are typically not candidates for minimally invasive surgery, including *da Vinci* Surgery. Other surgical approaches are available. Patients should review the risks associated with all surgical approaches. They should talk to their doctors about their surgical experience and to decide if *da Vinci* is right for them. For more complete information on surgical risks, safety and indications for use, please refer to http://www.davincisurgery.com/safety.

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, including statements regarding our medical device reporting practices, related device malfunction filings, product performance and the speed at which instrument changes can be accomplished. 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 the following: the impact of global and regional economic and credit market conditions on health care spending; health care reform legislation in the United States and its implications on hospital spending, reimbursement and fees which will be levied on certain medical device revenues; timing and success of product development and market acceptance of developed products; procedure counts; regulatory approvals, clearances and restrictions; guidelines and recommendations in the health care and patient communities; intellectual property positions and litigation; competition in the medical device industry and in the specific markets of surgery in which we operate; unanticipated manufacturing disruptions or the inability to meet demand for products; the results of legal proceedings to which we are or may become a party; our ability to expand into foreign markets; and other risk factors under the heading "Risk Factors"' in our report on Form 10-K for the year ended December 31, 2012, 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 to reflect events or circumstances after the date of this press release or to reflect the occurrence of unanticipated events.

[1] National Cancer Institute. "General Information About Bladder Cancer." Available from: http://www.cancer.gov/cancertopics/pdq/treatment/bladder/healthprofessional.

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