



Shockwave Medical Announces U.S. Launch of New Peripheral IVL Catheter

March 14, 2023

Shockwave L⁶ Provides Physicians with Larger-Diameter Catheters to Expand Potential Treatment of Peripheral Vessels

SANTA CLARA, Calif., March 14, 2023 (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 full U.S. commercial availability of the Shockwave L⁶ Peripheral IVL Catheter following clearance by the U.S. Food and Drug Administration (FDA). The Shockwave L⁶ catheter is purpose-built to modify calcification in otherwise difficult-to-treat lesions in large peripheral vessels, including the iliac and the common femoral arteries. Calcification in these arteries is common and associated with decreased procedural success and increased complications with standard endovascular techniques.¹

"The Shockwave L⁶ catheter pushes the boundaries of what IVL can help physicians achieve for patients with severe peripheral arterial disease," said Frank Arko, M.D., Chief of Vascular and Endovascular Surgery at Carolinas Medical Center, Sanger Heart and Vascular Institute in Charlotte, North Carolina. "The characteristics of the new catheter allow physicians to optimize IVL therapy in large peripheral vessels, which represent over 20% of peripheral interventions performed in the U.S. each year. The Shockwave L⁶ catheter may also be beneficial when IVL is utilized to facilitate transfemoral access for large bore procedures like TAVR, TEVAR and EVAR to minimize the risks of rupture and dissection."

The Shockwave L⁶ IVL catheter's compact emitter configuration, in conjunction with four new device sizes (8.0, 9.0, 10.0 and 12.0 millimeter diameters), enables effective delivery of sonic pressure waves in larger vessels. The Shockwave L⁶ enhances the company's peripheral IVL portfolio, extending the size offerings of the Shockwave M⁵⁺ and Shockwave S⁴ catheters, to provide physicians with a choice of catheters optimized for the challenges of infrapopliteal, femoropopliteal and iliac arterial territories.

"Shockwave L⁶ is another example of our team's commitment to developing technologies to address specific market needs while still maintaining the safety, effectiveness and ease of use of our core IVL technology," said Doug Godshall, Chief Executive Officer of Shockwave Medical. "We are pleased with the success of our limited release and the great feedback we have received from our customers. We now look forward to offering Shockwave L⁶ as an additional IVL option for the most complex and high-risk large vessel cases."

¹Armstrong et. al. Cardiovascular Revascularization Medicine, 2020. <https://doi.org/10.1016/j.carrev.2020.02.026>

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 macroeconomic conditions, including inflation, rising interest rates, volatile market conditions, and global events, including the COVID-19 pandemic, on our operations, financial results, liquidity, capital resources, 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; whether the acquisition of Neovasc is completed; 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 1A - Risk Factors in our most recent Annual Report on Form 10-K filed with the SEC, and in our 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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