# Shockwave Intravascular Lithotripsy FDA Approved to Treat Advanced Heart Disease

February 16, 2021

**Transformative Technology Now Available for Calcified Coronary Plaque**

SANTA CLARA, Calif., Feb. 16, 2021 (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 the company's sonic pressure wave therapy received Pre-Market Approval for severely calcified coronary artery disease from the U.S. Food and Drug Administration (FDA). The innovative technology, which was granted Breakthrough Device designation by the FDA, is a novel application of lithotripsy, an approach that has been used for decades to safely break up kidney stones. With this approval, IVL is now commercially available in the United States to treat problematic calcium in the coronary arteries, which can reduce blood flow in the heart.

As coronary artery disease progresses, plaque in the arterial wall often evolves into calcium deposits, which narrow the artery and restrict blood flow. These bone-like structures make the artery rigid and more difficult to reopen with conventional treatments including balloons, which attempt to crack the calcium when inflated to high pressure, and atherectomy, which drills through the calcium to open the artery. While atherectomy has been available for several decades, its use remains low, despite the high prevalence of calcium, due to its complexity of use and potential to result in adverse patient outcomes.

Intravascular Lithotripsy uses sonic pressure waves, also known as shockwaves, that pass through soft arterial tissue and preferentially disrupt calcified plaque by creating a series of micro-fractures. After the calcium has been cracked, the artery can be expanded at low pressure and a stent safely implanted to improve blood flow, with minimal trauma to normal arterial tissue. The coronary technology has been widely adopted internationally and is now available in 50 countries, with more than 25,000 patients successfully treated since the initial commercial availability in early 2018.

"Coronary calcification is a major challenge for physicians because it limits the success of coronary angioplasty procedures and our current tools for addressing calcium have limitations," said Dean Kereiakes, M.D., FACC, FSCAI, President of The Christ Hospital Heart and Vascular Institute, Professor of Clinical Medicine, The Ohio State University, and the Co-Principal Investigator of the pivotal Disrupt CAD III U.S. study. "This approval represents a major advance in both the safety and simplicity of some of our most challenging procedures – and potentially promises to become a new standard of care."

The approval comes on the heels of its U.S. pivotal study recently published in the *Journal of the American College of Cardiology (JACC)*, which confirmed that coronary IVL met both the primary safety and effectiveness endpoints with a low rate of major adverse events and a high rate of procedural success. Notably, coronary IVL was simple to use and demonstrated a low risk of rare but life-threatening complications that have been associated with the use of high-pressure balloons and atherectomy technologies, including tears in the artery, abrupt arterial closure and a sudden stop of blood flow.

"Obtaining FDA approval for this transformational technology marks a significant advance in the treatment of patients with calcified coronary lesions, and is the culmination of years of technical research, rigorous clinical studies and key learnings from our real-world global experience," said Doug Godshall, President and Chief Executive Officer of Shockwave Medical. "We are eager for U.S. cardiologists to have access to this technology and experience how a safe, efficient and predictable calcium modification strategy can positively impact their clinical outcomes."

The Shockwave IVL System with the Shockwave $C^2$ Coronary IVL Catheter is indicated for lithotripsy-enabled, low-pressure balloon dilatation of severely calcified, stenotic *de novo* coronary arteries prior to stenting in the United States. The technology has been cleared for the treatment of peripheral arterial disease in the United States since 2016.

**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.

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Source: Shockwave Medical, Inc.