Shockwave IVL Consistently Treats “Real World” Calcium Across Multiple Peripheral Vessel Beds

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Disrupt PAD III Observational Arm Confirms IVL Safely and Effectively Modifies Superficial and Deep Calcium in Complex Calcified Lesions

SANTA CLARA, Calif., Oct. 06, 2021 (GLOBE NEWSWIRE) -- Shockwave Medical, Inc. (NASDAQ: SWAV), a pioneer in the development and commercialization of Intravascular Lithotripsy (IVL) to treat severely calcified cardiovascular disease, announced today that an interim analysis from the Disrupt PAD III Observational Study (OS) showed that IVL performs consistently well across challenging peripheral vessels, lesions and patients. The study, which is the largest angiographic core lab adjudicated “real world” evidence for IVL in heavily calcified peripheral arteries, was presented earlier today in a late-breaking clinical trial session at VIVA21.

The key findings from the first 752 patients of the Disrupt PAD III OS interim analysis included:

- IVL consistently showed its ability to safely and effectively modify superficial and deep calcium across multiple vascular beds, lesion types and in patients with critical limb ischemia (CLI)
- IVL resulted in consistent reduction in the diameter of stenosis with no associated distal embolization, abrupt closure or thrombotic events at any time
- IVL outcomes were comparable to the previously reported Disrupt PAD III randomized clinical trial (RCT) outcomes showing minimal procedural complications and consistent reduction in diameter stenosis
- IVL was successfully used in combination with adjunctive technologies, including specialty balloons and atherectomy, in the treatment of complex calcified lesions

“Patients with heavy calcification have traditionally been excluded from endovascular treatment trials resulting in little available evidence to provide guidance for treating this challenging patient population,” said Ehrin J. Armstrong, M.D., Medical Director, Adventist Heart and Vascular Institute, St. Helena, CA. “The Disrupt PAD III OS shows that in common clinical situations that physicians encounter daily, peripheral IVL performs consistently well in a variety of peripheral vessels, lesions and subgroups.”

The Disrupt PAD III OS is a prospective, multicenter, single-blind study of “real world” patients, which augments the Disrupt PAD III RCT. The interim analysis looked at results from the first 752 consecutive patients enrolled in the study from November of 2017 to June of 2019 at 18 global sites. Of the 852 lesions treated in the iliac, common femoral, superficial femoral, popliteal and infra-popliteal arteries, 88 percent presented with moderate/severe calcification, with an average calcified length of 127mm. The use of IVL in these lesions resulted in a final residual stenosis of 24 percent, similar to the Disrupt PAD III RCT finding of 22 percent. Patients also experienced minimal procedural complications, with only 0.9 percent and 0.1 percent of patients experiencing final dissections (Type D-F) and perforations, respectively. Notably, there were no instances of embolization, thrombus, no reflow or abrupt closure.

The Disrupt PAD III OS completed enrollment in June 2021 with a total of 1,373 patients; analysis of the full data set will be presented in 2022.

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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