Shockwave Medical Announces FDA Clearance of the Company's Lithoplasty® System, the First and Only Technology to Use Sound Waves to Treat Calcified Peripheral Artery Disease

- *Revolutionary Technology Breaks Up Hardened Calcium, Minimizing Damage to Vessels*
- *Treating Calcified Plaque is a Growing Challenge for Physicians in an Aging Patient Population*

Fremont, Calif. — September 16, 2016 — Shockwave Medical, a pioneer in the treatment of calcified cardiovascular disease, today announced clearance from the U.S. Food and Drug Administration (FDA) of the Lithoplasty® System for the treatment of calcified plaque in patients with peripheral artery disease (PAD).

PAD, affecting nearly nine million people in the U.S.,[1] blocks blood flow to the legs and feet, causing significant pain and limited mobility potentially leading to surgery or even amputation in severe cases. Arterial calcification, caused by plaque that hardens over time, is increasingly common as preventive care and disease management have enabled patients to live longer, making vascular disease a chronic condition. In fact, over half of all patients with peripheral vascular disease have moderate or severe calcification in their arteries.[2] Unfortunately, limitations of currently available interventional devices make successful treatment of patients with calcified arteries increasingly more difficult. The Shockwave Medical Lithoplasty System is designed to overcome those limitations.

The Shockwave Medical Lithoplasty System is the first-ever device designed to selectively target hardened calcium in patients with cardiovascular disease. The device integrates two familiar and powerful technologies: the calcium-disrupting power of sound waves (known as "lithotripsy", which is commonly used to treat patients with kidney stones) with the simplicity of angioplasty balloon catheter devices. Intermittent lithotripsy pulses disrupt both superficial and deep vascular calcium, while minimizing soft tissue injury, and an integrated angioplasty balloon expands blockages at low pressures to restore blood flow.

"Lithoplasty represents a new mechanism of treatment and is revolutionary for the care of patients with calcified peripheral vascular disease, a difficult-to-treat patient population," said Kenneth Rosenfield, M.D., Section Head for Vascular Medicine and Intervention at Massachusetts General Hospital. "Existing devices for treating these patients have significant shortcomings that make it challenging to successfully open arteries, while minimizing vascular injury and complications. Lithoplasty is a unique approach that allows us to successfully treat these diseased vessels using a device built on a familiar balloon catheter platform, while minimizing the risk of vessel injury, including dissections that require stenting or other additional interventions."

"This marks an exciting milestone for the company as we prepare to begin our commercial activities in the United States," said Shockwave Medical CEO and co-founder Daniel Hawkins. "We view this as an important validation of our technology's potential to address the burdens of vascular calcification, and we are looking forward to working with the clinical community to deeply integrate Lithoplasty into the care pathway to improve outcomes for patients with advanced cardiovascular diseases."

Positive data from the DISRUPT PAD Study, a single-arm, two-phase, multicenter study evaluating the safety and performance of the Shockwave Medical Lithoplasty System to treat peripheral artery disease, supported the clearance. Clinical data from DISRUPT PAD demonstrated compelling safety, consistent procedural success across all patient subgroups, significant and immediate increases in blood flow in treated vessels, and minimal vessel injury. The latest clinical results from the DISRUPT PAD studies will be presented at the Vascular Interventional Advances (VIVA) conference on September 19, 2016 in Las Vegas, Nev.

"We are thrilled to reach this important milestone and we look forward to partnering with physicians to help advance the treatment of peripheral artery disease," said Todd Brinton, M.D., clinical associate professor of Medicine at Stanford and co-founder of Shockwave Medical.

The company plans a limited U.S. commercial release of the Lithoplasty System in 2017 and will initiate a global randomized trial to gather further clinical data on the benefits of Lithoplasty treatment.

About Shockwave Medical's Lithoplasty® System

The Lithoplasty System integrates the calcium-disrupting power of lithotripsy with the familiarity and simplicity of angioplasty balloon-based devices. Built on a balloon catheter platform, the Shockwave Medical Lithoplasty System uses lithotripsy to disrupt both superficial and deep vascular calcium, while minimizing soft tissue injury, and an integrated angioplasty balloon to dilate blockages at low pressures, restoring blood flow. The Lithoplasty System is commercially available in the European Union and the United States for treatment of peripheral vascular disease.

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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[1]Roger VL, Go AS, Lloyd-Jones DM, et. al. Heart Disease and Stroke Statistics 2011 Update: A Report from the American Heart Association. *Circulation* 2011;123:e18-e209.

[2] Rocha-Singh KJ, Zeller T, Jaff MR. Peripheral arterial calcification: prevalence, mechanism, detection and clinical implications. Catheterization and Cardiovascular Interventions 2014; 83:E212-E220