Cordis Receives FDA Approval for New Product To Treat Patients In-Stent Restenosis

MIAMI, Nov. 6 -- Cordis Corporation -- the Johnson & Johnson company that pioneered the cardiovascular stent -- received U.S. Food and Drug Administration approval on Friday to market the CHECKMATE(TM) System, an intravascular brachytherapy (radiation) system for recurrent blockages in coronary arteries previously treated with coronary artery stents.

"Over the past few years, we've witnessed incredible advances in the treatment of coronary artery disease, particularly in the area of coronary artery stents, the tiny mesh braces used to prop open narrowed heart vessels. But, until now, no development has been able to overcome the obstacle of recurrent blockages, or 'in-stent restenosis,' in treated coronary artery lesions," said Paul Teirstein, M.D., Director of Interventional Cardiology, Scripps Clinic, La Jolla, Calif., and a key investigator in the CHECKMATE System clinical trials.

"Our CHECKMATE System offers the unprecedented opportunity to make the winning move in this ongoing battle against in-stent restenosis," said Cordis Cardiology U.S. President Jesse Penn, who estimates 100,000 patients in the U.S. currently contend with recurrent in-stent restenosis.

Mr. Penn noted the incidence of in-stent restenosis has increased with advances in technology. Cardiologists can now reach and stent lesions that are inherently more prone to restenosis, such as long lesions and lesions in small vessels.

"Small vessels and long lesions are especially common among diabetics. The CHECKMATE System has produced some outstanding efficacy results in a variety of patients, including diabetics," said Mr. Penn.

Following placement of a coronary artery stent, the vessel wall sometimes responds by forming scar tissue that pushes through the openings in the stent mesh. The CHECKMATE System is intended to interrupt scar tissue growth in the vessel wall. This new system uses the gamma-radiating source Iridium-192 (Ir-192). Tiny Ir-192 seeds are encased in a source ribbon and delivered through a catheter to the site of blockage. The source ribbon is left in place for approximately 15 to 20 minutes and is then withdrawn.

Mr. Penn cited Cordis' partnerships with Best Medical and Varian (as suppliers of the source ribbon) and Nelco (for assistance in radiation readiness) as key to introducing this revolutionary new treatment.

"Physicians and patients can view this new therapy with tremendous optimism," said Dr. Teirstein. "Results of major clinical trials document both safety and effectiveness."

According to Dr. Teirstein, the radiation safety record of the CHECKMATE System is unsurpassed. In more than 1,000 patients treated in the United States, there have been no reportable events.

More information about the CHECKMATE System and other Cordis products is available at http://www.cordis.com.

Since its establishment in 1959, Cordis Corporation, along with its subsidiaries, has been a pioneer in circulatory disease management. Cordis is the world's largest, most comprehensive developer and manufacturer of innovative products for interventional medicine, minimally invasive computer-based imaging, and electrophysiology. In 1996, Cordis Corporation merged with Johnson & Johnson to form Cordis, a Johnson & Johnson company, with approximately 3,500 employees worldwide. SOURCE Cordis Corporation

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