FDA Clears da Vinci(R) System Use in Benign Base of Tongue Resection Procedures

September 18, 2014

SUNNYVALE, Calif., Sept. 18, 2014 (GLOBE NEWSWIRE) -- Intuitive Surgical (Nasdaq:ISRG) today announced that it has received FDA clearance for use of the *da Vinci* S® and *da Vinci Si*® Surgical Systems in benign, base of tongue resection procedures. These procedures are performed transorally, or through the mouth opening, by otolaryngologic surgeons. Otolaryngologists specialize in diseases of the ear, nose and throat (ENT). These procedures involve removal or resection of non-cancerous or benign tissue at the base of the tongue, near the opening of the throat.

"I am pleased with this next step in our progress in serving the transoral otolaryngology market," said Dave Rosa, Executive Vice President and Chief Scientific Officer at Intuitive Surgical. "The significance of this clearance is ENT physicians can now offer their patients a new minimally invasive option for benign base of tongue resection procedures."

The *da Vinci S* and *da Vinci Si* Surgical Systems were previously cleared for use in transoral otolaryngology procedures restricted to early stage benign or malignant (cancerous) tumors classified as T1 and T2. These systems may now also be utilized for benign base of tongue resection procedures. The *da Vinci Xi* System is not currently indicated for use in transoral otolaryngologic surgical procedures.

***da Vinci* System Description**

There are several models of the *da Vinci* Surgical System. The *da Vinci* Surgical Systems are designed to help doctors perform minimally invasive surgery. *da Vinci* Systems are not programmed to perform surgery on their own. Instead, the surgery is performed entirely by a doctor, who controls the system. *da Vinci* Systems offer doctors 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.

ENT / TORS Procedures

The *da Vinci S* and *da Vinci Si* Systems are indicated for transoral otolaryngologic surgical procedures restricted to benign and malignant tumors classified as T1 and T2, and for benign base of tongue resection procedures. The safety and effectiveness of this device for use in the treatment of obstructive sleep apnea have not been established.

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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