Shockwave Medical Announces Plans for Largest-Ever Randomized Study to Prospectively Target Calcified Lesions in the Peripheral Arteries

- New comparative study to evaluate Lithoplasty in combination with drug coated balloons
- Study will provide evidence to guide treatment of difficult-to-treat patient population with no current standard of care

Fremont, Calif. and Washington, D.C. — November 1, 2016 — Shockwave Medical, a pioneer in the treatment of calcified cardiovascular disease, today announced plans for DISRUPT PAD III, the largest ever multi-center randomized study to exclusively enroll patients with calcified peripheral artery disease (PAD). Previous DISRUPT PAD studies utilized Lithoplasty as primary therapy, demonstrating safe, effective and consistent revascularization of calcified lesions while maintaining future treatment options. To date, the potential benefit of combination therapy in these patients has not yet been evaluated. DISRUPT PAD III will study use of the Shockwave Medical Lithoplasty® System in combination with drug coated balloon (DCB) therapy to assess short- and long-term outcomes compared to those achievable using traditional balloon angioplasty (PTA) prior to DCB in a calcified patient population.

"Most contemporary randomized studies in peripheral artery disease have excluded calcified lesions. The available data on this difficult-to-treat patient cohort largely comes from post-hoc, subset analyses of single-arm registries. DISRUPT PAD III will be an important study because it will provide physicians foundational Level I evidence to guide treatment of this difficult-to-treat patient cohort," said William Gray, M.D., principal investigator of DISRUPT PAD III and system chief, Division of Cardiovascular Disease at Main Line Health and president, Lankenau Heart Institute, Wynnewood, Pa. "Today, there is no clear standard of care for interventional treatment of calcified peripheral artery disease."

"DISRUPT PAD III demonstrates our ongoing commitment to advancing the science behind interventional treatment of PAD," said Daniel Hawkins, CEO of Shockwave Medical. "Modifying calcium is the first step in any successful treatment of this patient cohort. Lithoplasty technology has been shown to effectively and consistently modify calcium, enabling successful revascularization of these patients while keeping subsequent treatment options open. With the multiple treatment approaches being used in PAD intervention today, and the absence of a consistent standard, understanding the benefits of using Lithoplasty in combination with other therapies is important to advancing the data on the treatment of calcified PAD."

More than half of all patients with PAD have moderate or severe calcification.[1] Unfortunately, limitations of currently available interventional devices make successful treatment of these patients very challenging. The Shockwave Medical Lithoplasty System is designed to overcome those limitations.

In September, the Shockwave Medical Lithoplasty System received clearance from the U.S. Food and Drug Administration (FDA) for use in the peripheral vasculature, including the iliac, femoral, ilio-femoral, popliteal, infra-popliteal, and renal arteries.[2]

Six-month follow up data from the DISRUPT PAD Study, presented last month at the VIVA 16 Conference, demonstrates that Lithoplasty is safe and the results are consistent and effective in the treatment of patients with calcified lesions. The 95-patient single-arm study evaluated Lithoplasty as a stand-alone, primary therapy.

DISRUPT PAD III will compare the safety and effectiveness of Lithoplasty followed by DCB versus DCB with standard pre-dilatation for the treatment of moderately and severely calcified femoro-popliteal arteries. The study will enroll up to 300 patients at 45 global centers in the United States, Europe and New Zealand. The IN.PACT™ Admiral™ DCB will be used in both treatment arms. DCBs have historically been shown to be very effective in non-calcified lesions, but results are far less favorable as calcification levels of increase.[3] The DISRUPT PAD III study is designed to assess the impact of Lithoplasty on outcomes of DCB use in calcified lesions. The primary endpoint of the study will be acute procedural success absent the need for stents and the secondary endpoint will be primary patency at 12 months.

“We are very pleased with positive, consistent DISRUPT PAD data and the durability of outcomes out to six months thus far,” said Todd Brinton, M.D., clinical associate professor of Medicine at Stanford and co-founder of Shockwave Medical. “The data to date demonstrates that Lithoplasty is a viable primary therapy for revascularization of calcified PAD. However, the combination of peripheral Lithoplasty to treat calcification and reduce the need for stents, in conjunction with a DCB to reduce long-term restenosis may be a highly attractive therapeutic option for patients with calcified PAD.”

DISRUPT PAD III will begin enrollment will begin in early 2017.

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.
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.

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

[2] Not intended for use in the coronary or cerebral vasculature.

[3] Fanelli F, Salvatori FM, et al. Calcium burden assessment and impact on drug-eluting balloons in peripheral artery disease. Cardiovasc Intervent Radiol 2014; 37(4):898-907.

###

Media Contact:
Jessica Volchok
jessica@nicoleosmer.com
310 849-7985