Shockwave Receives FDA Breakthrough Device Designation for the Coronary IVL System

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Agency's Breakthrough Device Designation Program Allows for Priority Review of Coronary Calcium Modification Technology

SANTA CLARA, Calif., Sept. 03, 2019 (GLOBE NEWSWIRE) -- Shockwave Medical, Inc., a pioneer in the development and commercialization of Intravascular Lithotripsy (IVL) to treat complex calcified cardiovascular disease, today announced that the company has received Breakthrough Device Designation from the U.S. Food and Drug Administration (FDA) for its Shockwave IVL System with the Shockwave C^2 Coronary IVL Catheter, which is currently the subject of an Investigational Device Exemption (IDE) study called DISRUPT CAD III. The Shockwave C^2 IVL Catheter is a proprietary tool designed to fracture problematic calcium using sonic pressure waves in order to facilitate stent delivery, deployment and optimal expansion, thereby improving blood flow to the heart muscle.

The FDA Breakthrough Device Program is intended to help patients and health care providers receive more timely access to medical devices that have the potential to provide more effective treatment or diagnosis for life-threatening or irreversibly debilitating diseases or conditions. Under the program, the FDA will provide Shockwave Medical with priority review and interactive communication during the Shockwave C^2 IVL Catheter premarket review phase.

"Receiving Breakthrough Device Designation is an important milestone, validating IVL as a unique solution for complex calcified coronary disease," said Doug Godshall, President and Chief Executive Officer of Shockwave Medical. "Our international customers have responded very positively to Shockwave's C ^{2} since its commercial launch last year, and our team has been working hard to bring this transformational technology to patients with coronary disease in the United States. We are encouraged that the FDA has determined that Shockwave C^2 qualifies as a Breakthrough Device and we look forward to working collaboratively with the agency so we can make Shockwave C^2 available as expeditiously as possible."

Coronary artery calcium physically impairs blood flow and restricts artery dilation, which inhibits stent expansion[i] and is perhaps the single most important predictor of restenosis and early stent thrombosis,[ii] or coronary artery re-narrowing and blood clots, within the stent after-stent procedures.

DISRUPT CAD III is a prospective, non-randomized, multicenter global IDE study to demonstrate the safety and effectiveness of the Shockwave IVL System with the Shockwave C^2 Coronary IVL Catheter in *de novo,* calcified, stenotic, coronary arteries prior to stenting. The study is approved to enroll 442 patients at 50 centers in the United States and Europe, and is led by co-principal investigators Drs. Dean Kereiakes and Jonathan Hill. As reported in the company's second quarter earnings call, the study had enrolled 108 patients as of June 30, 2019.

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 by establishing a new standard of care with Intravascular Lithotripsy (IVL). The company's differentiated and proprietary IVL approach to calcium modification 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. 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 statements regarding Shockwave's ability to receive FDA clearance for, and begin commercializing, the Shockwave IVL System with the Shockwave C^2 Coronary IVL Catheter), 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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[i] Chambers JW, et al. J Am Coll Cardiol Intv 2014; 7:510–8.
[ii] Généreux P, et al. J Am Coll Cardiol 2014;63:1845–54.

Source: Shockwave Medical, Inc.