



## Shockwave Announces Commercial Availability of Below-the-Knee IVL Catheter

November 4, 2019

*Shockwave S<sup>4</sup> Catheter Expands the Intravascular Lithotripsy System Portfolio to Address the Challenges of Critical Limb Ischemia*

SANTA CLARA, Calif., Nov. 04, 2019 (GLOBE NEWSWIRE) -- Shockwave Medical, Inc. (NASDAQ: SWAV), a pioneer in the development of Intravascular Lithotripsy (IVL) to treat complex calcified cardiovascular disease, today announced commercial availability of the Shockwave S<sup>4</sup> Peripheral IVL Catheter in select approved geographies. Shockwave S<sup>4</sup> is a low-profile catheter specifically designed to access and treat challenging calcified lesions in below-the-knee (BTK) arteries that are frequently associated with critical limb ischemia (CLI), a serious condition associated with significant morbidity and mortality. Many patients with CLI do not respond well to endovascular treatment, especially when calcium is present, often requiring repeat procedures or even limb amputation.

"The novel Shockwave S<sup>4</sup> IVL catheter has the potential to change the treatment paradigm for our most difficult-to-treat patients – those with non-healing ulcers and wounds on their lower limbs due to lack of sufficient blood flow which we call Critical Limb Ischemia or CLI," said Dr. George Adams, M.D., of UNC REX Health in Raleigh, NC, one of the first US physicians to use the new device. "IVL offers great promise as outcomes in patients with CLI remain poor, particularly for those who have significant, difficult to treat calcification of the small arteries below-the-knee."

IVL is an innovative therapy designed to treat calcified artery stenoses with lithotripsy—sonic pressure waves historically used to treat patients with kidney stones. The technology minimizes trauma within the artery by delivering pulsatile sonic pressure waves locally that fracture calcium inside the artery wall but pass through surrounding soft vascular tissue in a safe manner.

Shockwave S<sup>4</sup> complements the existing larger-diameter Shockwave M<sup>5</sup> IVL catheter, which has been available in the U.S. since 2017 for the treatment of calcified peripheral artery disease. Shockwave S<sup>4</sup> features many design modifications to enhance deliverability in small, distal vessels of the legs, including a longer, hydrophilic shaft, a lower crossing profile, and a lower tip profile.

"We are committed to optimizing IVL for specific patient populations and anatomies, and one of the most challenging is patients with below-the-knee disease suffering from CLI," said Doug Godshall, Chief Executive Officer of Shockwave Medical. "We look forward to continuing to roll out Shockwave S<sup>4</sup> over the coming months to provide our customers with a tool that we hope will help them achieve a high degree of luminal gain with decreased vessel recoil and minimal complications with the ultimate goal of reducing the frequency of amputation."

### 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](http://www.shockwavemedical.com).

### Forward-Looking Statements

This press release may contain statements relating to Shockwave's expectations, projections, beliefs, and prospects (including statements regarding the future success, safety profile or commercialization of IVL), 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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Source: Shockwave Medical, Inc.