Shockwave Medical Announces Global Launch of New Peripheral Intravascular Lithotripsy Catheter

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Shockwave M5+ IVL Catheter Broadens Options for Treatment of Peripheral Arteries

SANTA CLARA, Calif., March 31, 2022 (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 global commercial availability of the Shockwave M^{5+} peripheral IVL catheter after receiving both CE Mark and U.S. Food and Drug Administration (FDA) clearance. The Shockwave M^{5+} catheter, which has been in limited launch until today, is specifically designed to decrease IVL treatment time, provide alternative access options, and expand IVL therapy to patients with larger vessel sizes.

“Shockwave’s new peripheral catheter offers remarkable improvements that enable efficient and effective treatment for some of our most difficult-to-treat patients, some of whom previously could not have been treated with IVL,” said Peter Soukas, M.D., of Miriam and Rhode Island Hospitals in Providence, Rhode Island, and one of the first physicians to use the new catheter. “While treating patients with long, severely calcified lesions will always be challenging, the new Shockwave catheter is appropriately sized for larger vessels and has been optimized to expand options for facilitating vessel access, all while decreasing the amount of time needed to perform IVL in the procedure.”

Shockwave M^{5+} incorporates valued customer feedback to improve IVL efficiency in tackling complex calcified lesions, including quicker cycle time that delivers two pulses per second, an increased catheter length of 135 centimeters, and a new, larger 8.0 millimeter size. The catheter is specifically designed to treat otherwise difficult-to-treat calcified lesions in the peripheral arterial system of the lower extremities, including the iliac, femoral, ilio-femoral, popliteal, infra-popliteal, and renal arteries.

“The launch of Shockwave M $^{5+}$ is the latest step in our commitment to expanding the applicability of our technology for more diverse patient populations and anatomies,” said Doug Godshall, Chief Executive Officer of Shockwave Medical. “After a very successful limited launch, we are enthusiastic about the global rollout of Shockwave M^{5+} and the ability to provide our customers with a new tool to advance treatment options – with the consistent reliability and simplicity of IVL that physicians have come to expect when treating patients with Shockwave IVL.”

Shockwave M^{5+} is now commercially available in Europe and the United States.

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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