Shockwave Coronary IVL U.S. Pivotal Study Results to be Presented in Late-Breaking Session at TCT Connect

September 15, 2020

SANTA CLARA, Calif., Sept. 15, 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 pivotal results from the DISRUPT CAD III study have been accepted for presentation in a late-breaking clinical science session at TCT Connect. The Investigational Device Exemption (IDE) study is the first study powered to evaluate the safety and effectiveness of coronary IVL in the treatment of severely calcified coronary arteries.

"We are delighted that the CAD III data will be featured as part of a late-breaking session at TCT Connect," said Keith D. Dawkins, M.D., Chief Medical Officer of Shockwave Medical. "On behalf of the entire Shockwave team, I want to thank all of the investigators, research coordinators and patients who have supported this study from the start and whose enthusiasm and perseverance, even amid COVID, got us to this point today. Completing the CAD III study represents a significant milestone for Shockwave and we look forward to the results being shared by the investigators at TCT Connect."

In addition to the primary endpoint analysis, TCT Connect accepted and will post data from a prospective optical coherence tomography (OCT) sub-analysis of 100 patients within the CAD III cohort authored by Dr. Richard Shlofmitz, M.D., FACC, Chairman of Cardiology at St. Francis Hospital, The Heart Center.

The details of the late-breaking session are as follows:

Presentation Title**:**	**Disrupt CAD III: Safety and Effectiveness of Intravascular Lithotripsy for Treatment of Severe Coronary Calcification**
Time:	October 15, 2020 at 12:30 pm Eastern Time
Presenter:	Dr. 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; Co-Principal Investigator of DISRUPT CAD III

Shockwave will be hosting an event for analysts and institutional investors at 4:30 p.m. eastern time on Thursday October 15, 2020, after the late-breaking session. The webcast event will include remarks from Dr. Dean Kereiakes as well an interactive question and answer session with a panel of experts. Interested parties may access a live audio webcast of the presentation by visiting the "Investors" section of Shockwave's website at https://ir.shockwavemedical.com. A replay of the webcast will be available following the presentation.

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 DISRUPT CAD III

DISRUPT CAD III is a prospective, multicenter, single-arm, global IDE study designed 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 sites in the United States, France, Germany, and the United Kingdom. Patients will be followed for two years.

The 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 co-principal investigators of the study were Dean Kereiakes and Jonathan Hill, M.D., Consultant Cardiologist at Royal Brompton Hospital in London.

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 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: the impact of the COVID-19 pandemic on our operations, financial results, and liquidity and capital resources, including on sales, expenses, supply chain, manufacturing, research and development activities, clinical trials and employees; 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; 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
dkaster@shockwavemedical.com

Source: Shockwave Medical, Inc.