Shockwave Initiates Study of Coronary Intravascular Lithotripsy in Japan

November 7, 2019

First Patient Enrolled in DISRUPT CAD IV Clinical Study for Treatment of Severely Calcified Coronary Arteries

SANTA CLARA, Calif., Nov. 07, 2019 (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 initiated the DISRUPT CAD IV study of IVL in heavily calcified coronary arteries that is intended to support regulatory device approval in Japan.

The first CAD IV patient was enrolled earlier this week by the principal investigator of the study, Shigeru Saito, M.D., Director of Cardiology and Catheterization Laboratories and Vice President, Shonan Kamakura General Hospital. DISRUPT CAD IV is a prospective, multicenter, single-arm study 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 study is expected to enroll up to 64 patients at 8 sites in Japan.

“We are honored to initiate the clinical investigation of coronary IVL in Japan to evaluate calcium modification,” said Dr. Saito. “From the European results and our initial experience with the technology, IVL therapy has the potential to change the way we treat calcified lesions for the future benefit of patients.”

Similar to the DISRUPT CAD III Study protocol, CAD IV will assess 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 <50 percent, and without in-hospital MACE. Study enrollment is expected to be completed by June 2020, from which enrolled patients will be followed for two years.

“Based on the interest, feedback and rapid adoption in other Asia Pacific countries where we have introduced coronary IVL, we are excited for the prospect of providing Japanese physicians with access to this therapy for the first time,” said Doug Godshall, President and Chief Executive Officer of Shockwave Medical. “Japan holds tremendous potential for IVL, and we look forward to completing the study and working with the regulators so that Japanese patients and their providers will be able to access IVL therapy as soon as possible.”

Coronary artery calcium physically impairs stent expansion[i] and is perhaps the single most important predictor of early stent thrombosis and restenosis after stent procedures.[ii, iii, iv] Coronary IVL is a therapy designed to treat calcified artery blockages with sonic pressure waves historically used to treat patients with kidney stones. The technology seeks to minimize trauma within the artery by delivering pulsatile sonic pressure waves locally to fracture both intimal and medial calcium in the artery wall but pass through surrounding soft vascular tissue in a safe manner.

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. 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 medical device 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 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 may contain statements relating to Shockwave’s expectations, projections, beliefs, and prospects (including any statements regarding the future success, safety profile or commercialization of IVL and Shockwave’s ability to receive approval for, and begin commercializing, the Shockwave IVL System with the Shockwave C^2 Coronary IVL Catheter in various geographies), 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: failure to sustain or grow profitability; failure to effectively market existing products; failure to effectively introduce and market new products; delays in product introductions; significant competition; inability to further penetrate our current customer base and increase the frequency of use of our products by our customers; inability to achieve or maintain satisfactory pricing and margins; manufacturing difficulties; the inability to attain coverage and adequate reimbursement for procedures using our products; permanent write-downs or write-offs of our inventory; product defects or failures; unfavorable outcomes in clinical trials; inability to maintain our culture as we grow; fluctuations in foreign currency exchange rates; potential adverse regulatory actions; and potential impact of any future acquisitions, mergers, dispositions, joint ventures or investments we may make. These risks and uncertainties, as well as others, are discussed in greater detail in our filings with the Securities and Exchange Commission (SEC), including under the section entitled “Risk Factors” in our prospectus dated March 6, 2019. 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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Logo 1.png

Source: Shockwave Medical, Inc.