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# Spectranetics Completes Acquisition of Stellarex(TM) Drug Coated Balloon Assets From Covidien

COLORADO SPRINGS, Colo., Jan. 27, 2015 (GLOBE NEWSWIRE) -- The Spectranetics Corporation (Nasdaq:SPNC) today announced it has completed the acquisition of Covidien's Stellarex™ drug coated balloon angioplasty (DCB) platform. The transaction closed after the acquisition of Covidien by Medtronic.

The Stellarex DCB platform received European CE mark approval in December 2014. Spectranetics launched the product in Europe today, with U.S. commercialization anticipated in the 2017 timeframe, following FDA approval.

"This transaction meaningfully enhances Spectranetics' portfolio," said Scott Drake, President and CEO, Spectranetics. "Stellarex is an ideal strategic fit, complementing our suite of highly differentiated cardiovascular clinical solutions designed to enable physicians to cross, prepare and treat the most complex vascular disease. We are excited to have the Stellarex team become part of SPNC. They are an incredible asset and we are proud to advance their work as we continue with the ILLUMENATE clinical trials and product launch."

**About the Stellarex DCB Platform**

The Stellarex DCB platform is designed to treat peripheral arterial disease. Stellarex uses EnduraCoat™ technology, a durable, uniform coating designed to prevent drug loss during transit and facilitate controlled, efficient drug delivery to the treatment site. The Stellarex DCB platform received CE mark to be marketed in the European Union in December 2014. It is not approved in the United States, and is currently limited to investigational use.

**About ILLUMENATE First-in-Human (FIH) Study**

Data from the ILLUMENATE FIH Study was reported at the EuroPCR Scientific Congress in May 2014. The ILLUMENATE FIH Study is a prospective, multi-center, single-arm study designed to assess the clinical performance of the Stellarex DCB. In the study, 58 superficial femoral and/or popliteal lesions (up to 15 cm in length) in 50 patients were pre-dilated with an uncoated angioplasty balloon, followed by treatment with the Stellarex DCB. Clinical events were adjudicated by independent angiographic and sonographic core laboratories. The study found the Stellarex DCB to be safe, with durable results to 12 months, including:

- Primary patency (defined as the treated artery remaining open without further treatment required or renewed blockage detected by ultrasound scanning) was 89.5 percent at 12 months.
- Freedom from clinically driven target lesion revascularization through 12-month follow-up was 87.9 percent.
- No amputations or cardiovascular deaths were reported.

**About ILLUMENATE Clinical Trials**

The Stellarex DCB platform is being studied in an active Investigational Device Exemption (IDE) trial in the United States and internationally. There are four active ILLUMENATE clinical trials in addition to the First-in-Human ILLUMENATE trial, described above:

- ILLUMENATE Pharmacokinetic Study – to evaluate the drug levels in the blood; 25 patients to be enrolled at up to two sites
- ILLUMENATE Pivotal Trial – randomized trial to support PMA in the United States; up to 360 patients to be enrolled at 45 sites
- ILLUMENATE European Randomized Trial – similar to the U.S. Pivotal Trial; up to 360 patients to be enrolled at 30 sites
- ILLUMENATE Global Registry – non-randomized; up to 500 patients to be enrolled at 65 sites

These five clinical trials will be used to evaluate the safety and effectiveness of the Stellarex DCB platform and support United States and Canada regulatory approval.

**About Spectranetics**

SPNC develops, manufactures, markets and distributes single-use medical devices used in minimally invasive procedures within the cardiovascular system. The Company's products are sold in over 65 countries and are used to treat arterial blockages in the heart and legs and in the removal of pacemaker and defibrillator leads.

The Company's Vascular Intervention (VI) products include a range of laser catheters for ablation of blockages in arteries above and below the knee as well as the AngioSculpt® scoring balloon used in both peripheral and coronary procedures. The Company also markets support catheters to facilitate crossing of peripheral and coronary arterial blockages, and retrograde access and guidewire retrieval devices used in the treatment of peripheral arterial blockages, including chronic total occlusions. The Company markets aspiration and cardiac laser catheters to treat blockages in the heart.

The Lead Management (LM) product line includes excimer laser sheaths, dilator sheaths, mechanical sheaths and accessories for the removal of pacemaker and defibrillator cardiac leads.

For more information, visit www.spectranetics.com.

**Spectranetics' Cautionary Statement Regarding Forward-Looking Statements**

This news release contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities

Exchange Act of 1934 and the Private Securities Litigation Reform Act of 1995. You can identify these statements because they do not relate strictly to historical or current facts. Such statements may include words such as "anticipate," "will," "estimate," "expect," "look forward," "strive," "project," "intend," "should," "plan," "believe," "hope," "enable," "potential," and other words and terms of similar meaning in connection with any discussion of, among other things, future operating or financial performance, strategic initiatives and business strategies, clinical trials, regulatory or competitive environments, our intellectual property and product development. These forward-looking statements include, but are not limited to, statements regarding our expectation of continued growth and strength and the reasons for that growth, growth rates, strength, and outlook including projected revenue, net loss and Adjusted EBITDA. Such statements are based on current assumptions that involve risks and uncertainties that could cause actual outcomes and results to differ materially. You are cautioned not to place undue reliance on these forward-looking statements and to note they speak only as of the date of this release. These risks and uncertainties may include financial results differing from guidance, inability to successfully integrate AngioScore and the Stellarex platform into our business, market acceptance of excimer laser atherectomy technology and our vascular intervention and lead removal products, market acceptance of drug coated balloon technology, increasing price and product competition, increased pressure on expense levels resulting from expanded sales, marketing, product development and clinical activities, uncertain success of our strategic direction, dependence on new product development, loss of key personnel, uncertain success of or delays in our clinical trials, adverse results in any ongoing legal proceeding, or any legal proceeding in which we may become involved, adverse impact to our business of the health care reform and related legislation or regulations, including changes in reimbursements, continued or worsening adverse conditions in the general domestic and global economic markets and continued volatility and disruption of the credit markets, which affects the ability of hospitals and other health care systems to obtain credit and may impede our access to capital, intellectual property claims of third parties, availability of inventory from suppliers, adverse outcome of FDA inspections, the receipt of FDA approval to market new products or applications and the timeliness of any approvals, market acceptance of new products or applications, product defects, ability to manufacture sufficient volumes to fulfill customer demand, availability of vendor-sourced components at reasonable prices, unexpected delays or costs associated with any planned improvements to our manufacturing processes, and share price volatility due to the initiation or cessation of coverage, or changes in ratings, by securities analysts. For a further list and description of such risks and uncertainties that could cause our actual results, performance or achievements to materially differ from any anticipated results, performance or achievements, please see our previously filed SEC reports, including those risks set forth in our 2013 Annual Report on Form 10-K and our Quarterly Report on Form 10-Q for the quarter ended June 30, 2014. We disclaim any intention or obligation to update or revise any financial or other projections or other forward-looking statements, whether because of new information, future events or otherwise.

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