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Nexeon MedSystems, Inc., Announces Enrollment of First Patient in Feasibility Trial for Novel Prohealing Stent System

New Class of Stent Could Offer Non-DES Solution to Restenosis and Late Stent Thrombosis

CHARLESTON, W.Va. & CARLSBAD, Calif.--(BUSINESS WIRE)--

Nexeon MedSystems, Inc., a developer of medical technology for the treatment of cardiovascular disease, announced today that the company has initiated PROTEX I, a first-in-man trial designed to evaluate the safety of the prohealing PROTEX(TM) Coronary Stent System for the treatment of coronary artery disease. The first patient was enrolled by Professor Eberhard Grube, Chief of Cardiology and Angiology, Heart Center Siegburg in Siegburg, Germany.

"The enrollment of the first patient in Nexeon's initial clinical trial marks a significant milestone for the company and is the culmination of many years work from talented clinicians, engineers and scientists," said Mark C. Bates, M.D., CEO and founder of Nexeon MedSystems, professor of Medicine and Surgery at West Virginia University, and leading interventional cardiologist at CAMC Vascular Center of Excellence in Charleston. "Preclinical studies suggest that this prohealing alternative to the delayed healing seen with DES systems may give way to an entirely new class of stents that combat restenosis while eliminating the risk of late stent thrombosis."

The investigational PROTEX Coronary Stent System is designed to offer an advantage over currently available therapies by reducing or eliminating rates of two complications of some stenting procedures: that of late stent thrombosis, a rare but potentially fatal occurrence following implantation of a drug eluting stent, and that of restenosis, or the re-narrowing of the stented vessel, which occurs in approximately 20 percent of bare metal stent procedures. In addition, the PROTEX Stent System may eliminate the need for long-term antiplatelet therapy, thereby decreasing costs and reducing bleeding risks to the patient.

The PROTEX system integrates Nexeon's unique low-profile (0.86 mm) cobalt alloy stent platform with SurModics, Inc.'s (Nasdaq: SRDX) Finale(TM) prohealing extracellular matrix coating. This thin layer of natural coating is designed to promote rapid population of normal lining cells (endothelialization) rather than scar tissue, resulting in a healthy, functional artery. The stent system is the result of the collaboration between Nexeon MedSystems and SurModics announced in July 2007.

The trial, called PROTEX I, will enroll 50 patients at five sites in Europe. Follow-up examinations will be performed at 30 days, six months and nine months. The six-month

follow-up examination will evaluate both neointimal volume by intravascular ultrasound (IVUS) and percent binary restenosis by angiography. Dr. William Wijns, M.D., of the Cardiovascular Center Aalst in Belgium, will serve as the principal investigator of the clinical trial.

"There is a significant clinical need for a low-restenosis stent that does not carry the late-thrombosis risk of drug-eluting stents," said Dr. Wijns. "I am excited about the potential of this type of breakthrough coating on a highly deliverable coronary stent."

About the PROTEX Stent System

The investigative PROTEX Stent System's Finale(TM) Prohealing Coating, developed by SurModics, is designed to accelerate tissue repair through the body's own healing mechanisms by attracting endothelial cells from the surrounding tissue and circulating endothelial progenitor cells. Since the nanolayer of coating accelerates healing, only a short one-month antiplatelet therapy regimen is expected to be required. This regimen contrasts with the minimum one-year antiplatelet therapy regimen recommended for patients treated with drug eluting stents.

The stent platform used in the system incorporates Nexeon's Inversion Point(TM) technology, making the crossing profile of the cobalt alloy PROTEX stent 20 percent lower than today's market-leading bare metal stent, resulting in a highly deliverable system that retains important front-line stent characteristics such as radial strength, vessel coverage, and visibility.

About Nexeon MedSystems, Inc.

Nexeon MedSystems, Inc. is committed to saving and improving lives through the development of breakthrough therapies for cardiovascular disease. With proven medical device industry engineering talent, a strong intellectual property portfolio and the leadership of a veteran interventional cardiologist, Nexeon has created an extensive pipeline of products that promise to bring physician-led innovation to common clinical problems. Privately held, the company is based in Charleston, W.Va., with a research and development innovation center in Carlsbad, Calif. For more information please visit www.nexeonmedsystems.com.

Source: Nexeon MedSystems, Inc.