Shockwave Medical Announces U.S. Commercial Availability of Lithoplasty® System and Enrollment of First Patient in DISRUPT PAD III Global Clinical Trial

Novel Technology Uses Sonic Pressure Waves to Treat Peripheral Artery Blockages

FREMONT, Calif. -- June 21, 2017 -- Shockwave Medical, a pioneer in the treatment of calcified cardiovascular disease, today announced two milestones for its Lithoplasty® System for the treatment of calcified plaque in patients with peripheral artery disease (PAD): enrollment of the first patient in the global DISRUPT PAD III clinical trial at the Medical University of Graz, Austria, and the treatment of the first patient in a commercial case in the United States, at Pottstown Memorial Medical Center in Pottstown, Pa.

The Lithoplasty System is an innovative therapy designed to treat calcified leg artery blockages with lithotripsy, sonic pressure waves historically used to treat patients with kidney stones. The technology is now commercially available in both the United States and Europe for the treatment of calcified plaque in peripheral arteries.

DISRUPT PAD III is the largest ever multi-center randomized trial to exclusively enroll patients with heavily calcified PAD. The objective of the post-market trial is to assess the optimal therapy to dilate heavily calcified lesions by comparing the Shockwave Medical Lithoplasty System versus traditional angioplasty, with a primary goal of achieving less than 30 percent residual stenosis without the need for stenting. In addition, all patients who do not receive a stent will be treated with a drug-coated balloon. The trial will enroll 334 patients in up to 45 global sites.

Marianne Brodmann, M.D., of the Medical University of Graz, Austria, enrolled the first patient in the trial.

“I’m pleased to be taking part in this important study of the Lithoplasty System for the treatment of complex peripheral artery disease,” said Prof. Brodmann. “Patients with challenging heavily calcified PAD have been excluded from previous drug coated balloon trials. The results of the DISRUPT PAD III randomized trial will bear important implications for treatment of this very important patient population.”

Edward Pavillard, D.O., a vascular surgeon with Pottstown Memorial Medical Center, used the Lithoplasty System to treat a patient with PAD in the first commercial U.S. case.

“Peripheral artery disease is a common, painful and possibly limb threatening disease that can be challenging to treat,” Dr. Pavillard said. “Calcified plaque has long been an Achilles heel for many endovascular interventions. The Lithoplasty System is a significant advancement in the treatment of PAD, as it provides a new treatment option with potentially less risk of damage or injury to the vessel. I am excited to be among the first in the United States to use this technology to help restore blood flow and improve the quality of life for my patients with complex, traditionally difficult to treat peripheral lesions.”

About Shockwave Medical’s Lithoplasty® System

Shockwave Medical’s Lithoplasty System integrates angioplasty balloon catheter devices with the calcium-disrupting power of sonic pressure waves, known as lithotripsy. Each Lithoplasty catheter incorporates multiple lithotripsy emitters activated with the touch of a button after the integrated balloon is inflated. Once activated, these emitters

produce therapeutic sonic pressure waves that are inherently tissue-selective, passing through the balloon and soft vascular tissue, preferentially disrupting the calcified plaque inside the vessel wall by creating a series of micro-fractures. When the calcium has been modified, the vessel can be dilated using low pressures, thereby enabling even historically challenging PAD patients to be treated effectively with minimal injury to the vessel.

To view an animation of the Lithoplasty System visit http://shockwavemedical.com.

The Shockwave Medical Lithoplasty System is intended for lithotripsy-enhanced balloon dilatation of lesions, including calcified lesions, in the peripheral vasculature, including the iliac, femoral, ilio-femoral, popliteal, infra-popliteal, and renal arteries. Not for use in the coronary or cerebral vasculature.

About Shockwave Medical
Shockwave Medical, based in Fremont, Calif., is working to reshape interventional therapy with Lithoplasty® Technology for the treatment of calcified peripheral vascular, coronary vascular and heart valve disease. For more information, visit www.shockwavemedical.com.

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