Shockwave Medical Enrolls First Patient in Disrupt BTK II Study for Long, Calcified, Below the Knee Lesions

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Global Post-Market Study Will Assess Long-Term Benefit of Peripheral IVL on the Most Challenging Calcified Lesions, Including Patients with Critical Limb Ischemia

SANTA CLARA, Calif., Nov. 22, 2021 (GLOBE NEWSWIRE) -- Shockwave Medical, Inc. (NASDAQ: SWAV), a pioneer in the development of Intravascular Lithotripsy (IVL) to treat severely calcified cardiovascular disease, today announced the start of the Disrupt BTK II post-market study to assess the safety, effectiveness and optimal clinical use of the Shockwave Peripheral IVL System for the treatment of calcified peripheral lesions below the knee (BTK), including some of the most challenging patients with critical limb ischemia (CLI).

Disrupt BTK II is a post-market, prospective, multicenter, single-arm study led by Ehrin Armstrong, M.D., Medical Director and Interventional Cardiologist, Adventist Heart & Vascular Institute, and Venita Chandra, M.D., Vascular Surgeon and Clinical Associate Professor, Division of Vascular Surgery, Stanford Health Care. The study is expected to enroll 250 patients across 40 sites globally that will be followed for two years to assess the long-term durability of IVL in this difficult to treat patient population. The first Disrupt BTK II patient was enrolled at Midwest Cardiovascular Research Foundation by Dr. Nicolas Shammas.

“Patients with severely calcified, diffuse below the knee disease, and especially those with critical limb ischemia, are often in severe pain with limited treatment options to achieve adequate arterial revascularization. The unmet clinical need for this population is extremely high,” said Dr. Armstrong. “Disrupt BTK II will further evaluate how IVL may be optimally used to treat patients who have historically been excluded from most endovascular treatment trials.”

The primary effectiveness endpoint of Disrupt BTK II is procedural success, defined as ≤50 percent residual stenosis for all treated target lesions without serious angiographic complications (flow-limiting dissection, perforation, distal embolization, or acute vessel closure), as assessed by an independent angiographic core lab. The study will assess the absence of major adverse limb events (MALE) within 30 days of the index procedure as a primary safety endpoint.

“More and more patients with CLI also present with end-stage renal disease, advanced diabetes, or other comorbidities that impact their overall health and our ability to effectively treat their CLI,” said Dr. Chandra. “We already know that IVL can reduce significant dissection as well as reduce the need for provisional stenting over conventional PTA in peripheral vessel beds, but what makes Disrupt BTK II even more exciting is that we are now isolating the treatment effect to get a clearer picture about what role IVL can offer as a definitive therapy for these very complex patients.”

About Shockwave Medical, Inc.
Shockwave is focused on developing and commercializing products intended to transform the way calcified cardiovascular disease is treated. Shockwave aims to establish a new standard of care for the interventional treatment of atherosclerotic cardiovascular disease through differentiated and proprietary local delivery of sonic pressure waves for the treatment of calcified plaque, which the company refers 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 our expectations, projections, beliefs, and prospects, which are “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995. In some cases, you can identify these statements by forward-looking words such as “may,” “might,” “will,” “should,” “expects,” “plans,” “anticipates,” “believes,” “estimates,” “predicts,” “potential” or “continue,” and similar expressions, and the negative of these terms. You are cautioned not to place undue reliance on these forward-looking statements. Forward-looking statements are only predictions based on our current expectations, estimates, and assumptions, valid only as of the date they are made, and subject to risks and uncertainties, some of which we are not currently aware.

Important factors that could cause our actual results and financial condition to differ materially from those indicated in the forward-looking statements include, among others: the impact of the COVID-19 pandemic on our operations, financial results, and liquidity and capital resources, including the impact on our sales, expenses, supply chain, manufacturing, research and development activities, clinical trials, and employees; our ability to develop, manufacture, obtain and maintain regulatory approvals for, market and sell, our products; our expected future growth, including the size and growth potential of the markets for our products; our ability to obtain coverage and reimbursement for procedures performed using our products; our ability to scale our organizational culture; the impact of the development, regulatory approval, efficacy and commercialization of competing products; the loss of key scientific or management personnel; our ability to develop and maintain our corporate infrastructure, including our internal controls; our financial performance and capital requirements; and 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 factors, as well as others, are discussed 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. Except to the extent required by law, we do not undertake to update any of these forward-looking statements after the date hereof to conform these statements to actual results or revised expectations

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