# Shockwave Confirms Consistent Outcomes for IVL in the Largest Prospective “Real World” Study of Patients with Heavily Calcified Peripheral Arterial Disease

November 1, 2022

**Disrupt PAD III Observational Study Results Confirm Safety and Effectiveness of IVL in Patients with Complex Calcified Lesions**

LAS VEGAS, Nov. 01, 2022 (GLOBE NEWSWIRE) -- Shockwave Medical, Inc. (NASDAQ: SWAV), a pioneer in the development of Intravascular Lithotripsy (IVL) to treat severely calcified cardiovascular disease, announced today that the final 1,373-patient cohort analysis from the Disrupt PAD III Observational Study (OS) again demonstrates consistent IVL outcomes in complex and challenging lesions across multiple peripheral vessel beds. The study represents the largest prospective “real world” evidence supporting the treatment of complex, heavily calcified peripheral artery disease (PAD) with IVL. The final analysis was presented earlier today at VIVA22 in a late-breaking clinical trial session.

The key findings from Disrupt PAD III OS include:

- IVL resulted in consistent reduction in the diameter of stenosis with no associated distal embolization, abrupt closure or thrombotic events at any time
- IVL was the only calcium-modifying therapy used in most cases, required a limited need for adjunctive therapy tools (i.e., embolic protection), and had better results with appropriate IVL sizing
- IVL results were comparable to the previously reported outcomes from the Disrupt PAD III randomized clinical trial (RCT) showing that IVL safely and effectively modifies calcium across multiple peripheral vessel beds

“These consistent results in a ‘real world’ population, combined with the recent long-term outcomes from the Disrupt PAD III RCT, reinforce the positioning of IVL as a reliable, potential first-line therapy for the treatment of large and diverse patient populations with calcified peripheral arterial disease,” said Ehrin J. Armstrong, MD, Medical Director, Adventist Heart and Vascular Institute, St. Helena, CA. “The significant amount of data on IVL continue to show both consistent efficacy and safety across the most challenging lesions, various peripheral vessel beds, and even in the most complex, high-risk patients.”

Disrupt PAD III OS is a prospective, multicenter, single-blind study of “real world” patients. The analysis looked at the total 1,373-patient cohort enrolled in the study from November 2017 to June 2021 at 30 global sites. Of the 1,531 lesions treated in the iliac, common femoral, superficial femoral, popliteal and infra-popliteal arteries, 90 percent presented with moderate/severe calcification, with an average calcified length of 115 millimeters. The use of IVL in these lesions resulted in a final residual diameter stenosis of 24 percent, similar to Disrupt PAD III RCT (22 percent). Patients also experienced minimal procedural complications, with only 0.7 percent and 0.2 percent experiencing final dissections (Type D-F) and perforations, respectively. Notably, there were no instances of embolization, thrombus formation, no reflow or abrupt closure.

**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 predictably 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.

Media Contact:
Scott Shadiow
+1.317.432.9210
sshadiow@shockwavemedical.com

Investor Contact:
Debbie Kaster
dkaster@shockwavemedical.com

Source: Shockwave Medical, Inc.