SHOCKWAVE COMPLETES ENROLLMENT IN PIVOTAL STUDY FOR CORONARY INTRAVASCULAR LITHOTRIPSY

April 6, 2020

Last Patient Enrolled in DISRUPT CAD III, the U.S. FDA IDE Study for IVL in Severely Calcified Coronary Arteries

SANTA CLARA, Calif., April 06, 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, announced today that the company has completed enrollment in the pivotal U.S. Food and Drug Administration (FDA) Investigational Device Exemption (IDE) study – DISRUPT CAD III – for the use of IVL in heavily calcified coronary arteries. The investigational Shockwave IVL System with the Shockwave C^2 Coronary IVL Catheter, which has been granted Breakthrough Device Designation by the FDA, is an innovative therapy designed to fracture problematic calcium using sonic pressure waves in order to facilitate stent delivery, deployment and optimal expansion.

The co-principal investigators of the study are Dean Kereiakes, M.D., FACC, FSCAI, Medical Director of The Christ Hospital Heart and Vascular Center and the Christ Hospital Research Institute, Professor of Clinical Medicine, The Ohio State University, and Jonathan Hill, M.D., Consultant Cardiologist at Royal Brompton Hospital in London.

“The speed and ease with which we were able to enroll the study speaks volumes to the value of IVL for treating this challenging group of patients with calcified coronary disease,” said Dr. Kereiakes. “If coronary IVL is shown to be safe and effective, similar to the outcomes demonstrated in the earlier CAD I and CAD II studies, it could be a game changer for the way we treat calcified arteries today.”

DISRUPT CAD III is a prospective, multicenter, single-arm, global IDE study to demonstrate the safety and effectiveness of the Shockwave Coronary IVL System with the Shockwave C^2 Coronary IVL Catheter in *de novo,* calcified, stenotic, coronary arteries prior to stenting. The study enrolled 384 patients, exceeding the minimum requirement of 372 patients, per the *a priori* statistical plan agreed by the FDA. Patients were enrolled at 47 global sites in the United States, France, Germany, and the United Kingdom.

The DISRUPT CAD III study is assessing freedom from major adverse cardiac events (MACE) within 30 days of the index procedure as the primary safety endpoint. The primary effectiveness endpoint is procedural success defined as stent delivery with a residual stenosis less than 50 percent and without in-hospital MACE.

The study chairman is Gregg W. Stone, M.D., FACC, FSCAI, Professor of Medicine (cardiology) at Icahn School of Medicine at Mount Sinai in New York. The angiographic and optical coherence tomography (OCT) core labs are at the Cardiovascular Research Foundation, also based in New York.

“We eagerly await the opportunity to share the DISRUPT CAD III results with the global interventional community later this year,” said Dr. Hill. “IVL has been a significant advance for our management of calcified lesions in Europe and I am excited about the potential for the technology to have a similar impact in helping patients across the United States.”

‘’Despite the global challenges of COVID-19, the CAD III investigators, research staff and site monitors have done an outstanding job in bringing this important study to a timely conclusion,” said Doug Godshall, President and Chief Executive Officer of Shockwave Medical. “Based on recent collaborative interactions with the FDA, it is our expectation that the PMA will be submitted in the third quarter of this year, with U.S device approval anticipated in the first quarter of 2021, consistent with previous guidance.’’

Shockwave C^2 Coronary IVL catheters are commercially available for the treatment of *de novo* coronary artery disease in Europe and select other geographies; they are limited to investigational use in the United States.

About Shockwave Medical, Inc.
Shockwave Medical is focused on developing and commercializing products intended to transform the way calcified cardiovascular disease is treated. We aim to establish a new standard of care for the interventional treatment of atherosclerotic cardiovascular disease through our differentiated and proprietary local delivery of sonic pressure waves for the treatment of calcified plaque, which we refer 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 Shockwave’s expectations, projections, beliefs, and prospects (including statements regarding Shockwave’s product development outlook), which are “forward-looking statements” within the meaning of the federal securities laws and by their nature are uncertain. Words such as “believe,” “may,” “will,” “estimate,” “continue,” “anticipate,” “intend,” “expect,” “plans,” and similar expressions are intended to identify forward-looking statements. Such forward-looking statements are not guarantees of future performance, and you are cautioned not to place undue reliance on these forward-looking statements. Our business and operations are subject to a variety of risks and uncertainties and, consequently, actual results may differ materially from those projected by any forward-looking statements. Factors that could cause actual results to differ from those projected include, but are not limited to: our ability to design, develop, manufacture and market innovative products to treat patients with challenging medical conditions, particularly in peripheral artery disease, coronary artery disease and aortic stenosis; our expected future growth, including growth in international sales; the size and growth potential of the markets for our products, and our ability to serve those markets; the rate and degree of market acceptance of our products; coverage and reimbursement for procedures performed using our products; the performance of third parties in connection with the development of our products, including third-party suppliers; regulatory developments in the United States and foreign countries; our ability to obtain and maintain regulatory approval or clearance of our products on expected timelines; our plans to research, develop and commercialize our products and any other approved or cleared product; our ability to scale our organizational culture of cooperative product development and commercial execution; the development, regulatory approval, efficacy and commercialization of competing products; the loss of key scientific or management personnel; our expectations regarding the period during which we qualify as an emerging growth company under

the JOBS Act; our ability to develop and maintain our corporate infrastructure, including our internal controls; our financial performance and capital requirements; the impact of the current COVID-19 pandemic on our operations and financial results; and our expectations regarding 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 risks and uncertainties, as well as others, are discussed in greater detail 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. . There may be additional risks of which we are not presently aware or that we currently believe are immaterial which could have an adverse impact on our business. Any forward-looking statements are based on our current expectations, estimates and assumptions regarding future events and are applicable only as of the dates of such statements. We make no commitment to revise or update any forward-looking statements in order to reflect events or circumstances that may change.

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

Investor Contact:
Debbie Kaster, Gilmartin Group
investors@shockwavemedical.com

Source: Shockwave Medical, Inc.