Shockwave IVL Meets Safety and Effectiveness Endpoints in U.S. Coronary Pivotal IDE Study

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Positive Disrupt CAD III Data Submitted to FDA in Premarket Approval Application

SANTA CLARA, Calif., Oct. 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 coronary Investigational Device Exemption (IDE) study, Disrupt CAD III, met the primary safety and effectiveness endpoints. The results were presented earlier today in a late-breaking clinical session at the virtual 2020 Transcatheter Cardiovascular Therapeutics conference, TCT Connect, and published simultaneously in the *Journal of the American College of Cardiology (JACC)*.

Disrupt CAD III is a prospective, multicenter, single-arm, global IDE study investigating the Shockwave Coronary IVL System in *de novo*, calcified, stenotic, coronary arteries prior to stenting. The study enrolled 384 patients at 47 sites in the United States, France, Germany, and the United Kingdom, including 100 patients in an optical coherence tomography (OCT) sub-study. All data were core-lab adjudicated.

CAD III represents one of the most challenging series of calcified lesions ever treated in an IDE, with all lesions determined by the core lab to be severely calcified. The average calcium lesion length was 47.9mm, and the average calcium arc was 292.5 degrees with a thickness of 0.96mm at the site of maximum calcification as measured by OCT.

“The correlation between calcium severity and poor percutaneous coronary intervention outcomes is well established and is a challenge we face on a daily basis in the cath lab. Given the severity of lesion and vessel calcium that was present in CAD III, it makes the findings of the study even more significant and noteworthy,” said 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; the Co-Principal Investigator of Disrupt CAD III. “The high rate of procedural success, combined with the low rate of major adverse cardiovascular events in CAD III, not only met the performance goals, but it also surpassed our expectations as investigators.”

Disrupt CAD III was based on a predicate study – the single-arm ORBIT II IDE study of orbital atherectomy – to develop performance goals that would allow FDA to evaluate the safety and effectiveness of IVL in a single arm study. Coronary IVL met both the safety and effectiveness goals in Disrupt CAD III with a 30-day freedom from MACE rate of 92.2 percent (p<0.0001) and a procedural success rate of 92.4 percent (p<0.0001), respectively.

Coronary IVL prior to stent implantation was well tolerated with a low rate of major peri-procedural clinical and angiographic complications. The individual components of the 7.8 percent MACE rate included low rates of cardiac death (0.5 percent), myocardial infarction (7.3 percent), and target vessel revascularization (1.6 percent) at 30 days following the index procedure.

Freedom from any serious angiographic complication following IVL delivery and at any point during the procedure were 97.4 percent and 96.9 percent, respectively. Coronary IVL showed a low risk of complications, including perforation (0.3 percent), major dissection (0.3 percent), abrupt closure (0.3 percent), and slow flow/no reflow (0 percent) at the end of the procedure.

CAD III demonstrated the effectiveness of coronary IVL in treating calcium with large lumen gains that facilitated stent delivery. On the primary effectiveness endpoint of procedural success (92.4 percent), the individual endpoints included successful stent delivery in 99.2 percent of patients, a residual stenosis of less than 50 percent in all cases, and no in-hospital MACE in 93.0 percent of patients.

Despite the marked severity of the calcified lesions treated, IVL was able to cross and deliver therapy in 98.2 percent of lesions (377/384), which reflected successful stent delivery 99.2 percent of the time. At the end of the procedure post-stent, IVL resulted in an average acute gain of 1.7mm and an average final in-stent residual stenosis of 11.9 percent.

“The presentation and publication of the CAD III study is not only a significant milestone for the investigators and the company, but also for the interventional cardiology community at large,” said Keith D. Dawkins, M.D., Chief Medical Officer of Shockwave Medical. “CAD III sets a new benchmark for the treatment of complex coronary calcification. I want to commend the many physicians and their clinical coordinators for their diligent work in evaluating this novel technology.”

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 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, including statements regarding [our product development outlook, 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. Such forward-looking statements are subject to risks, uncertainties, and assumptions about us and are not guarantees of future performance. You are cautioned not to place undue reliance on these forward-looking statements.

Forward-looking statements contained in this press release may include, but are not limited to, statements about: the impact of

the COVID-19 pandemic on our operations, financial results, and liquidity and capital resources, including on our 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 forward-looking statements are only predictions based on our current expectations and projections about future events. There are important factors that could cause our actual results, level of activity, performance or achievements to differ materially from the results, level of activity, performance or achievements expressed or implied by the forward-looking statements. 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. Forward-looking statements we make are based on our current expectations, estimates and assumptions regarding future events and are applicable only as of the dates of such statements. 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. Although we believe the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee future results, level of activity, performance, or achievements. Except to the extent required by law, we do not undertake to update any of these forward-looking statements after the date of this press release to conform these statements to actual results or revised expectations.

Media Contact:	Investor Contact:
Scott Shadiow	Debbie Kaster
+1.317.432.9210	dkaster@shockwavemedical.com
sshadiow@shockwavemedical.com	

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