Updated SCAI Guidance Includes Coronary IVL as a Treatment Option in All U.S. Catheterization Labs Regardless of Surgical Backup Status

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Guidance Expands Number of Hospitals that Can Access IVL to Include Sites Where Calcium Modification Tools Were Previously Not Recommended

SANTA CLARA, Calif., Jan. 31, 2023 (GLOBE NEWSWIRE) -- Shockwave Medical, Inc. (NASDAQ: SWAV), a pioneer in the development of Intravascular Lithotripsy (IVL) to treat severely calcified cardiovascular disease, today announced that coronary IVL was included in a treatment guidance document published by the Society of Cardiovascular Angiography and Intervention (SCAI) as a potential therapeutic option in all U.S. catheterization labs. - including facilities without on-site surgical backup. The latest guidance – SCAI Expert Consensus Statement on PCI Without On-Site Surgical Backup – was published online in the *Journal of the Society of Cardiovascular Angiography and Intervention (JSCAI).*

The updated guidelines, which modify the previous 2014 guidelines by no longer restricting recommended treatment to facilities with on-site surgical backup, will now endorse expanded treatment options and access for patients with calcified coronary lesions.

"When a lesion is more heavily calcified than is readily apparent on angiography, it is critical to have a strategy to safely and immediately modify the calcium to be able to successfully proceed with the case," said Dr. Clay Sizemore, Interventional Cardiologist at Cardiovascular Consultants of South Georgia in Thomasville, Ga., who has been using coronary IVL in his catheterization lab without surgical backup since the technology was FDA approved in 2021, despite the previous guidance. "The previous guidelines required these patients in facilities without surgical backup be transferred interprocedurally via an ambulance to a cath lab with onsite surgical backup. Not only were these transfers sub-optimal for the patient, but they consumed resources in two hospitals as well as valuable physician time that was taken away from treating additional patients."

"Now, with IVL we have a tool that can safely modify severely calcified lesions, but that does not have the associated risk that requires onsite surgical backup. IVL has allowed us to streamline patient care while providing the best possible outcomes for these patients – it is a win for physicians, the system and for the patients," continued Dr. Sizemore.

The 2014 guidelines recommended avoiding treatment of high-risk lesions defined as "more than moderate calcification" in facilities without surgical backup. The updated guidelines note the old recommendation "restricted practice, limited patient choice and exposed interventional cardiologists to legal risk."

"With the interventional field rapidly evolving, we commend SCAI for continuously evaluating current interventional practices to ensure that their consensus documents accurately provide the best possible guidance for optimal patient care," said Doug Godshall, Chief Executive Officer of Shockwave Medical. "We look forward to working with sites that have not yet adopted coronary IVL due to their lack of surgical backup and to expanding the number of centers that have access to our technology due to this new guidance."

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, 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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