Shockwave IVL Is Superior to Angioplasty in Severely Calcified Peripheral Artery Disease

November 7, 2020

Disrupt PAD III is Largest Randomized Study of Complex Patients Typically Excluded from Clinical Trials

SANTA CLARA, Calif., Nov. 07, 2020 (GLOBE NEWSWIRE) -- Shockwave Medical, Inc. (NASDAQ: SWAV), a pioneer in the development and commercialization of Intravascular Lithotripsy (IVL) to treat severely calcified cardiovascular disease, reported today that investigators unveiled data from the Disrupt PAD III study, which showed IVL to be superior to percutaneous transluminal angioplasty (PTA) on the primary endpoint of procedural success. The largest randomized trial of severely calcified peripheral lesions, Disrupt PAD III found that IVL was also associated with a statistically significant reduction in diameter stenosis, arterial dissections and bail-out stenting versus PTA. The results were presented earlier today in a late-breaking clinical trial session at VIVA20.

Disrupt PAD III is a prospective, multicenter, randomized study designed to demonstrate the safety and effectiveness of IVL as a vessel preparation procedure in moderate to severely calcified superficial femoral and popliteal lesions, followed by a drug-coated balloon (DCB) or stent. The study enrolled 306 patients randomized between IVL and PTA at 45 sites in the United States, Germany, Austria and New Zealand. In the IVL arm, 83 percent of patients were classified by the angiographic core lab as having severe calcification, with an average calcified lesion length of 129 millimeters. The co-principal investigators of the study were William A. Gray, M.D., FACC, FSCAI, Chief of the Division of Cardiovascular Disease at Main Line Health, Wynnewood, Penn., and Gunnar Tepe, M.D., Head of the Department of Diagnostic and Interventional Radiology, RoMed Clinic Rosenheim, Germany.

“Until the Shockwave PAD III trial, there have been few data available to provide treatment guidance for this challenging population, as patients with severe calcification have historically been excluded from endovascular treatment trials,” said Dr. Gray, who presented the PAD III results. “IVL superiority over PTA in acute procedural success establishes the new standard in safety and effectiveness, and we now have Level I evidence to help inform our lesion preparation strategy.”

IVL demonstrated superiority over PTA in the primary endpoint analysis, defined as procedural success with a residual stenosis less than or equal to 30 percent without flow-limiting dissection (greater or equal to Grade D), prior to DCB or stenting, with a rate of 65.8 percent versus 50.4 percent (p=0.0065) as determined by an independent angiographic core lab. Additionally, PAD III showed that IVL achieved more atraumatic treatment based on the following findings:

- Reduction in frequency and severity of major arterial dissections (Grade C and Grade D, both p=0.03)
- Reduction in the need for bail-out stenting (75% relative risk reduction) and stent implantation rate (4.6% vs 18.3%, p=0.0002)
- Lower balloon maximum inflation pressure (6.3 atm vs 11.3 atm, p<0.0001)
- Reduction in categorical percent diameter stenosis after treatment with IVL versus PTA (p=0.02)

“I would like to compliment the physicians, clinical coordinators and institutions who worked diligently to generate this new Level I evidence in a difficult-to-treat patient population,” said Keith D. Dawkins, M.D., Chief Medical Officer of Shockwave Medical. “The acute safety and effectiveness of IVL in the PAD III core lab adjudicated randomized clinical trial are remarkably consistent with the excellent outcomes published earlier this year from a meta-analysis of previous studies across different peripheral arterial vessel beds, including the concurrent PAD III ‘real-world’ registry.”

About Shockwave Medical, Inc.
Shockwave is focused on developing and commercializing products intended to transform the way calcified cardiovascular disease is treated. Shockwave aims to establish a new standard of care for the interventional treatment of atherosclerotic cardiovascular disease through differentiated and proprietary local delivery of sonic pressure waves for the treatment of calcified plaque, which the company refers to as Intravascular Lithotripsy (IVL). IVL is a minimally invasive, easy-to-use and safe way to significantly improve patient outcomes. To view an animation of the IVL procedure and for more information, visit www.shockwavemedical.com.

Forward-Looking Statements
This press release contains statements relating to our expectations, projections, beliefs, and prospects, [including statements regarding our product development outlook], which are “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995. In some cases, you can identify these statements by forward-looking words such as “may,” “might,” “will,” “should,” “expects,” “plans,” “anticipates,” “believes,” “estimates,” “predicts,” “potential” or “continue,” and similar expressions, and the negative of these terms. You are cautioned not to place undue reliance on these forward-looking statements. Forward-looking statements are only predictions based on our current expectations, estimates, and assumptions, valid only as of the date they are made, and subject to risks and uncertainties, some of which we are not currently aware.

Important factors that could cause our actual results and financial condition to differ materially from those indicated in the forward-looking statements include, among others: the impact of the COVID-19 pandemic on our operations, financial results, and liquidity and capital resources, including the impact on our sales, expenses, supply chain, manufacturing, research and development activities, clinical trials, and employees; our ability to develop, manufacture, obtain and maintain regulatory approvals for, market and sell, our products; our expected future growth, including the size and growth potential of the markets for our products; our ability to obtain coverage and reimbursement for procedures performed using our products; our ability to scale our organizational culture; the impact of the development, regulatory approval, efficacy and commercialization of competing products; the loss of key scientific or management personnel; our ability to develop and maintain our corporate infrastructure, including our internal controls; our financial performance and capital requirements; and our ability to obtain and maintain intellectual property protection for our products, as well as our ability to operate our business without infringing the intellectual property rights of others. These factors, as well as others, are discussed in our filings with the Securities and Exchange Commission (SEC), including in Part I, Item IA - Risk Factors in our most recent Annual Report on Form 10-K filed with

the SEC, and in our other periodic and other reports filed with the SEC. Except to the extent required by law, we do not undertake to update any of these forward-looking statements after the date hereof to conform these statements to actual results or revised expectations.

Media Contact:
Scott Shadiow
+1.317.432.9210
sshadiow@shockwavemedical.com

Investor Contact:
Debbie Kaster
dkaster@shockwavemedical.com

Source: Shockwave Medical, Inc.