SHOCKWAVE MEDICAL INC | Disrupt Calcium. Restore Flow. Expand Possibilities.™

Shockwave Medical Announces CE Mark for Coronary Lithoplasty® System and Activities at EuroPCR 2017

First-In-Human Data from Study of Lithotripsy for the Transcatheter Treatment of Aortic Valve Stenosis to be Presented in Paris

FREMONT, Calif.-- May 15, 2017 --Shockwave Medical, a pioneer in the treatment of calcified cardiovascular disease, today announced conformité européenne (CE) Mark for the company's Coronary Lithoplasty® System for the treatment of calcified plaque in conjunction with stenting in patients with coronary artery disease.

The Shockwave Medical Coronary Lithoplasty System is an innovative therapy designed to treat calcified coronary artery blockages with lithotripsy, sonic pressure waves historically used to treat patients with kidney stones.

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] Specialty balloons and atherectomy are current adjunctive therapies designed to modify coronary calcium. Their use is limited due to risk of complications, degree of technical difficulty, operator dependency or lack of sufficient evidence.[1,3]

"Cardiovascular calcification presents a persistent treatment challenge for the interventionalist," said Jean Fajadet, M.D., co-director of the Interventional Cardiovascular Group at Clinique Pasteur in Toulouse, France, and co-principal investigator of the DISRUPT CAD I clinical trial of the technology. "The use of Lithoplasty in the coronary arteries is an important new option that has shown, in the DISRUPT CAD I clinical study of the device, to effectively prepare the vessel for stent implantation with minimal complications. I look forward to commercial availability of the system."

Safety and performance was supported by clinical data from results of DISRUPT CAD I, a pre-market, prospective multi-center single-arm study conducted at seven centers in Europe and Australia. The study evaluated the use of the Shockwave Medical Coronary Lithoplasty System as a treatment for calcified coronary arteries prior to drug eluting stent (DES) implantation. Primary endpoint results from the study were reported last fall at the annual Transcatheter Cardiovascular Therapeutics (TCT) conference in Washington, D.C.

"CE Mark for the Coronary Lithoplasty System is an important milestone for Shockwave Medical," said Shockwave Medical CEO Doug Godshall. "With this achievement, we are a step closer to bringing Lithoplasty to patients and physicians in Europe as a potentially paradigm-changing technology for the treatment of coronary artery disease. We look forward to sharing our final six-month results from DISRUPT CAD I at EuroPCR this week, and to continuing to gather clinical evidence on the benefits of this promising treatment for a challenging patient population."

Shockwave Announces Presentations at EuroPCR 2017

In addition, Shockwave Medical announced the following schedule of presentations at the annual EuroPCR 2017 conference taking place May 16-19 at the Palais des Congrès in Paris:

- On Tuesday, May 16, in Room 351, at 14:18, Dr. Todd Brinton will present first-in-human results of a study of lithotripsy for the transcatheter treatment of aortic valve stenosis.

- On Thursday, May 18, in Room Maillot at 09:48, Dr. Todd Brinton will present the six-month results of the DISRUPT CAD I study of Lithoplasty for the treatment of calcified coronary lesions prior to stenting.

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 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 and 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 patients to be treated effectively with minimal injury to the vessel.

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

In the European Union, the Shockwave Medical Coronary Rx Lithoplasty System is indicated for lithotripsy enhanced, low-pressure balloon dilatation of calcified, stenotic *de novo* coronary arteries prior to stenting.

The Shockwave Medical Coronary Lithoplasty System and the Shockwave Medical Transcatheter Aortic Valve Lithotripsy System are investigational devices in the United States and are not available for sale.

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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1 Madhavan M, Généreux P, et al. Coronary Artery Calcification: Pathogenesis and Prognostic Implications. J Am Coll Cardiol 2014;63:1703–14.
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.