



## Shockwave Completes Enrollment of Disrupt CAD II Study

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### European Post-Market Study to Demonstrate Ongoing Safety of Coronary Intravascular Lithotripsy

SANTA CLARA, Calif., April 03, 2019 (GLOBE NEWSWIRE) -- Shockwave Medical, Inc. (NASDAQ: SWAV), a pioneer in the development and commercialization of Intravascular Lithotripsy (IVL) to treat complex calcified cardiovascular disease, has completed enrollment of its DISRUPT CAD II study, a regulatory-required European post-market registry of coronary IVL. IVL is an innovative lesion preparation tool designed to fracture calcium using sonic pressure waves in order to facilitate stent delivery, deployment and expansion.

DISRUPT CAD II is a prospective, non-randomized, multicenter, real-world study to confirm the safety and performance results from the DISRUPT CAD I study, which was used to obtain European approval of the Shockwave Coronary IVL System. DISRUPT CAD II enrolled more patients (120) with *de novo*, calcified, stenotic, coronary arteries at more European centers (15) than the first study (60 patients and 7 centers, respectively) to determine if the previous strong safety results could be replicated in more patients and with more operators in a real-world setting.

The study's primary safety endpoint is freedom from in-hospital major adverse cardiac events (MACE); patients will also be followed out to 30 days per the protocol. The co-principal investigators are Professor Jean Fajadet of Clinique Pasteur in Toulouse, France and Professor Carlo Di Mario of University of Florence in Florence, Italy, who also had the largest enrollment with 16 patients.

"While DISRUPT CAD I enrolled a limited number of patients, its safety results were quite compelling to those of us who treat challenging calcified lesions on a daily basis," said Professor Fajadet. "If DISRUPT CAD II can confirm the safety results found in the first study, I think it will help establish IVL as a new standard in safety that operators can expect when treating patients with challenging, heavily calcified coronary artery disease. We look forward to sharing these data with our colleagues as soon as possible."

Shockwave C<sup>2</sup> 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 with the DISRUPT CAD III IDE Study.

#### About Intravascular Lithotripsy

We have adapted the use of lithotripsy to the cardiovascular field with the aim of creating what could potentially become the safest, most effective means of addressing the growing challenge of cardiovascular calcification. Lithotripsy has been used to successfully treat kidney stones (deposits of hardened calcium) for over 30 years. By integrating lithotripsy into a device that resembles a standard balloon catheter, physicians can prepare, deliver and treat calcified lesions using a familiar form factor, without disruption to their standard procedural workflow. Our differentiated IVL System works by delivering shockwaves through the entire depth of the artery wall, modifying calcium in the medial layer of the artery, not just at the superficial most intimal layer.

The IVL System includes a generator, connector cable and a family of IVL catheters designed to treat PAD and CAD. IVL cracks calcium through short bursts of sonic pressure waves, which are generated within the IVL catheter and travel through the vessel to crack calcium with an effective pressure of up to 50 atmospheres ("atm") without harming the soft tissue. IVL catheters utilize multiple lithotripsy emitters that are integrated into a standard, semi-compliant balloon-catheter platform, which is advanced to the target lesion and the integrated balloon is inflated with fluid at a low pressure to make contact with the arterial wall. IVL is then activated through the generator with the touch of a button, creating a small bubble within the catheter balloon which rapidly expands and collapses. The rapid expansion and collapse of the bubble creates sonic pressure waves that travel through the vessel and crack the calcium, allowing the blood vessel to expand under low static pressure. To view an animation of the Intravascular Lithotripsy procedure visit <http://shockwavemedical.com>.

#### About Shockwave Medical, Inc.

We are a medical device company 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.' For more information, visit [www.shockwavemedical.com](http://www.shockwavemedical.com).

#### Caution Regarding Forward-Looking Statements

This press release may contain forward-looking statements regarding Shockwave's current expectations. Words such as "may," "might," "will," "should," "believe," "expect," "anticipate," "estimate," "continue," "predict," "forecast," "project," "plan," "intend" or similar expressions, or statements regarding intent, belief, or current expectations are forward-looking statements. These statements are not guarantees of future performance and are subject to certain risks, uncertainties and assumptions that are difficult to predict. Factors that could cause actual results to differ include, but are not limited to, those described more fully in the section captioned "Risk Factors" in the final prospectus related to the public offering filed with the Securities and Exchange Commission. Forward-looking statements contained in this announcement are made as of this date, and Shockwave undertakes no duty to update such information except as required under applicable law.

Media Contact:  
Scott Shadiow  
+1.317.432.9210

[sshadiow@shockwavemedical.com](mailto:sshadiow@shockwavemedical.com)

Investor Contact:

Debbie Kaster, Gilmartin Group

[investors@shockwavemedical.com](mailto:investors@shockwavemedical.com)



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