Shockwave Completes Enrollment of Coronary Intravascular Lithotripsy Study in Japan

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DISRUPT CAD IV Clinical Study to Support Regulatory Device Approval in Japan

SANTA CLARA, Calif., April 13, 2020 (GLOBE NEWSWIRE) -- Shockwave Medical, Inc. (NASDAQ: SWAV), a pioneer in the development of Intravascular Lithotripsy (IVL) to treat complex calcified cardiovascular disease, announced today that the company has completed enrollment in their DISRUPT CAD IV study of IVL in heavily calcified coronary arteries that is intended to support regulatory device approval in Japan.

DISRUPT CAD IV is a prospective, multicenter, single-arm confirmatory study that enrolled 64 patients in eight sites across Japan to demonstrate the safety and effectiveness of the Shockwave Coronary IVL System with the Shockwave C^2 IVL Catheter in the treatment of *de novo,* calcified, stenotic, coronary arteries prior to stenting.

"The fact that we were able to enroll this study in only five months showcases the potential value that IVL has for the patients of Japan who are suffering from calcified cardiovascular disease," said Shigeru Saito, M.D., FACC., Director of Cardiology and Catheterization Laboratories and Vice President, Shonan Kamakura General Hospital and the principal investigator of the study. "We are very enthusiastic about IVL and its place in our treatment regimen, and we eagerly await the opportunity to share the DISRUPT CAD IV results with the global interventional community as soon as possible."

Similar to the DISRUPT CAD III study protocol, DISRUPT CAD IV assesses the absence of 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 of less than 50 percent, and without in-hospital MACE. The enrolled patients will be followed for two years.

"We have been impressed by the swift enrollment of CAD IV in Japan, which is indicative of both the excitement and potential for IVL as a treatment option for patients in this region," said Doug Godshall, President and Chief Executive Officer of Shockwave Medical. "Our investigators executed this trial in a stellar fashion, particularly in light of the challenges posed by COVID19, and we now look forward to following the CAD IV subjects and working with the regulators to bring IVL to the broader population of patients in Japan."

Shockwave C^2 Coronary IVL catheters are commercially available for the treatment of *de novo* coronary artery disease in Europe and other select countries; in Japan they are limited to investigational use within the DISRUPT CAD IV Study and in the United States they are limited to investigational use within the DISRUPT CAD III Study.

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.

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