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PRAIRIE EDUCATION & RESEARCH COOPERATIVE (PERC) AND ST. JOHN'S HOSPITAL FIRST TO ENROLL PATIENT IN WORLDWIDE DRUG-COATED BALLOON TRIAL

New Device Under Study May Help Patients with Peripheral Arterial Disease

Springfield, IL – Prairie Cardiovascular Cardiologists at St. John's Hospital were the first to enroll a patient into Lutonix's LEVANT 2, a global, multicenter, randomized trial evaluating the safety and efficacy of the Moxy™ Drug Coated Balloon compared to a standard angioplasty balloon for the treatment of peripheral arterial disease (PAD). Dr. Jeffrey Goldstein, an interventional cardiologist at St. John's, performed the first case.

LEVANT 2 is the first drug-coated balloon pivotal trial to be approved by the FDA. PERC, along with St. John's, is one of only 55 centers around the world participating in the trial, which is expected to randomize 476 patients with diseased femoropopliteal leg arteries. The trial will investigate whether the Moxy balloon is more effective than standard angioplasty at keeping leg arteries open and free from re-blockage over time.

LEVANT 2 is the largest randomized peripheral drug-coated balloon trial to date, and one of the largest peripheral vascular studies ever conducted. The purpose of this study is to investigate if the treatment of narrowed leg blood vessels with the Moxy Drug Coated Balloon is safe and beneficial. This study has been approved for use by the Food & Drug Administration (FDA) in order to determine if this treatment is safe and beneficial. The Moxy Drug Coated Balloon is designed to help reduce the occurrence of re-narrowing in the treated leg vessel. It is believed that after the treatment opens the vessel, the drug delivered during the inflation will help reduce the potential for the vessel to re-narrow over time, which may reduce the need for further procedures.

“PERC and St. John's Hospital have a long history of making significant scientific contributions that help advance patient care and our understanding of disease process,” said Dr. Jeffrey Goldstein, site principal investigator of LEVANT 2. “We are proud to play a role in such an important trial.”

Drug-coated balloons are similar to standard angioplasty balloons except they are coated with an anti-restenotic drug aimed at preventing the artery from becoming blocked again. During the procedure, the Moxy balloon is inserted inside the narrowed area of the artery and then inflated in order to open the blockage and deliver the drug to the artery. After this short inflation, the balloon is removed from the body, leaving nothing but the drug coating behind in the artery.

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“Although there are several treatment options currently available for patients with peripheral arterial disease, none have proven to be as effective or durable as we’d like,” said Dr. Krishna Rocha-Singh, PERC Medical Director. “We are excited to explore whether a drug-coated balloon is able to provide better long-term results.”

LEVANT 2 is a follow-on trial to LEVANT 1, which was a 101-patient multicenter randomized trial. Patients either received the Moxy balloon or standard angioplasty for the treatment of diseased femoropopliteal arteries. Based on the success and positive results of the LEVANT 1 trial, LEVANT 2 was designed to investigate the device in a larger patient population.

“In trials of this magnitude and scientific rigor, it’s imperative to have world-class research centers as your partners in the process. St. John’s is such an institution and we are greatly appreciative of the early leadership role they’ve taken by enrolling the first patient,” said Dr. Dennis Wahr, CEO and co-founder of Lutonix.

About Restenosis

Restenosis refers to the re-narrowing of an artery following angioplasty or stenting. Restenosis is caused by an overgrowth of tissue inside the artery, typically in response to arterial injury at the original treatment site.

Restenosis often occurs within the first six months following an intervention, and most often results in re-treatment.

About the Moxy Drug Coated Balloon

The Moxy balloon is very similar to a standard angioplasty balloon, but is coated with an anti-restenotic drug designed to help keep arteries open and free from re-blockage. During the procedure, the Moxy balloon is inflated for 30-seconds during which it opens up the artery to restore blood flow, and delivers the drug into the artery wall. The Moxy balloon is then removed from the body leaving nothing behind but the drug coating, which works inside the artery over time to prevent restenosis. The Moxy balloon is an investigational device, which is not approved for, or available for sale in, the United States.

About Prairie Education & Research Cooperative (PERC): Prairie Education and Research Cooperative is the non-for-profit research division for Prairie Cardiology, founded in 1983. PERC was established to facilitate cardiovascular and vascular clinical research.

About Hospital Sisters Health System: Hospital Sisters Health System (HSHS) is a multi-institutional health care system that operates 13 hospitals in 12 communities across Illinois and Wisconsin and an integrated physician network. As our name implies, we are a healing ministry guided by the historic mission of the Hospital Sisters of St. Francis. At the same time, we are firmly grounded in modern best practices. Learn more by visiting www.hshs.org.

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