Cordis and Medinol Announce FDA Approval of the Innovative EluNIR Drug-Eluting Stent System

EluNIR is shown to effectively treat highly complex disease with optimized stent and delivery system

DUBLIN, Ohio, Nov. 30, 2017 /PRNewswire/ -- Cordis, a Cardinal Health company, and Medinol today announced United States Food and Drug Administration (FDA) approval of the EluNIR™ drug-eluting stent (DES) for the treatment of patients with narrowing or blockages to their coronary arteries. The EluNIR™ stent system is designed with a novel metallic spring tip and the narrowest strut width of any stent on the U.S. market to help clinicians easily deliver this new DES in highly complex anatomy and disease.

The EluNIR™ DES demonstrated outstanding efficacy and safety results in two randomized clinical trials, including BIONICS, a global pivotal study of 1,919 patients from 76 sites in eight countries. In BIONICS, the EluNIR™ stent demonstrated a 5.4 percent Target Lesion Failure (TLF), the lowest reported TLF in a contemporary U.S. pivotal study, and a zero percent rate of late stent thrombosis at 12 months. Medinol recently obtained CE-mark for the EluNIR™ stent, and it is currently being used by physicians in Europe.

"The BIONICS study demonstrated the excellent performance of the EluNIR™ DES in a broad, less selected, 'more comers' population," said David Kandzari, M.D., F.A.C.C., director of Interventional Cardiology at Piedmont Heart Institute in Atlanta, and principal investigator for the BIONICS trial. "Clinicians now have another safe, reliable option for treating the many patients whose lives are impacted by coronary artery disease."

Cardinal Health's long-term distribution agreement with Medinol enables Cordis, Cardinal Health's interventional vascular business, to sell Medinol's coronary stent portfolio, which now includes the EluNIR™ DES and NIRxcell™, a cobalt-chromium bare metal stent (BMS), in the U.S.

"The FDA approval of the EluNIR™ stent expands the Cordis portfolio with a DES designed for deliverability, in even highly complex cases, with its novel stent and delivery system," said Luis Davila, vice president of R&D at Cordis. "Cordis is committed to ensuring physicians will soon have this new DES in their Cath Labs to deliver the best patient care available."

"Medinol has a legacy of developing innovative interventional cardiovascular technologies, which has culminated today with the FDA approval of the EluNIR™ DES," said Dr. Yoram Richter, chief scientific officer at Medinol. "For more than 20 years, Medinol has continuously raised the bar for the quality and performance of stenting systems. With our innovative manufacturing process, the EluNIR™ DES offers clinicians the latest generation DES. Notably, the FDA approval of the EluNIR™ DES marks the first such approval for a privately held company based outside of the U.S."

About Percutaneous Coronary Intervention (PCI)
PCI is a nonsurgical procedure that often uses a catheter to place a stent to open blocked coronary arteries caused by coronary artery disease, which is a common type of cardiovascular disease. Cardiovascular disease is the leading global cause of death, accounting for more than 17.3 million deaths per year in 2013, a number that is expected to grow to more than 23.6 million by 2030. In the U.S., about 2,200 people die of cardiovascular disease each day, an average of one death every 40 seconds.[i]

About Medinol
Medinol was founded in 1992 by Drs. Judith and Kobi Richter. It's a privately held company with offices in

the U.S. and Israel and employs more than 400 people. Medinol has an extensive patent portfolio, including a long, established history in the coronary stent market over the past 20 years. The unique design of its products, along with its rigorous standards of manufacturing and safety, makes Medinol a leading developer in this space. All Medinol's cardiovascular intervention solutions are manufactured in-house using its proprietary QualitySurface™ manufacturing technology. This unique manufacturing method enables Medinol to conduct strict and automated quality control on each individual stent, ensuring consistently exceptional product quality and safety. Medinol's EluNIR™ DES was developed to offer clinicians a new generation DES with an optimized stent and delivery system. With more than two million stents delivered globally to date, Medinol's cutting-edge cardiovascular intervention technology continues to demonstrate extraordinary clinical results.

About Cardinal Health
Cardinal Health, Inc. is a global, integrated healthcare services and products company, providing customized solutions for hospitals, healthcare systems, pharmacies, ambulatory surgery centers, clinical laboratories and physician offices worldwide. The company provides clinically proven medical products and pharmaceuticals and cost-effective solutions that enhance supply chain efficiency from hospital to home. Cardinal Health connects patients, providers, payers, pharmacists and manufacturers for integrated care coordination and better patient management. Because Cardinal Health helps ensure pharmacists and the consumers they serve have access to medications they need while working to help prevent prescription drug diversion, the company and its education partners created Generation Rx, a national program to help prevent the misuse of prescription medications. Backed by nearly 100 years of experience, with approximately 50,000 employees in nearly 60 countries, Cardinal Health ranks #15 on the *Fortune* 500. For more information, visit cardinalhealth.com, follow @CardinalHealth on Twitter and connect on LinkedIn at linkedin.com/company/cardinal-health.

[i] https://www.heart.org/idc/groups/ahamah-public/@wcm/@sop/@smd/documents/downloadable/ucm_491265.pdf

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