Cook Medical’s Zilver® PTX® Earns FDA Approval As First Drug-Eluting Stent in U.S. to Treat Peripheral Arterial Disease

The Associated Press

BLOOMINGTON, Ind.--(BUSINESS WIRE)--Nov 15, 2012--Cook Medical has received U.S. Food and Drug Administration (FDA) marketing approval for the first devices in its Zilver® PTX® Drug-Eluting Peripheral Stent portfolio, company officials reported today. It’s the first time the FDA has approved a drug-eluting stent to treat blockages in a peripheral artery.

“This approval marks the start of Cook’s program to bring the benefits of drug elution to U.S. physicians treating the peripheral arteries,” said Rob Lyles, vice president and global leader of Cook Medical’s Peripheral Intervention division. “No other company can match Cook’s commitment to this technology, and by the end of 2013, we expect to have a full suite of drug-eluting peripheral stents in the most commonly used lengths and diameters available to U.S. physicians.” The Zilver PTX Drug-Eluting Stent is intended to treat peripheral arterial disease (PAD) in the superficial femoral artery (SFA).

In order to supply as many physicians as possible with this new technology, Cook is making Zilver PTX available initially in 80 mm lengths in 6 mm and 7 mm diameters. The products indications for use also allow two Zilver PTX 80 mm stents to be overlapped to treat longer lesions up to 140 mm. The FDA approval also includes 40 mm and 60 mm lengths, which will be introduced to the U.S. early in 2013. Cook expects to receive regulatory approval for 120 mm length stents in both diameters next year.

Data from Cook’s pivotal clinical trial indicate: Eight out of ten patients treated with Zilver PTX still had open arteries (primary patency) after one year 1. That compares to only 3 out of 10 patients treated with angioplasty alone. Patients who received a bare metal stent required more than twice as many reintervention procedures to reopen the SFA as patients who received Zilver PTX. 2 “After conducting the largest randomized controlled study of peripheral stenting ever undertaken, we now see remarkable results in patients treated with Zilver PTX,” said Michael Dake, M.D., a professor in the Department of Cardiothoracic Surgery at Stanford University School of Medicine and medical director of the Cath/Angio Laboratories at Stanford Medical Center, Palo Alto, Calif.

“With this approval, treating PAD in the U.S. will begin to undergo the same revolution that drug elution did for treating coronary artery disease,” added Gary Ansel, M.D., director for the Center for Critical Limb Care at Riverside Methodist Hospital in Columbus, Ohio, and an assistant clinical professor of medicine in the Department of Internal Medicine at the University of Toledo Medical Center in Toledo, Ohio. “Drug-eluting stents such as Zilver PTX will move quickly, in my

opinion, to become the standard of care for PAD patients worldwide.” Cook’s Zilver PTX stent is already approved for sale in more than 50 markets, including the European Union, Japan, Brazil and most of South America, Australia, New Zealand and Taiwan. The device is being introduced to the U.S. market in a five-step process designed to make this technology available to as many patients as possible initially.

(Drs. Dake and Ansel, who served as global principal investigators for the Zilver PTX clinical trial, are paid consultants to Cook Medical with respect to its medical devices.) About Zilver PTX How does Zilver PTX work? A physician gains arterial access through the groin and guides a Zilver PTX stent to the narrowed artery with a catheter. The stent is deployed and expands like a scaffold to help keep the artery open after the catheter is withdrawn. The drug paclitaxel, which coats the stent, is taken up by the cells of the arterial wall to help prevent the renarrowing of the artery over time.

What are the main features of the device? A combination therapy device, Zilver PTX both restores patency (blood flow) and provides targeted delivery of paclitaxel, a cell growth-limiting drug proven to reduce arterial restenosis (post-procedural blockages). This drug coats the stent without the use of a polymer, eliminating risks that may arise directly from a polymer. Zilver PTX is made of nitinol, a "shape memory" metal alloy, and is engineered to withstand the dynamic forces of the superficial femoral artery (SFA). Zilver PTX is the first peripheral vascular device that combines the mechanical support of stenting with the drug paclitaxel to reduce the risk of restenosis.

What data supports the efficacy of Zilver PTX? 3 Two-year data from the Zilver PTX Randomized Controlled Trial of Paclitaxel-Eluting Stents for Femoropopliteal Disease indicate that the stent demonstrated 74.8 percent primary patency at 24 months in the PTX group, compared to just 57.8 percent for patients with optimal percutaneous transluminal angioplasty and bare metal stents in the 479 patient study.

What are other current means of treatment for PAD? 4 Current treatment options for PAD include lifestyle changes, medication, exercise, angioplasty, bare metal stenting and bypass surgery.

What is Zilver PTX indicated for and what are the risks and contraindications for this device? INDICATIONS: indicated for improving luminal diameter for the treatment of de novo or restenotic symptomatic lesions in native vascular disease of the above-the-knee femoropopliteal arteries having reference vessel diameter from 4mm to 7mm and total lesion lengths up to 140 mm per limb and 280 mm per patient. CONTRAINDICATIONS: Women who are pregnant, breastfeeding, or plan to become pregnant in the next 5 years should not receive a Zilver PTX Drug-Eluting Peripheral Stent. Patients who cannot receive recommended anti-platelet and/or anti-coagulant therapy. Patients judged to have a lesion that prevents proper placement of the stent or stent delivery system. WARNINGS: Persons with allergic reactions to nitinol may suffer an allergic reaction to this implant • Persons allergic to paclitaxel may suffer an allergic reaction to this implant • The safety and effectiveness of implanting more than four Zilver PTX Drug Eluting Peripheral Stents in a patient has

not been clinically evaluated. PRECAUTIONS: To avoid involvement of the common femoral artery, the proximal end of the stent should be placed at least 1 cm below the origin of the superficial femoral artery. To avoid involvement of the below-the-knee popliteal artery, the distal end of the stent should be placed above the plane of the femoral epicondyles • This product is intended for use by physicians trained and experienced in diagnostic and interventional vascular techniques. Standard techniques for interventional vascular procedures should be employed • Manipulation of the Zilver PTX Drug-Eluting Peripheral Stent requires fluoroscopic control • Do not try to remove the stent from the introducer system before use • Ensure that the red safety lock is not inadvertently removed until final stent release • Deploy the stent over an extra stiff or ultra stiff wire guide • Do not push the hub toward the handle during deployment • Do not expose the delivery system to organic solvents (e.g., alcohol) • Do not use power injection systems with the delivery system • Do not rotate any part of the system during deployment • The device is intended for single use only. Do not resterilize and/or reuse this device • Repositioning of the device after deployment is not possible since the introducer catheter cannot be re-advanced over the stent once deployment begins. POTENTIALADVERSE EVENTS: Potential adverse events that may occur include, but are not limited to Allergic reaction to anticoagulant and/or antithrombotic therapy or contrast medium • Allergic reaction to nitinol • Arterial aneurysm • Arterial rupture • Arterial thrombosis • Arteriovenous fistula • Atheroembolization (Blue Toe Syndrome) • Death • Embolism • Hematoma/hemorrhage • Hypersensitivity reactions • Infection • Infection/abscess formation at access site • Ischemia requiring intervention (bypass or amputation of toe, foot or leg • Pseudoaneurysm formation • Renal failure • Restenosis of the stented artery • Stent embolization • Stent malapposition • Stent migration • Stent strut fracture • Vessel perforation or rupture • Worsened claudication/rest pain. Paclitaxel: Although systemic effects are not anticipated, refer to the Physicians' Desk Reference for more information on the potential adverse events observed with paclitaxel. Potential adverse events, not described in the above source, may be unique to the paclitaxel drug coating, including • Allergic/immunologic reaction to the drug coating • Alopecia • Anemia • Blood product transfusion • Gastrointestinal symptoms • Hematologic dyscrasia (including leukopenia, neutropenia, thrombocytopenia) • Hepatic enzyme changes • Histologic changes in vessel wall, including inflammation, cellular damage, or necrosis • Myalgia/Arthralgia • Myelosuppression • Peripheral neuropathy About Cook Medical A global pioneer in medical breakthroughs, Cook Medical is committed to creating effective solutions that benefit millions of patients worldwide. Today, we combine medical devices, drugs, biologic grafts and cell therapies across more than 16,000 products serving 41 medical specialties. Founded in 1963 by a visionary who put patient needs and ethical business practices first, Cook is a family-owned company that has created more than 10,000 jobs worldwide. For more information, visit www.cookmedical.com. Follow Cook Medical on Twitter and LinkedIn.

1 , 2 Dake M., et. Al, Paclitaxel-Eluting Stents Show Superiority to Balloon Angioplasty and Bare Metal Stents in Femoropopliteal Disease: Twelve Month Zilver PTX Randomized Study Results. Circulation: Cardiovascular Interventions, August 5, 2011 2 Dake M. Zilver PTX Randomized Controlled Trial of Paclitaxel-Eluting Stents for Femoropopliteal Disease: Two Year Results, Presented at International Symposium on Endovascular Therapies (ISET), January 17, 2011, Miami Beach,

Florida 3 Dake M. Zilver PTX Randomized Controlled Trial of Paclitaxel-Eluting Stents for Femoropopliteal Disease: Two Year Results, Presented at International Symposium on Endovascular Therapies (ISET), January 17, 2011, Miami Beach, Florida 4 National Institute of Health, National Heart Lung and Blood Institute. How Is Peripheral Arterial Disease Treated? http://www.nhlbi.nih.gov/health/health-topics/topics/pad/treatment.html. Accessed August 10, 2012
CONTACT: Cook Medical David McCarty, 812-339-2235, ext. 2387 Global Director, Public Relations dave.mccarty@cookmedical.com or Racepoint Group Jackie Hanley and Cheri Keith 617-794-6939 and 781-258-6727 jhanley@racepointgroup.com ckeith@racepointgroup.com
KEYWORD: UNITED KINGDOM UNITED STATES EUROPE ASIA PACIFIC NORTH AMERICA CENTRAL AMERICA SOUTH AMERICA CANADA INDIANA MIDDLE EAST IRELAND INDUSTRY KEYWORD: SURGERY HEALTH BIOTECHNOLOGY CARDIOLOGY HOSPITALS MEDICAL DEVICES PHARMACEUTICAL OTHER HEALTH MEDICAL SUPPLIES GENERAL HEALTH SOURCE: Cook Medical
Copyright Business Wire 2012 PUB: 11/15/2012 03:58 PM/DISC: 11/15/2012 03:58 PM http://www.businesswire.com/news/home/20121115006771/

Source URL (retrieved on *04/25/2014 - 2:52am*):
http://www.mdtmag.com/news/2012/11/cook-medical%E2%80%99s-zilver%C2%AE-ptx%C2%AE-earns-fda-approval-first-drug-eluting-stent-us-treat-peripheral-arterial-disease