Shockwave IVL Maintains Superiority to Angioplasty in Calcified Peripheral Disease at Two Years

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Randomized Disrupt PAD III Study Finds Superior Vessel Preparation Leads to Excellent Long-Term Outcomes and Preserved Future Treatment Options

SANTA CLARA, Calif., May 19, 2022 (GLOBE NEWSWIRE) -- Shockwave Medical, Inc. (NASDAQ: SWAV), a pioneer in the development of Intravascular Lithotripsy (IVL) to treat severely calcified cardiovascular disease, announced today that long-term data from the Disrupt PAD III trial found that superior vessel preparation with IVL led to excellent long-term outcomes out to two years with preservation of future treatment options compared to percutaneous transluminal angioplasty (PTA) in the treatment of calcified peripheral artery disease. The final outcomes of the largest randomized trial of severely calcified peripheral lesions were presented by investigators today in a featured clinical research session at the 2022 Scientific Sessions of the Society for Cardiovascular Angiography & Interventions (SCAI) and published simultaneously in *JSCAI*.

As previously published, IVL at 30 days 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, prior to drug-coated balloon (DCB) or stent, 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 a reduction in frequency and severity of flow-limiting major dissections (1.4 percent vs. 6.8 percent, p=0.03), a reduction in stent implantation rate (4.6 percent vs 18.3 percent, p<0.001) and no distal embolization or perforation events.

These new long-term results found that the powered secondary endpoint of primary patency (defined as freedom from CD-TLR, restenosis determined by duplex ultrasound and provisional stenting) favored IVL over PTA at one year (80.5 percent vs. 68.0%, p=0.017) and remained favorable through two years (Kaplan-Meier estimate: 74.4 percent vs. 57.7 percent, p=0.005), respectively.

“Prior to the PAD III study, there were limited long-term data available to provide treatment guidance for this challenging population since patients with severe calcification have historically been excluded from endovascular trials,” said William A. Gray, M.D., FACC, FSCAI, Co-Director of the Lankenau Heart Institute and System, Chief of the Division of Cardiovascular Disease at Main Line Health, Wynnewood, PA, and co-principal investigator of PAD III who presented the long-term results. “The primary end point at 30 days showed IVL to be a superior vessel preparation strategy by demonstrating stenosis resolution with significantly fewer complications including severe dissections and the subsequent need for bail-out stent implantation. Avoiding unplanned stent implantations allows interventionalists to preserve all their future treatment options should reintervention be necessary. These new long-term data show that vessel preparation with IVL followed by DCB result in excellent efficacy and durable patency out to two years, and taken together the acute and long-term results reinforce IVL as a preferred vessel preparation strategy for calcified femoropopliteal disease.”

Disrupt PAD III was 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 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, 82.9 percent of patients were classified by the angiographic core lab as having severe calcification, with an average calcified lesion length of 129.4 millimeters. Joining Dr. Gray as co-principal investigator of the study was Gunnar Tepe, M.D., Head of the Department of Diagnostic and Interventional Radiology, RoMed Clinic Rosenheim, Germany.

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, 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, and 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

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