Shockwave Medical Reports Positive Results from First Study of Lithoplasty System in Calcified Coronary Lesions

- Intravascular imaging sub-study demonstrates unique modification of calcium
- Study demonstrates safety and effective dilation of calcified lesions

Fremont, Calif. and Washington, D.C. — October 31, 2016 — Shockwave Medical, a pioneer in the treatment of calcified cardiovascular disease, today reported positive safety, performance and intravascular imaging data from the DISRUPT CAD study at the annual Transcatheter Cardiovascular Therapeutics (TCT) conference taking place at the Washington Convention Center in Washington, D.C.

DISRUPT CAD, a pre-market, prospective multi-center single arm study conducted at seven centers in Europe and Australia, evaluated the use of the Shockwave Medical Coronary Lithoplasty System as a treatment for calcified coronary arteries prior to drug-eluting stent (DES) implantation. The principal investigators of the study were Jean Fajadet, M.D., co-director of the Interventional Cardiovascular Group at Clinique Pasteur in Toulouse, France, and Carlo Di Mario, M.D., professor of Clinical Cardiology, Royal Brompton Hospital, London.

The study enrolled 60 patients with complex calcified obstructive coronary artery disease, including 80% of patients who were classified as having severe calcification. Acute performance results showed high device success (98%) and excellent angiographic outcomes, in particular a large acute gain in vessel diameter (1.7 mm) and low residual percent stenosis (13%) post procedure. Safety results demonstrate minimal vascular injury, with no incidence of perforation, abrupt closure or slow/no-reflow events. The rate of major adverse cardiac events (MACE) at 30 days was low (5%), with all events being non-Q wave myocardial infarction.

Intravascular imaging was performed using optical coherence technology (OCT) on 31 of 60 patients and demonstrated that calcium was fractured completely through all calcified layers of the artery and around the circumference of the artery. The resulting gain in luminal area after treatment was significant and was achieved independent of the degree of calcification.

“The resistance to balloon expansion is fundamentally reduced after the disruption of both superficial and deep calcium with the Lithoplasty System, which enables successful DES implantation with uniform expansion and minimal complications,” said Todd Brinton M.D., clinical associate professor of Medicine at Stanford University and co-founder of Shockwave Medical, who presented the data today. “The OCT results demonstrate that Lithoplasty is modifying arterial calcium in a unique way not seen before. The data demonstrate an ability to dilate calcified lesions safely, independent of the degree of calcium, which is unprecedented and highly encouraging for this difficult-to-treat patient cohort who often experience suboptimal results.”

Shockwave Medical developed the Lithoplasty System to address unmet needs in the treatment of calcified arteries. The presence of calcified coronary artery disease leads to suboptimal outcomes for all treatment options – medical therapy, interventional treatment and cardiac surgery.[1] For angioplasty with a stent, the presence of calcified

lesions is associated with suboptimal lesion expansion, poor stent apposition and complications, including dissection, distal embolization, coronary hypoperfusion and procedural failure.[2] Current adjunctive devices designed to modify coronary calcium are either balloon- or atherectomy-based, but their routine use is limited due to risk of complications, degree of technical difficulty, operator dependency or lack of sufficient evidence[1,3].

“These early results of Lithoplasty in the coronary arteries are highly encouraging, particularly considering the severity of calcification of the patients enrolled in the trial,” said Dr. Fajadet. “Calcification in cardiovascular arteries create numerous treatment challenges. These data demonstrate an effective preparation of the vessel for stent implantation with minimal complications. In addition, because the device is a balloon, the technical challenges associated with treating these complex patients are significantly reduced.”

About Shockwave Medical’s Lithoplasty® System

The Shockwave Medical Lithoplasty System is the first-ever device designed to selectively target hardened calcium in patients with cardiovascular disease. The system integrates the calcium-disrupting power of lithotripsy with the familiarity and simplicity of a balloon angioplasty. Built on a deliverable balloon catheter platform, the device emits intermittent sound waves (lithotripsy) that target and disrupt calcified plaques that then require only a low-pressure balloon inflation to dilate the blockage and restore blood flow. The result is an effective and consistent revascularization of calcified lesions while minimizing complications.

The Peripheral Lithoplasty System is commercially available in the European Union and the United States for treatment of peripheral vascular disease. The Coronary Lithoplasty System is an investigational device and is not available for sale.

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

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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[2] Lee M, Shah N. The Impact and Pathophysiologic Consequences of Coronary Artery Calcium Deposition in Percutaneous Coronary Interventions. J Invasive Cardiol 2016;28(4):160-167.
[3] Tomey M, Kini A, Sharma S. Current Status of Rotational Atherectomy. J Am Coll Cardiol Intv 2014;7:345–53.

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